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RESEARCH PODIUM PRESENTATIONS – SESSION I

CANCER OUTCOMES RESEARCH STUDIES

CN1
LONG-TERM IMPACT OF THE DUTCH COLORECTAL CANCER SCREENING PROGRAMME ON CANCER INCIDENCE: EXPLORATION OF THE SERIATED PATHWAY

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OBJECTIVES: The Netherlands has recently started with the stepwise implementation of biennial faecal immunochemical testing for colorectal cancer (CRC). We evaluated the impact of the transition to, and the fully implemented screening programme on the long-term CRC incidence and colonoscopy demand. METHODS: The previously reported and calibrated ASCCA model was set up to simulate the Dutch CRC screening programme between 2014 and 2044. We adopted an open-model approach by simulating model-specific input parameters and combining the results while accounting for the ageing of the population. Besides a no screening scenario, we evaluated the impact of screening under three sets of natural history assumptions which differed in the contribution of the serrated pathway to the CRC incidence (0%, 15%, and 30%). Model-predicted outcomes were CRC incidence and colonoscopy demand per year. RESULTS: Due to ageing, the model-predicted CRC incidence in the no screening scenario increased from 77/100,000 in 2014 to 109/100,000 in 2044. Under screening, the predicted CRC incidence in 2014 was between 105/100,000 (assuming all CRCs originate from adenomas) and 109/100,000 (assuming that 30% of CRCs arise from serrated lesions) due to the detection of asymptomatic, prevalent tumours. After this peak, the predicted incidence gradually decreased until in 2039 a new equilibrium was reached, ranging between 65/100,000 and 71/100,000 assuming that 100% versus 70% of CRCs originate from adenomas, respectively. Due to the stepwise implementation, the predicted number of colonoscopies required for the screening programme increased gradually over time from 38,000 (752,199 invitees in 2014 to 117,000 (2,154,875 invitees) in 2044. CONCLUSIONS: The Dutch screening programme will markedly decrease CRC incidence in the next 25 years. The conclusions of the model would be further compounded should drug wastage not be adequately captured. The use of only mean patient weight consistently underestimated costs compared to methods that incorporated the distribution of weight data. Sampling from the observed patient weight distribution provides a more accurate estimation of costs; the use of mean patient weight was £18,750, £3,696, £2,147 and £482 per administration of ipilimumab, cabazitaxel, ustekinumab and romilpinostat, respectively. These results increased by 4.9%, 2.3%, 10.3% and 36.6% when fitting a distribution to the patient weights. The use of only mean patient weight consistently underestimated costs compared to methods that incorporated the distribution of weight data. Sampling from the observed patient weight distribution provides a more accurate estimation of costs; however, it is subject to over- or under-estimation, depending on enrolment in a trial programme, particularly amongst patients who are substantially over- or under-weight. CONCLUSIONS: Accurate estimation of drug costs requires an under-standing of the distribution of patient weights. Failing to take this into account can result in cost estimates that are substantially lower than will be seen in practice, which could (in turn) impact treatment (implementation) decisions. These errors would be further compounded should drug wastage not be adequately captured. Modellers should be mindful of these issues when costing therapies or conducting health technology assessment submissions.

CN2
PRIMARY TREATMENTS FOR INTERMEDIATE-RISK PROSTATE CANCER: A COST-EFFECTIVENESS AND VALUE-OF-INFORMATION ANALYSIS

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OBJECTIVES: Intermediate-risk prostate cancer patients are recommended primary treatment with either radical prostatectomy (RP), external beam radiotherapy (EBRT), brachytherapy (BT), or EBRT plus high-dose-rate BT boost (EBRT + HDR-BT); or expectant management with active surveillance (AS). The costs of these treatments differ considerably, whilst the amount and quality of evidence for their comparative effectiveness in terms of disease progression, adverse events and health-related quality of life is unbalanced and inconclusive. Therefore, we undertook a cost-effectiveness analysis of RP, EBRT, BT, EBRT + HDR-BT and AS, and performed a value-of-information analysis to direct future research. METHODS: We developed a probabilistic Markov model estimating the expected incremental cost (Quality-Adjusted Life Years) from a UK NHS-perspective, with a time horizon of 10 years. Input data were obtained from the best available literature. We explored the uncertainty around the model outcomes by identifying the most influential parameters and estimating the expected value of perfect (parameter) information. RESULTS: AS is most likely to be cost-effective at a cost/QALY threshold (£) of £3,000/QALY, BT for £3,000 to £12,000/QALY, and RP for > £12,000/QALY. One-way sensitivity analysis shows that utilities and probabilities of adverse events are main effect drivers and initial treatment costs are main cost drivers. Large decision uncertainty exists around λ £11,000 with a population EVPI of nearly £110 million. The EVPI suggests that eliminating uncertainty around costs and utilities is most worthwhile. CONCLUSIONS: With current information AS and BT are cost-effective treatments for intermediate-risk prostate cancer at relatively low cost/QALY thresholds, and RP is expected to be the most cost-effective of available treatments at the prevailing range of cost/QALY thresholds (i.e. £20,000–£30,000). However, large decision uncertainty exists and acquiring further information is likely cost-effectiveness. Future research on costs and utilities associated with treatment outcome and adverse events is expected to be most valuable.

CN3
EARLY STAGE COST-EFFECTIVENESS ANALYSIS OF A BRCA1-LIKE TEST TO DETECT TRIPLE NEGATIVE BREAST CANCERS RESPONSIVE TO HIGH DOSE ALKYLYATING CHEMOTHERAPY

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OBJECTIVES: Triple negative breast cancers (TNBC) with a BRCA1-like profile may benefit from high dose alkylating chemotherapy (HDAC). This study examines whether treating TNBC with personalized HDAC based on BRCA1-like testing can be more cost-effective than current clinical practice. Additionally, we estimated the minimum required prevalence of BRCA1-likeness and the required positive predictive value (PPV) for a BRCA1-like test to render this strategy cost-effective. METHODS: Our markov model compared the outcomes of treating TNBC women with personalized HDAC based on BRCA1-like testing with current clinical practice from a societal Dutch perspective and a 20-year time horizon. From our base-case model we assessed: 1) the incremental number of respondents; 2) the incremental number of Quality Adjusted Life Years; 3) the incremental costs, and 4) the incremental cost-effectiveness ratio (ICER). We performed one-way sensitivity analysis (SA) of all model parameters, and two-way SA of prevalence and PPV. Data were obtained from a current trial (NCT0105708), published literature and expert opinions where necessary. RESULTS: Based on our base-case analysis with 68% BRCA1-like prevalence, 100% PPV, and costs of £164 per test, treating TNBC according to BRCA1-like testing would be cost-effective (£/16.192/QALY). One-way SA on the prevalence and PPV demonstrated that only the PPV drives the ICER changes. In two-way SA, the lower bound for the two parameters was: prevalence 39.6% and PPV 46.4%. Regardless of prevalence, at PPVs > 46.4% BRCA1-like testing was always cost-effective. CONCLUSIONS: Treating TNBC with personalized HDAC based on BRCA1-like testing is expected to be cost-effective at a minimum PPV of 46%. This information can help test developers in decisions on further research and development.

CN4
THE APPLICATION OF DRUG PRICES IN ECONOMIC MODELS DUE TO DIFFERING PATIENT WEIGHTS

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OBJECTIVES: Drug costs are generally a key driver of the results of economic models. We tested the impact on drug cost estimates for the following common approaches: • using mean patient weight, individual patient weights or fitting a distribution to the observed patient weights. METHODS: For the analysis, we utilised patient weight and height data from trial CA184-024 (517 patients) in metastatic melanoma. Based on this dataset, costs of a single administration of drug therapy were calculated using UK list prices. Costs were calculated for four recently licensed treatments with different posologies: ipilimumab (mg/kg, with 2 vial sizes), cabazitaxel (mg/m²), ustekinumab (doubled dosage over 10kg patient weight) and romilpinostat (µg/kg, with a large, single vial size). RESULTS: Cost estimates using the mean patient weight were £1,780, £3,692, £2,147 and £482 per administration of ipilimumab, cabazitaxel, ustekinumab and romilpinostat, respectively. These results increased by 4.9%, 2.3%, 10.3% and 36.6% when fitting a distribution to the patient weights. The use of only mean patient weight consistently underestimated costs compared to methods that incorporated the distribution of weight data. Sampling from the observed patient weight distribution provides a more accurate estimation of costs; however, it is subject to over- or under-estimation, depending on enrolment in a trial programme, particularly amongst patients who are substantially over- or under-weight. CONCLUSIONS: Accurate estimation of drug costs requires an under-standing of the distribution of patient weights. Failing to take this into account can result in cost estimates that are substantially lower than will be seen in practice, which could (in turn) impact treatment (implementation) decisions. These errors would be further compounded should drug wastage not be adequately captured. Modellers should be mindful of these issues when costing therapies or conducting health technology assessment submissions.

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CONCEPTUAL PAPERS

CP1 THE EVALUATION OF ECONOMIC METHODS TO ASSESS THE SOCIAL VALUE OF MEDICAL INTERVENTIONS FOR ULTRA-RARE DISORDERS (URDs)


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Rapid development of medical innovations in the face of rising health care costs have been calling for a more value-conscious adoption and diffusions of innovations. This conceptual paper departs from swift adoption of the da Vinci surgical robot in the Netherlands. It describes three challenges facing health care systems to evaluate promising, yet complex and often expensive medical innovations. Firstly, they are often adopted prior to their clear and quantified net benefits. Secondly, formal evaluation frameworks are somehow detached from the dynamics for ultra-rare disorders, which have been used or proposed to estimate the social value of medical interventions for URDs. RESULTS: The group identified a broad set of potential criteria, which may be grouped according to the following dimensions: theoretical foundations (normative premises, i.e., links to moral and economic theories), including - but not limited to - non-nutritarian consequentialist and deontological reasoning, definition and treatment of care concepts of economic thinking such as opportunity costs and efficiency), empirical underpinnings (sociological preferences related to attributes of the health condition or of the person afflicted with it), and pragmatic aspects (feasibility of implementation and potential for bias and misuse). For each of the dimensions, a set of criteria has been agreed upon, which in turn will need further scrutiny and justification. CONCLUSIONS: Previously, a need had been identified for modifications or alternatives to the conventional logic of cost-effectiveness analysis (CEA) that could be more widely used for the valuation of achievable benefits with a limited time-adjusted life year (QALY). We propose a framework for the systematic assessment how well different evaluation approaches reflect prevalent social norms and value judgments. As a next step, the framework shall be applied on multi-criteria decision analysis methods and social cost value analysis (either using the person trade-off (PTO) or the relative social willingness-to-pay (RS-WTP) instrument.

CP2 VALUE IN THE MAKING: HARVESTING THE VALUE OF COMPLEX MEDICAL INNOVATIONS IN PRACTICE

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This conceptual paper elaborates on the evaluation of medical innovations, especially those for the diagnosis of significant coronary artery disease (CAD). With the new NICE guide on the diagnosis of coronary artery disease in patients with intermediate pre-test likelihood (NICE, 2013), the group has identified a broad set of potential criteria, which may be grouped according to the following dimensions: theoretical foundations (normative premises, i.e., links to moral and economic theories), including - but not limited to - non-nutritarian consequentialist and deontological reasoning, definition and treatment of care concepts of economic thinking such as opportunity costs and efficiency), empirical underpinnings (sociological preferences related to attributes of the health condition or of the person afflicted with it), and pragmatic aspects (feasibility of implementation and potential for bias and misuse). For each of the dimensions, a set of criteria has been agreed upon, which in turn will need further scrutiny and justification. CONCLUSIONS: Previously, a need had been identified for modifications or alternatives to the conventional logic of cost-effectiveness analysis (CEA) that could be more widely used for the valuation of achievable benefits with a limited time-adjusted life year (QALY). We propose a framework for the systematic assessment how well different evaluation approaches reflect prevalent social norms and value judgments. As a next step, the framework shall be applied on multi-criteria decision analysis methods and social cost value analysis (either using the person trade-off (PTO) or the relative social willingness-to-pay (RS-WTP) instrument.

CP3 EVALUATING THE QUALITY OF EVIDENCE FROM A NETWORK META-ANALYSIS

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Systematic reviews that collate data about the relative effects of multiple interventions are highly informative for multiple purposes. A network meta-analysis provides two types of findings for a specific outcome: the relative treatment effect for all pairwise comparisons, and a rank-order of interventions. It is important to consider the confidence in the results from these two types of results can enable clinicians, policy makers and patients to make informed decisions. We propose an approach to determining confidence in the output of a network meta-analysis, based on methodology developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group for pairwise meta-analyses. The suggested framework for evaluating a network meta-analysis acknowledges (i) the key role of indirect comparisons (ii) the contributions of each of direct evidence to the network meta-analysis estimates of effect size, (iii) the importance of the transitivity assumption to the validity of network meta-analysis, and (iv) the possibility of disagreement between direct evidence and indirect evidence. We illustrate the framework using a network meta-analysis of topical antibiotics without for chronically draining ears with underlying eardrum perforations.

DIAGNOSTIC RESEARCH STUDIES

D1 COST-EFFECTIVENESS (CE) OF IMAGING-GUIDED STRATEGIES FOR THE DIAGNOSIS OF CORONARY ARTERY DISEASE (CAD): RESULTS FROM THE EVINCI STUDY

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Objectives: To evaluate the cost-effectiveness (CE) of imaging-guided strategies for the diagnosis of significant coronary artery disease (CAD) in patients with intermediate pre-test likelihood. METHODS: Significant CAD was defined as invasive coronary angiography (ICA) > 50% stenosis in the left main or > 70% stenosis in a major coronary artery in patients with non-parametric bootstrap. RESULTS: Among the strategies analysed only three resulted cost-effective for the diagnosis of significant CAD. These included stress ECHO and CTCA as single non-invasive test, CTCA first then ECHO, CTCA first and then stress PET, all followed by ICA when required. Stress ECHO approach was the least costly but also the least effective, while CTCA alone [ICER: 2345 (2287-2400)] or in combination with PET [ICER: 5227 (5161-5296)] had increasingly higher effectiveness for a willingness to pay (WTP) exceeding 2,000 Euro and 5,000 Euro, respectively. CONCLUSIONS: Results from the health-economic analysis of the EVINCI study showed that stress ECHO guided diagnostic strategy could be cost-effective when the WTP is low. Strategies involving CTCA alone or as first line exam followed by stress PET could allow a more accurate diagnostic workflow for higher WTP.

D2 THE VALUE OF RISK-STRATIFIED INFORMATION IN THE NATIONAL LUNG CANCER SCREENING TRIAL

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OBJECTIVES: Clinical guideline recommendations are generally informed by population-based evidence. However, interventions that are (cost) -effective on average may be (cost) -ineffective for subgroups of patients. This study aims to investigate the value of risk-stratified recommendations for lung cancer screening among current or former smokers between the ages of 55 and 74 years compared to a screen-all policy. METHODS: Using data from the National Lung Screening Trial (NLST), we calculated the costs and QALY’s for low-dose computed tomography (CT) versus chest radiography (X-ray) from empirically observed health states and 6 years life expectancy. Based on Kovalchik’s risk of lung cancer death prediction model, we stratified 5345 NLST trial patients into quintiles. The expected value of individualized care (EVC) was calculated to

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OBJECTIVES: A binary reimbursement prediction model was previously developed based on a dataset of submissions to the Scottish Medicines Consortium (SMC) between 2006 and 2014. The objective of this study is to build on the previous model by identifying factors that influence the different levels of SMC recommendation, defined as “recommend”, “restrict” or “not recommend” pharmacological technologies. Only head-to-head comparisons (with at least two test strips per day). We calculated incidence rates to estimate the risk for hypoglycemic therapy and the direct costs due to diabetes-related hospitalizations and outpatient services. RESULTS: We identified 394 insulin-users patients with no SMBG use and 1350 with SMBG performed more than twice per day. Compared with non-SMBG patients, compared with non-SMBG patients, are associated with better glycemic control and reduced risk of diabetes-related hospitalizations or death (30,0 vs 60,8 per 100 person-years, p<0.001) and of diabetes-related hospitalizations or death (30,0 vs 60,8 per 100 person-years, p<0.001). The higher hospitalization rate resulted in higher hospitalization costs per patient (€2,419 vs €1,512 of those with SMBG use) and consequently higher total annual direct costs per patient (€3,060 vs €2,738 of those using SMBG). CONCLUSIONS: Results indicate that patients using SMBG, compared with non-SMBG patients, are associated with better glycemic control and reduced risk of diabetes-related hospitalizations and consequently with lower overall total annual cost per patient.

DI4 DIAGNOSING ANXIETY DISORDERS IN PRIMARY CARE: A SYSTEMATIC REVIEW AND META-ANALYSIS

OBJECTIVES: Anxiety and mood disorders are highly prevalent in Primary Care but research shows that general practitioners (GPs) fail to diagnose up to half of cases. In this study we compared the diagnostic capacity of standard anxiety and mood disorder tools with and without any help from diagnostic assisted (unassisted diagnosis). METHODS: We searched for articles published from January 1980 to June 2014 in 7 databases. We included studies in English, Spanish, French, and German reporting the ability of GPs to identify any anxiety disorder (DSM-IV/IV-TR diagnostic crite- ria) in Primary Care community samples. We excluded studies from general population and those addressing specific physical or mental disorders, along with vignette and case-series studies. Two authors independently performed abstract and full-text reviews and data extraction. Study was assessed with the QUADAS-2. Coupled forest plots summarized estimated studies’ sensitivity and specificity and 95% confidence intervals. We fitted random-effects meta-analysis models and undertook a bivari- ate meta-analysis to construct a summary Receiver Operator Characteristic curves (sROC). RESULTS: From a total 17,964 detected papers, 443 were included for full text review. So far, we have analyzed 111 papers, out of which 8 studies were included with N= 3808 patients with pooled anxiety prevalence 26% (CI:25-27%). Preliminary results show an overall ROC curve with lower GP diagnostic accuracy when per- forming unassisted diagnoses for a total diagnostic accuracy 80% (CI=79-84) 1 with overall sensitivity=49% (CI=45-53), and Specificity = 92% (CI=90-94). GP’s accuracy was higher with assisted diagnoses (86.7%, CI:85-89%) than unassisted diagnoses (45.5%, CI=43-7%47.3%). Specificity was lower in assisted (89.15%), CI=87-9.904) than unassisted diagnosis (92.5%, CI=91-93.1). CONCLUSIONS: Low diagnostic sensitivities might be related to the low priority given by the primary care. Results suggest that detection might be improved by using diagnostic tools. Results for all included articles will be presented.

HEALTH CARE EXPENDITURE STUDIES

HC1 DETERMINANTS OF INCREASING THE LIKELIHOOD FOR A POSITIVE DRUG REIMBURSEMENT RECOMMENDATION IN SCOTLAND

OBJECTIVES: Incentives are offered to pharmaceutical companies in order to increase the number of treatments for patients with rare diseases. As a conse- quence, a number of new drugs have been introduced on the market—drugs that often fail to meet traditional cost-effectiveness criteria. This study aims to inves- tigate if there are societal preferences for treating patients with rare diseases dif- ferently in priority setting situations compared with common diseases. Moreover, psychological mechanisms that potentially could explain such preferences are explored. METHODS: A postal questionnaire in three versions was sent out to a representative sample of the general Swedish population. Respondents were asked to choose to give treatment to a patient with a rare or a common disease in eight different scenarios. Rarity of the disease, different alternative costs, and group/ individual level decisions was investigated. Psychological aspects in the presented scenarios were modulated between high and low levels to test individuals’ preferences. RESULTS: This study identified superior efficacy using an active control as well as a beneficial cost-effectiveness outcome to increase the likely- hood of receiving a positive recommendation from the SMC.

HC2 BIOSIMILARS VERSUS BRANDS FOR RHEUMATOID ARTHRITIS: EU5 Payers and Prescribers Place Their Bets

OBJECTIVES: Biosimilars for rheumatoid arthritis (RA) has generated a lucrative market. However, amid ongo- ing economic constraints, the EUS (France, Germany, Italy, Spain, and the UK) must tighten their health care belts. As biosimilars versions of brand drugs are available on the horizon, this study explored the expected impact of these cheaper options on reimbursement and prescribing for RA in each country. METHODS: Across the EU5, 254 rheumatologists were surveyed regarding their views on biosimilars for RA and on current and expected prescribing patterns. In addition, 15 patients who influence reimbursement at national or regional level were interviewed. RESULTS: Considering 54-week Phase III data, ≥80% of surveyed rheumatologists in each coun- try believe CT-P13 (biosimilar infliximab) has similar efficacy to branded Humira, however, respondents are concerned with the bioequivalence and safety. Furthermore, >80% of respondents in most countries are willing to prescribe biosimilars of infliximab, and of etanercept and rituximab, though largely not before branded biolog- ics. Unsurprisingly, given likely price discounts, interviewed patients will somewhat encourage biosimilar uptake. However, excluding those in Germany, consensus is that discounts offered on biosimilars will not significantly impact their budgets. German patients, however, report that additional rebates to statutory insurers are expected for a positive assessment of biosimilars. Thus, manufacturers may consider robust uptake will compensate for hefty discounts. CONCLUSIONS: Available data have inspired prescriber confidence in biosimilar efficacy, although safety concerns, likely stemming from complex bio- similar manufacturing and lack of long-term safety data, will ensure continued brand uptake, at least initially. Furthermore, the expected modesty of biosimilar discounted prices in most countries will somewhat curb payer policy promoting use of such products. However, as prescribers become more familiar with biosimilars, as the full extent of cost savings are realised, increasing uptake of biosimilars is probable.

HC3 PREFERENCES FOR PRIORITIZING PATIENTS WITH RARE DISEASES: A SURVEY OF THE GENERAL POPULATION IN SWEDEN

OBJECTIVES: Whether or not these should make when setting priorities related to rare diseases. Whether or not these should...
be viewed as biases or an expression of true preferences is a matter for further discussion.

HC4

UNDERSTANDING THE PAVER DILEMMA WITH BIOSIMILAR MABS: STRIKING THE BEST BALANCE BETWEEN BUDGET NEEDS AND PATIENT OUTCOMES

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OBJECTIVES: The first infliximab biosimilars reached the EU in September 2013, representing the first biosimilar monoclonal antibodies (mAbs) to obtain EMA approval. Although commercialization in the major European markets will only start in February 2015, payers in Nordic and Eastern European countries have already faced the dilemma of striking the balance between potential savings accrued from use of less expensive infliximab biosimilars and demands for robust proof of clinical efficacy and safety. This work identifies payers’ evidence expectations, their reliance on reference situations and how payers make recommendations to target patient populations. METHODS: Exploratory qualitative primary research with payers (N=12) from France, Italy, Spain, UK, Germany and Netherlands. Collection of data about the current and future attitudes towards biosimilar health technology assessments at the national and, if applicable, local levels will be conducted, as well as perceived price and access trade-offs. RESULTS: (1) Payers will mainly defer to the EMA the decision on acceptability of biosimilar indication extrapolation (indications where biosimilars do not have direct clinical trial data). (2) It is understood that mAb biosimilar clinical development is more onerous and costly than small molecule generics, thus payers do not expect the same magnitude of discounts offered vs. originator. (3) Although eager to obtain savings from use of biosimilar patient populations, payers will not implement pharmacy-level substitution or enforce biosimilar use in originator-experienced patients; (4) Use in naive patients will be recommended in most markets. CONCLUSIONS: Across the EU, payers acknowledge physicians’ concerns over long term safety and efficacy of biosimilars. Nonetheless, they will rely on the regulators’ evaluations and expert panels to justify implementing recommendations, and in some markets, restrict formulary access based on cost. Moreover, they have conservative discount expectations at launch, with the long-term aim of strengthening further restriction from other biosimilar manufacturers.

RESEARCH ON METHODS – Modeling Studies

M01

QUASI-MONTE CARLO SIMULATION AND VARIANCE REDUCTION TECHNIQUES SUBSTANTIALLY REDUCE COMPUTATIONAL REQUIREMENTS OF PATIENT-LEVEL SIMULATION MODELS: AN APPLICATION TO A DISCRETE EVENT SIMULATION MODEL OF ATRIAL FIBRILLATION

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OBJECTIVES: Patient-level simulation models provide increased flexibility to overcome the limitations of cohort-based approaches in health-economic analysis. However, computational requirements of reaching convergence is a notorious barrier. The objective was to assess the impact of using quasi-monte carlo simulation (QMC) and variance reduction techniques (VRTs) on computational requirements. METHODS: A recently published discrete event simulation model assessing the cost-effectiveness of an adjunctive antipsychotic treatment for depression was used. The following VRTs were implemented: antithetic variables, common random numbers (CRN) and the combination (Anti_CRN). In addition, QMC was conducted using the Sobol low discrepancy sequence. The minimal number of patients required to reach convergence was estimated for each of the following two stages; (a) model selection via the AIC and secondly (b) parameters estimation. RESULTS: Reference INMB (SE) was £1,413 (76). The average number of patients required to reach reference precision were 92,628, 35,692, 41,683 and 36,803 for antithetic variables, CRN, Anti_CRN and Sobol respectively. This implied a computation time reduction ranging between 7% and 96% compared to simple MCS. MSE was 346,036, 16,314, 155,250 and 7,474 respectively. MAE was 588, 105, 387 and 86 respectively. Antithetic variables and Anti_CRN structurally underestimated INMB (99% and 100%). CRN marginally overestimated INMB in 76 replica-

tions. CONCLUSIONS: QMCS and VRT reduce computational requirements in terms of simulated patients and computational time up to 96%, enhancing the practical feasibility of patient-level simulation models. This particularly applies to Sobol and CRN. Antithetic variables should be used with caution and its structural bias warrants further research.

M02

TRANSITION PROBABILITY ESTIMATION USING REPEATED SAMPLING FROM A FITTED MIXED MODEL

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OBJECTIVES: Markov model is one of the most used decision analytic models in health care. Transitions between health states in a Markov model is driven by transition probability matrix. When the number of patients and observed transitions are limited, transition probability estimation becomes challenging. The objective of this exercise is to demonstrate how transition probabilities can be estimated by simulating data from a statistical model fitted to patient-level data. METHODS: An economic model for a monotherapy, in mCVN secondary to pathological myopia (submitted to NICE in June 2013) was adapted for forthcoming Asian reimbursement submissions. BCVA (Best Corrected Visual Acuity) scores were available for limited number of East Asian patients (N=15) from a phase III, 12 month, randomized, double-masked, multicenter, active-controlled study (RADIANCE). To populate a transition probability matrix with 8 health states based on BCVA scores, a statistical model was proposed to simulate a larger hypothetical patient cohort. A mixed-effect model was fitted on the observed BCVA scores with baseline BCVA score as covariate, patients as random effect and an autoregressive AR(1) error correlation structure amongst the repeated observations. This model was used to simulate a patient cohort of 50,000. Transition probabilities were estimated using traditional division by row sum method. Several simulations were run to confirm consistency of results. RESULTS: From baseline to month 3, percentage of patients with BCVA ≥ 20 letters gain was 22.45% in observed data vs 22.49% in simulated data, and percentage of patients with BCVA ≥ 20 letters loss was 0.08% in observed data vs 0.09% in simulated data. BCVA change from baseline to month 3 in simulated data (mean=13.3, SD=8.3) was verified with that of the observed data (mean=13.3, SD=8.3). CONCLUSIONS: Transition probability estimation by simulation from a fitted statistical model can overcome the challenges posed by small patient cohorts and multiple state transitions.

M03

EXTRAPOLATION OF TRIAL-BASED SURVIVAL CURVES USING EXTERNAL INFORMATION

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OBJECTIVES: In cost-effectiveness analysis (CEA), mean survival difference (QALY-difference) is the primary outcome. However, a lifetime horizon is required. Parametric models are necessary to extrapolate survival outcomes beyond the Randomized Controlled Trial (RCT) period. However, mean survival is very sensitive to the assumed model and different mean survival models may result in models fitting similarly well to the RCT data. We investigate the idea that other sources of information, external to the trial data, could be used to inform model choice and estimation. METHODS: We explored survival models of RCTs and how external information can be used to put constraints on spline-based survival models. We illustrate with a Technology Appraisal (TA) of head and neck cancer where RCT evidence had 5 year follow up. A US cancer database (SEER), general population data and expert opinion were used to impose constraints on overall survival, conditional survival, and hazard ratio. RCT and external data were fitted simultaneously within a Bayesian framework. RESULTS: Standard survival time distributions were insufficiently flexible to simultaneously fit both the RCT and general population data. Piecewise spline models were sufficiently flexible, although there were difficulties choosing initial values. A good fit to all sources of internal and external evidence was achieved within one integrated model using splines on the log hazard. Geynema in addition to radiotherapy improved the expected survival by 4.7 months [95% CI: 0.4, 9.1] compared to radiotherapy alone. CONCLUSIONS: The method enabled us to estimate models consistent with all evidence. Clinical knowledge is essential to guide the interpretation of the external data sources. The method could be used to analyze other RCTs on other cancers and with other treatments. Other flexible models than splines could be investigated.

M04

ESTIMATING SURVIVAL DATA FROM PUBLISHED KAPLAN-MEIER CURVES: A COMPARISON OF METHODS

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OBJECTIVES: Health technology assessment of treatments often requires estimates of their survival curves. Individual patient data (IPD) are often unavailable and the survival curves are usually calculated by fitting a nonlinear least squares (NLS) model directly to Kaplan Meier plots provided in the published literature. This method does not account for the uncertainty associated with the Kaplan Meier curve and can lead to biased estimates. Although the IPD are often missing, the Kaplan Meier curve itself can be digitised and used to approximate what the original IPD could have been. METHODS: We simulated trial IPD data from different survival distributions in order to assess the accuracy of the IPD reconstruction methods. The assessment of accuracy is made at multiple stages and ultimately the effects on the incremental cost effectiveness ratio (ICER) estimates are compared. To do so, a simple cost-effectiveness model was developed, assuming two health states (alive and dead), and assigning costs (£1,000 per month plus drug costs) and a utility score (0.70) to generate ICERs. Two additional methods to curve fitting are compared against the NLS approach – those suggested by Guyot (G), and by Hoyle & Henley (HH). RESULTS: We find that the methods differ in accuracy at each of the following two stages; (a) model selection via the AIC and secondly (b) survival model parameter estimation. When an underlying Weibull function was assumed, the true ICER should be £28,924, compared against £31,182, £34,449 and £31,650 for the NLS, HH and G methods respectively. When an underlying loglogistic function was assumed, the NLS, HH and G methods produced ICERs of £26,507, £25,559 and £25,857, compared to a true ICER of £25,779. CONCLUSIONS: These findings demonstrate that inherent model fit may be approximate in general, and these may manifest themselves differently, depending upon the ‘true’ shape of the underlying data.

QALY-RELATED STUDIES

Q41

ECONOMIC ORPHANS? THE PREVALENCE OF CHILD-SPECIFIC UTILITIES IN NICE APPRAISALS FOR PAEDIATRIC INDICATIONS

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OBJECTIVES: Children have been termed “therapeutic orphans” due to the paucity of age-specific therapeutic data. Here we review the extent to which utility data derived from under-18s were used to inform National Institute for Health and Care Excellence (NICE) Technology Appraisals (TAs) providing cost-effectiveness guidance in paediatric indications, in line with the NICE reference case. METHODS: All 319 NICE TAs published between 2010 and 2015 were identified. When relevant, country-specific recommendations for children. Identified TAs were reviewed to determine if a cost-effectiveness analysis (CEA) was performed. For each CUA, the published TA along with the assessment report and any other relevant publication were examined to determine the origin of the utilities used. RESULTS: Of 35 published TAs reviewed, 27 analysed cost-per-QALY and made recommendations for treatment of under-18s. Of these, 17 used adult utilities, 1 of which attempted to adjust the adult values for children, 3 considered child and adult populations as one, with child-derived data used within the overall model inputs for the whole population, 1 of which adjusted both child and adult utilities by age. Only 6 studies used disease-specific utilities. 1 assumed several utility strategies. Incremental reimbursement decisions made by the reimbursement agency TVL in Sweden. METHODS: Cost-effectiveness is measured through the continuous variable cost per QALY, while disease severity is measured by a dichotomous variable indicating high or low disease severity. We compare the CEA results of two hypothetical patients: one was data available on cost per QALY and disease severity. Logistic regressions are used to evaluate the impact of cost-effectiveness and disease severity on the drug reimbursement decisions. RESULTS: There are 102 decisions with the required data available, 86 where reimbursement was granted and 16 where reimbursement was denied. The median cost per QALY for the drugs that were granted reimbursement was 39,000 euro (€39,000), ranging from a negative cost per QALY (better and cheaper) to 136,000 euro. The median cost per QALY for the drugs that were denied reimbursement was 111,000 euro, ranging from 78,000 euro to 1,111,000 euro. The results from the logistic regression analysis show that both the cost per QALY and the disease severity significantly related to the probability of a drug being granted reimbursement. When the cost per QALY exceeds 56,000 euro for non-severe diseases, and 92,000 euro for severe diseases, the probability that reimbursement is denied is higher. When the disease severity is granted. Conclusions: In Sweden, it is sometimes stated as a rule of thumb that 55,000 euro per QALY is a threshold for cost-effectiveness interventions. Our model shows that at this cost-effectiveness ratio, the probability of a new drug becoming reimbursed is 91% or 98%, depending on disease severity.

RESEARCH PODIUM PRESENTATIONS – SESSION II

CARDIOVASCULAR DISEASE RESEARCH STUDIES

CV1
THE IMPORTANCE OF TREATMENT CLASSIFICATIONS THAT ACCOUNT FOR CONCURRENCY TREATMENTS IN THE CONTEXT OF A NETWORK META-ANALYSIS COMPARING PHARMACOLOGICAL TREATMENTS FOR CHRONIC HEART FAILURE
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OBJECTIVES: The aim of the study was to assess the comparative efficacy of recommended treatments for chronic heart failure with reduced ejection fraction in terms of all-cause mortality based on a network meta-analysis (NMA) of randomized controlled trials (RCTs) and to explore the impact of different treatment classifications on the results of NMA. METHODS: A systematic literature research identified 56 relevant RCTs (1980-2013) that reported mortality data that were synthesized using a Bayesian Poisson regression NMA model. Treatment regimens were classified as angiotensin-converting enzyme inhibitors (ACEI), beta blockers (BB), angiotensin II receptor blockers (ARB), mineralocorticoid/aldosterone receptor antagonists (MRA) and the ß1-channel inhibitor (ß1) ibradine. Analysis 1 classified treatments according to the main drugs of interest, whereas Analysis 2 treated combinations according to the main drugs of interest as well as the concomitant treatments belonging to classes of interest if more than 50% of patients were taking concomitant drugs. RESULTS: Six regimens were compared in Analysis 2 and 10 regimens were compared in Analysis 2. Analysis 1 resulted in the following rate ratios (RR) versus placebo: ACEI: 0.81 (0.75, 0.94); BB: 0.81 (0.75, 0.98); BB: 0.57 (0.35, 0.87); ARB: 0.81 (0.63, 1.01); ACEI+BB: 0.61 (0.54, 0.68). The treatments that are expected to be most efficacious depended on the treatment classification: Analysis 1 supported ACEI+BB and BB, whereas Analysis 2 supported ACEI+BB+MRA+MRA+MRA. RR: 0.44 (0.34, 0.58) and 0.48 (0.38, 0.66), respectively. Conclusions: Combination treatments were likely to be more efficacious than monotherapy and adding a class to a regimen was likely to make it more efficacious regardless of the regimen. However, treatment classifications affect the results and interpretation. The approach that accounts for concomitant treatments is preferred.

CV2
PRODUCTIVITY LOSS AND INDIRECT COSTS ASSOCIATED WITH NEW CARDIOVASCULAR EVENTS IN HIGH-RISK PATIENTS WITH HYPERLIPIDEMIA - ESTIMATES FROM POPULATION-BASED REGISTRY DATA IN SWEDEN
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OBJECTIVES: Despite NICE’s reference case specifying that utilities derived from under-18s were used to inform National Institute for Health and Care Excellence (NICE) Technology Appraisals (TAs) providing cost-effectiveness guidance in paediatric indications, in line with the NICE reference case. Here we review the extent to which utility data derived from under-18s were used to inform National Institute for Health and Care Excellence (NICE) Technology Appraisals (TAs) providing cost-effectiveness guidance in paediatric indications, in line with the NICE reference case. METHODOLOGY: A systematic literature search identified 56 relevant RCTs (1980-2013) that reported mortality data that were synthesized using a Bayesian Poisson regression NMA model. Treatment regimens were classified as angiotensin-converting enzyme inhibitors (ACEI), beta blockers (BB), angiotensin II receptor blockers (ARB), mineralocorticoid/aldosterone receptor antagonists (MRA) and the ß1-channel inhibitor (ß1) ibradine. Analysis 1 classified treatments according to the main drugs of interest, whereas Analysis 2 treated combinations according to the main drugs of interest as well as the concomitant treatments belonging to classes of interest if more than 50% of patients were taking concomitant drugs. RESULTS: Six regimens were compared in Analysis 2 and 10 regimens were compared in Analysis 2. Analysis 1 resulted in the following rate ratios (RR) versus placebo: ACEI: 0.81 (0.75, 0.94); BB: 0.81 (0.75, 0.98); BB: 0.57 (0.35, 0.87); ARB: 0.81 (0.63, 1.01); ACEI+BB: 0.61 (0.54, 0.68). The treatments that are expected to be most efficacious depended on the treatment classification: Analysis 1 supported ACEI+BB and BB, whereas Analysis 2 supported ACEI+BB+MRA+MRA+MRA. RR: 0.44 (0.34, 0.58) and 0.48 (0.38, 0.66), respectively. Conclusions: Combination treatments were likely to be more efficacious than monotherapy and adding a class to a regimen was likely to make it more efficacious regardless of the regimen. However, treatment classifications affect the results and interpretation. The approach that accounts for concomitant treatments is preferred.
OBJECTIVES: To estimate productivity loss and associated indirect costs in work- ing-age high-risk patients treated for hyperlipidemia who experience new cardio-vascular (CV) events. METHODS: A retrospective population-based cohort study was conducted using Swedish electronic medical records linked to national health registers and the Social Insurance Register. Patients were included based on a pre-scription indication of hyperlipidemia between January 1, 2006 and December 31, 2011 and followed until December 31, 2012 for identification of CV events and estimation of work productivity loss (e.g. sick leave and disability pension) and indirect cost. Patients were stratified into two groups based on the CV risk level. Baseline score matching was applied to compare patients with new events (cases) to patients without new events (controls). For all outcomes, the incremental effect estimate of a new CV event was the difference between cases and controls in the differences between the year before and the year after the cases’ new CV event. The incremental effect estimate on mean indirect costs of sick leave was largest in the CV risk-equivalent (RE) cohort (n=2,996) at 38.39 SEK. The corresponding figure in the non-risk-equivalent RE cohort was 10.56 SEK. These two groups had a substantial variation in work productivity loss with regard to type of new CV event. Transient ischemic attack and percutaneous transluminal coronary angioplasty had no sig- nificant effect on indirect cost. Other types of CV events yielded a substantial incre- ment in indirect costs. The highest indirect cost was related to myocardial infarction (27,189 SEK) and most notably ischemic stroke at 61,500 SEK. New CV events did not have a significant impact on disability pension in either cohort. CONCLUSIONS: High indirect costs are related to work productivity losses associated with new CV events in high-risk patients treated for hyperlipidemia. The effect of new CV events on indirect costs varied by event type.

CV3 INCIDENCE DESCRIPTION AND COSTS OF ACUTE HEART FAILURE IN THE NETHERLANDS

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OBJECTIVES: Acute heart failure (AHF) is frequent, severe and costly, however detailed population-based epidemiological data are currently unavailable for the Netherlands. Our aim was to characterize the incidence, clinical features and outcomes of AHF, and estimate associated hospitalization costs in the Netherlands. METHODS: Using the 2010 Dutch Hospital Data (DHID), we identified all patients admitted to hospital with AHF as a primary diagnosis. DHID provide data on patient characteristics, primary diagnosis, date of admission and discharge, sur- gical procedures, prior location and discharge destination. We applied contemporary estimates of health care activity associated with AHF in order to calculate its cost in 2014. Major sources of health care activity included in this estimate were hospital admissions associated with a primary diagnosis of AHF, associated drug uti- lization, pathology and diagnostic testing. We then estimated the unit costs of health care based on national health care activity and cost data. RESULTS: Primary analysis of the data identified 7,717 patients to be admitted at least once into Dutch hospitals in 2010 due to primary diagnosis of AHF. The mean age of patients was 77.1 (±11.3) and 51% were women. The most common comorbid conditions were cardiac dysrhythmias, essential hypertension, old myocardial infarction, other diseases of endocardium and diabetes. The mean hospital length of stay was 8.67 days during the first admission event and 3.35 days during the year after the cases’ new event. The percentage of mortality was 11.3% and readmission to hospital was observed in 13.8% of the patients. Finally, the cost of an AHF hospitalization in the Netherlands was estimated to be 14,623. CONCLUSIONS: Our study provided important insights into the clinical characteristics and costs of AHF hospitalizations in the Netherlands. Further analysis including secondary diagnosis will indicate what the exact number of AHF hospitalizations is, and whether this resembles previously published figures from the National Institute for Public Health and the Environment of 29,838 patients hospitalized and diagnosed with congestive HF.

CV4 HEALTH UTILITY IN PATIENTS FOLLOWING CARDIOVASCULAR EVENTS

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OBJECTIVES: Cardiovascular (CV) disease is a major contributor to morbidity and mortality in the UK. Health-related quality of life (HRQoL) data is an important requirement of the development process and is used to inform the healthcare state utilities within economic models. METHODS: EuroQol-5 dimension (EQ-5D) surveys were sent to patients (age ≥18 years) from three centres in the UK (Barnet, Cheadle, Peterborough) 1 month following hospital admission for a myocardial infarction (MI), unstable angina (UA) or stroke. Patient demographics, lifestyle and baseline utility score were collected in the first survey. Follow-up surveys were sent at 6, 12, 18 and 24 months capturing subsequent health events and utility scores. Descriptive statistics and general linear regression models were used to describe the patients and to identify changes in utility over time. RESULTS: 1,350 patients (mean age 68 years) were included. Of these, 750 patients had MI, 471 patients had UA and 24 (1.8%) had a stroke. 345 (25.6%) patients also had diabetes. Baseline utilities were 0.690 (SD 0.322) in patients with a MI and 0.623 (SD 0.322) in patients with UA. Using a EQ-5D-5L with an average electoral discount rate of 0.036, the three-month utility was 0.846 (SD 0.24) at 1 month, changing to 0.846 (SD 0.24) at 6 months, 0.877 (SD 0.14) at 12 months, 0.855 (SD 0.14) at 18 months, and 0.836 (SD 0.14) at 24 months. Diabetes was associated with a decrement of 0.016, 0.046, 0.076, 0.076 and 0.059 at 1, 6, 12, 18 and 24 months, respectively. CONCLUSIONS: Health utility in patients following MI, UA or stroke is relatively well and non-elective patient admission rates, general practitioner (GP) referral rates and prescribing spend in 20 North London Clinical Commissioning Groups (CCGs). METHODS: Using information provided by National Health Service (NHS) England CGG information packs and the NHS CGG Outcomes Tool, age and sex standard-ized elective and non-elective admissions rates, GP referral rates and average prescribing spend were extracted and compared to national averages and to the prevalence of 19 commonly occurring diseases available through the Outcomes Tool (2011). RESULTS: Of the 20 North London CCGs included in this analysis, 4 reported a higher non-elective admission rate (per 1,000 of the population) than the national average (26.8%). Of these, 750 (4%) were from MI, 471 (24%) from UA and 24 (1.8%) had a stroke. 46.5% during PCPI and 76.7% in ECPI. Also, there was monthly cost saving by both PCPI and ECPI (4880 $ and 8052 $ respectively). This means that ECPI resulted in more improvement in cost saving in per patient, per 1,000 (28% vs. 16%). The per patient, per 1,000 dispensed quantity was saved by PCPI and 90% by ECPI. Likewise there was a significant cost saving per month that is 3052 $ for PCPI and 5799 $ for ECPI. Thereby 4% of all the cost saving result from ECPI. Regarding Cefepime, although both PCPI and ECPI reduced the dispensing cost, the interesting result was that ECPI (25% and 5.8% respectively) could be due to the clinical pharmacist recommendation according to local antibiotic. CONCLUSIONS: PCPI generally results in cost saving of therapeutic plan. ECPI can lead to more remarkable cost saving.

HEALTH SERVICES RESEARCH STUDIES

HS1 FOLLOW-UP AUTOANTIBODY TESTING AND HEALTH CARE UTILIZATION AMONG PATIENTS WITH (SUSTAINED) CELIAC DISEASE ACTIVITY IN THE NETHERLANDS

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OBJECTIVES: To examine follow-up of autoantibody testing and health care utilization among patients with (sustained) celiac disease. METHODS: From the PHARMO Database Network, patients with a positive autoantibody test for deamidated gliadin peptide (anti-DGP) or tissue transglutaminase (anti-TG) (period 1998-2008) were classified as celiac disease patients. The first positive test served as index date. For patients with ≥12 months follow-up, autoantibody tests in the year after the index date were performed. A new positive test was defined as the same cut-off; between 6-12 months after index date were classified as ‘sustained celiac disease’ patients and matched 1:1 on gender, birth year and index date of celiac disease patients without a second positive test. For these patients, health care utilization in 2012 was determined. RESULTS: 1,815 patients had at least one positive autoantibody test, of which anti-TG was most common (86%). 1,724 patients had ≥12 months follow-up, of which 75% did not have any type of autoantibody test in the year after index date. 183 patients (11%) were classified as ‘sustained celiac disease’ patients. Of these, 63 were active in the database in 2012 and could be matched. The proportion of patients with at least one GP visit and/ or hospitalization in 2012 was lower among sustained celiac disease patients. 76% and 36% vs. 63% and 24% for hospitalization without sustained celiac disease. However, the mean (±SD) number of GP visits was higher among sustained celiac disease patients (4.3 ± 7.3 vs. 3.4 ± 5.3) as was the mean (±SD) number of outpatient drug dispensings (6.6 ± 9.6 vs. 3.7 ± 5.0). CONCLUSIONS: This study shows limited follow-up autoantibody testing among patients with celiac disease and does not suggest higher health care utilization with sustained celiac disease. These findings are important with notion of patients managing the disease without engaging the health care system.
the prediction of these events challenging for primary care management and NHN community provision. This could potentially result in increased hospital admissions, irrespective of morbidity in the population. Alternatively, the discrepancy may be influenced by patient proximity to accident and emergency (A&E).

**H54** INFORMATION USED IN THE DECISION-MAKING PROCESS REGARDING INFLUENZA VACCINATION POLICY: PERCEPTIONS OF STAKEHOLDERS IN FRANCE AND THE NETHERLANDS

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**OBJECTIVES:** To minimize the medical and societal impact of influenza, most WHO countries recommend seasonal vaccination in targeted populations; however, little is known about the decision-making procedures at a country-level. In Europe, the Netherlands has the highest rate of influenza vaccination and France is not far behind. Our purpose was to analyze differences and similarities in the information used in the decision-making process between these two countries, according to the stakeholders involved. **METHODS:** A preliminary documentary analysis identified all stakeholders, at national level in both countries, as decision-makers (governmental authorities), advisors and information providers (research institutions, groups of experts), and vaccine manufacturers. We undertook a qualitative study including at least one actor from each stakeholder group involved in the process. Thirty-three face-to-face or telephone semi-structured interviews were conducted during summer 2013 in France (n=16), and autumn 2013 in the Netherlands (n=17). Every interview was recorded and transcribed. NVivo10 was used for the qualitative analysis. **RESULTS:** Stakeholders in France and the Netherlands follow international recommendations. The most relevant information is clinical trials and epidemiological studies. Economic models gained importance after the 2009 influenza pandemic, especially in the Netherlands, as part of studies conducted for government. All types of studies are assessed through a standard checklist for public health vaccinations in the Netherlands. In France, the assessment is not standardized, but based on general checklists. Decision-makers are increasingly worried about the quality of studies, due to the lack of standardized methods and influenza uncertainty. When published studies are not generalizable, local studies are required. **CONCLUSIONS:** Information used in the decision-making process is similar in both countries, although economic models have greater importance in the Netherlands. The excellence of the process is challenged by the poor quality of influenza data. Efforts should be made on standardization of study methods, together with harmonization of European policy.

**MEDICATION ADHERENCE STUDIES**

**MA1** COST-EFFECTIVENESS OF REAL-TIME MEDICATION MONITORING IN CHILDREN WITH ASTHMA

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**OBJECTIVES:** Poor asthma control in children is partly caused by poor adherence to medication. The aim of this study was to investigate the effectiveness and costs of monitoring adherence to medication. The intervention group text messages were sent to parents to remind them to check inhalers. The control group received no text messages. **RESULTS:** The mean number of days with moderate or severe exacerbation was lower in the intervention group (6.9±5.3 days) than in the control group (7.3±5.4 days). **CONCLUSIONS:** Real-time medication monitoring increases adherence and is cost-effective.

**MA2** THE BURDEN ASSOCIATED WITH NON-ADHERENCE IN EUROPEAN PATIENTS WITH DEPRESSION

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**OBJECTIVES:** Adherence to medication is regarded as an important factor for predicting clinical outcomes in mental disorders such as depression, bipolar disorders or schizophrenia. The current study investigates the relation between adherence and the burden of depression on society and individuals. **METHODS:** Data were from the 2013 EU National Health and Wellness Survey (NHWS), an internet-based survey from a representative sample of adults from France, Germany, Italy, Spain and UK stratified by age and gender. Of 63,000 respondents, 8,462 (13%) reported a diagnosis of depression and 3,937 (6%) having a prescription medication for depression (Rx). Respondents classified as adherent according to the Morisky Medication Adherence Scale (MMAS) were compared to the non-adherent on severity (FHQ-9), sociodemographicstrich characteristics, health-related quality of life (SF-36), work productivity and activity impairment (WPAI) and health care resource use (physician, hospital and emergency visits). **RESULTS:** Compared to adherent respondents (44%) those who were non-adherent (46%) were more severe (33% vs. 31% with FHQ-9 score ≥ 15); had lower Mental Component Summary (MCS: 32 vs. 33); higher Absenteeism (18 vs. 16); more emergency visits in the previous 6 months (0.49 vs. 0.42); and their satisfaction with medication was lower (4.97 vs. 5.27) (All p<0.05). About 75% of both groups were participating in psychotherapy at the time of survey and showed no significant difference in Physical Component Summary (PCS); Presenteeism; and number of hospitalizations. **CONCLUSIONS:** While efficacy measured during clinical trials are one of the most influential measures in treatment assessment, its ecological validity may be jeopardized by non-adherence to medication in real life. The current study shows that low adherence is associated with more severe depression, lower treatment satisfaction and lower mental quality of life (MCS). It is recommended that future studies are not generalizable, local studies are required. **CONCLUSIONS:** Information used in the decision-making process is similar in both countries, although economic models have greater importance in the Netherlands. The excellence of the process is challenged by the poor quality of influenza data. Efforts should be made on standardization of study methods, together with harmonization of European policy.

**MA3** ASSESSING THE RELATIONSHIP BETWEEN PATIENT COMPLIANCE TO BLOOD GLUCOSE MONITORING AND HEALTH RELATED QUALITY OF LIFE

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**OBJECTIVES:** The objective of our research was to evaluate whether there is a relationship between patient compliance to blood glucose monitoring (BGM) and HRQoL. According to previous research, there is a significant relationship between BGM and what their actual BGM frequency was during the past month. Moreover patients were asked to explain why they were not compliant to the recommended BGM frequency. **RESULTS:** Not being compliant explained 52% (R² = 0.52) of the variance in HRQoL. The main reasons for not being compliant to the recommended BGM frequency were: no coverage of strips by the insurance, pain and discomfort related to blood testing, not willing to know the test result. Other less important drivers of non-compliance were: inconvenience, issues with food intake and meter malfunctioning. **CONCLUSIONS:** Medication manufacturers are right when they reckon that BGM is crucial to diabetes patients’ disease management. Manufacturers have been innovating to make the blood testing as convenient as possible. Yet an important driver for not complying to the recommended BGM frequency remains to be pain and discomfort during blood testing. Manufacturers should also continue their efforts to ensure coverage of strips by the different insurance providers in the USA.

**MA4** ADHERENCE TO ANTIRETROVIRAL THERAPY (ART) AMONG ADULT HIV POSITIVE PATIENTS IN VOLTA REGIONAL HOSPITAL, GHANA

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**OBJECTIVES:** Adherence to antiretroviral therapy (ART) is a critical element towards reducing the emergence and spread of drug resistant strains of the virus. To achieve a sustained virological suppression, at least a 95% optimal adherence is necessary. This study sought to explore the level of adherence and also identify the factors contributing to non-adherence to therapy among people living with the HIV/AIDS. **METHODS:** The study was a descriptive cross sectional type. A systematic sampling method was used to recruit 146 adult ARV users who have been on therapy for at least 3 months and attended the ART clinic between March to May, 2014. Using a structured and pretested questionnaire, data on medication adherence were collected by adopting a one month visual analogue scale (VAS) recall, a 4 days self reported adherence, and a pill identification test technique (FIT). A multivariate logistic regression was then used to determine key factors that were associated with adherence. **RESULTS:** Of the three methods used, the optimal adherence (> 95%) for the pill identification test (FIT) was 76%, followed by the visual analogue scale (71.2%). The 4 days self report recorded the least adherence rate (65.1%). The overall rate of high optimal adherence was found to be 51.4%. Respondents aged 46 years or more were highly adherent (61%) than their counterparts who are less than 25years (60.0%). Those between 25 to 46years of age were the least adherent (45.0%). However, the association between the level of adherence and the socio-demographic variables (sex, age, employment, and marital status) was not statistically significant. **CONCLUSIONS:** The overall adherence found to be related to age and gender fell below the expected optimum level. Adherence to ART should aim at improving the pre treatment counselling and ensure the availability of ART’s at all times.

**STUDIES ON NICE ASSESSMENTS**

**N11** EXPLORING THE FLAWS IN CLINICAL DATA THAT LEAD TO REJECTION OF NICE SUBMISSIONS

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OBJECTIVES: New health technologies are required to demonstrate clinical- and cost-effectiveness before being recommended by NICE for use in the National Health Service. A large proportion of submissions are rejected, at least in part, due to poor trial design or flaws in the presented clinical data. Published NICE guidance includes a comprehensive critique of submitted clinical evidence. Therefore, failure of the clinical data leading to early or quick rejections by NICE is seen as a means of providing guidance for future submissions. METHODS: All single-technology appraisals from January 2006 to May 2014 from NICE were included in the analysis. Multiple technology appraisals, resubmissions, vaccination programmes, and requests for advice were excluded. The recommendation and reasoning behind each decision were assessed, focusing on the critique of the clinical evidence. RESULTS: 121 NICE submissions met the inclusion criteria, of which 28 (18.9%) were rejected. Notable flaws in the presented clinical data were reported in 22 (17.8%) of the submissions. Major drivers of rejection due to clinical flaws included: uncertainty in the clinical evidence (32.1%), statistical flaws in trial design or analysis (26.6%), and the absence of long-term follow-up data (20.6%). These factors contributed to a perceived failure to demonstrate clinical superiority over the comparator in 42.9% of the rejected submissions. CONCLUSIONS: A failure to convincingly demonstrate clinical superiority over the comparator in 42.9% of the rejected submissions suggests that further work is required to improve the quality of trial submissions to NICE, often due to clinical trial design weaknesses or uncertainty surrounding the data presented. Manufacturers should not underestimate the need for effective planning and review of trial design early in the clinical development process, in order to avoid rejection by HTA agencies in later development stages.

N22 PREDICTING THE IMPACT OF VALUE-BASED ASSESSMENT ON FUTURE NICE APPRAISALS

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OBJECTIVES: Value-based assessment will be introduced into National Institute for Health and Care Excellence (NICE) appraisals where the willingness-to-pay above £50,000 per Quality-Adjusted Life Year (QALY) is considered poorly justified. The objective of this research was to re-evaluate past appraisals and determine whether there was a relationship between the absolute and proportional QALY shortfalls and the NICE rejection rates. METHODS: Final incremental cost-effectiveness ratios (ICERs) were identified from NICE single technology appraisals published between January 2013 and May 2014. The age that treatment commenced was taken from manufacturer submissions and combined with the average life expectancy in the UK to calculate the discounted QALYs accrued by a healthy person (X). Discounted QALYs accrued by current treatment were extracted from manufacturer submissions (Y). Consequently, absolute (X-Y) and proportional (absolute/X) QALY shortfalls were calculated for each condition. Logistic regression (LR) was performed on the data. Appraisals were excluded if the manufacturer submission was missing. RESULTS: Of the appraisals assessed, 23 appraisals met the selection criteria; 13 were recommended and 10 not recommended by NICE. The LR confirmed that the probability of an intervention being recommended was reduced significantly if the ICER was >£50,000 per QALY and the absolute shortfalls were significant (p<0.05). Taking into account the ICER, LR analysis demonstrated that neither the proportional nor absolute QALY shortfall had a significant effect on recommendation by NICE (p>0.05). CONCLUSIONS: These results suggest that in recent appraisals, proportional and absolute QALY shortfalls have had little to no significant effect on the NICE committee’s decisions, and that the introduction of value-based assessments may therefore cause a substantial change in the future outcomes of HTA processes. It is recognised that further appraisals before 2013 should be evaluated to confirm these results, as the sample size was small.

N3 NICE’S PROPOSED VALUE-BASED ASSESSMENT OF HEALTH TECHNOLOGIES: CONCERNS OF INCORRECT CONSIDERATION OF SOCIAL VALUES

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BACKGROUND: The UK’s National Institute for Health and Care Excellence (NICE) recently proposed amendments to its health technology appraisal methods. Previous amendments in 2009 and 2011 placed a greater value on the health of patients at the “end of life” and in cases where “treatment effects are both substantial in restoring health and sustained over a very long period”. The recent proposals re-emphasise the need to assess the willingness to pay above £50,000 per QALY. The UK’s National Health Service (NHS) was established to provide healthcare free at the point of delivery for the majority of patients in control of arm of clinical studies commonly switch to the experimental drug or receive other post-study treatments. The objective of this study was to assess the willingness to pay for the interventions that are available that are able to adjust overall survival (OS) estimates for resulting bias. METHODS: PubMed and the AIDS R&D Insights database were searched to identify pivotal trials involving treatment switching. Related HTA appraisals, published between January 2011 and June 2014 were compared to submissions from selected HTA agencies. RESULTS: Sixteen pivotal trials and 45 related HTA appraisals were identified from the selected HTA agencies websites for further analysis. Reports from 10 agencies were considered for review. CONCLUSIONS: Sixteen pivotal trials and 45 related HTA appraisals were identified from the selected HTA agencies websites for further analysis. Reports from 10 agencies were considered for review. These results suggest that in a Discrete Choice Experiment (DCE) affects study results with respect to the relative importance of the attributes, trading behavior and potential uptake rates. METHODS: By means of ongoing data collection, two versions of a DCE questionnaire containing nine D-efficiently designed choice tasks were distributed among a representative sample of the Dutch population aged 55-65yrs. The DCE consisted of four attributes related to the decision whether to participate in preventive screening for colorectal cancer (CRC). Three fixed attributes were: risk of being genetically predisposed, risk of developing CRC, and frequency of follow-up colonoscopies. The included risk attribute was framed positively as survival rate and negatively as mortality rates. Mixed logit models were conducted to estimate the relative importance of the attributes. Dominant decision behavior was determined and potential uptake rates were calculated. RESULTS: Overall, risk attribute framing significantly interacted with most of the attribute level estimates. Based on the positive versus negative framing, the frequency of follow-up colonoscopies was most important followed by survival rate, while based on the negative frame, mortality rate was most important. Twice as many respondents dominated on the survival attribute compared to the mortality attribute. Potential uptake rates were calculated for multiple hypothetical scenarios, in all cases they were lower based on the data of the negative frame. CONCLUSIONS: The use of a positive frame leads to significantly increased frequency of dominant choices. Negative framing of the risk attribute resulted in a different relative importance of the attributes and a lower willingness to participate in genetic screening for CRC compared to positive framing. These results call for greater attention and more research with regard to the impact of framing risk attributes in DCEs aiming to elicit preferences within the health care or public health context.

R22 MAPPING FROM SF-36 TO EQ-5D: CHANGES IN ESTIMATES BASED ON THE CHOICE OF ALGORITHM

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OBJECTIVES: Where data collected using a preferred utility instrument are not available, alternative mapping algorithms may be available. However, the quality of existing algorithms are poorly justified. The second of the three flaws is particularly significant, as the failure to apply special considerations to displaced services may result in NICE’s cost-effectiveness thresholds being too high to adequately represent opportunity cost. Furthermore, the baseline threshold of £20,000 per QALY is greater than current estimates of the opportunity cost. Overall, these flaws lead to several undesirable consequences including age discrimination, a systematic bias in favour of new interventions and, on the basis of an early analysis of a trial of a cancer intervention being recommended was reduced significantly if the ICER was >£50,000 per QALY. The objective of this study was to investigate the similarity of a widely used older mapping from SF-36 to EQ-5D and the newer algorithms. METHODS: Three fixed attributes were: risk of being genetically predisposed, risk of developing CRC, and frequency of follow-up colonoscopies. The included risk attribute was framed positively as survival rate and negatively as mortality rates. Mixed logit models were conducted to estimate the relative importance of the attributes. Dominant decision behavior was determined and potential uptake rates were calculated. RESULTS: Overall, risk attribute framing significantly interacted with most of the attribute level estimates. Based on the positive versus negative framing, the frequency of follow-up colonoscopies was most important followed by survival rate, while based on the negative frame, mortality rate was most important. Twice as many respondents dominated on the survival attribute compared to the mortality attribute. Potential uptake rates were calculated for multiple hypothetical scenarios, in all cases they were lower based on the data of the negative frame. CONCLUSIONS: The use of a positive frame leads to significantly increased frequency of dominant choices. Negative framing of the risk attribute resulted in a different relative importance of the attributes and a lower willingness to participate in genetic screening for CRC compared to positive framing. These results call for greater attention and more research with regard to the impact of framing risk attributes in DCEs aiming to elicit preferences within the health care or public health context.

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Replicating a published regression predicting EQ-SD based on Health Assessment Questionnaire Disability Index (HAQ-DI) as a covariate, patients in the current study provided significantly different utility scores (range 0.66-0.82) were observed for the anchor HS (minimal disease activity) scenario compared to those associated with the anchor HS: mild flare HS (0.55-0.71), moderate flare HS (0.58-0.53), severe renal flare HS (0.33-0.45), severe Central Nervous System (CNS) flare HS (0.30-0.45) and severe peripheral flare HS (0.19-0.28). Significant differences were observed between the anchor state and each flare state across all countries (p<0.05). Mean VAS scores followed the same trend. The severe generalised flare HS received the lowest mean VAS utility score across all six countries suggesting that the perceived day-to-day impact of a flare was generalised at severe CNS or severe renal flare.

**CONCLUSIONS:** These results show that a decrease in utility, representing a detrimental impact on HRQoL, was observed with increasing severity of flare. These results could be applied in cost-utility analyses for interventions for SLE.

**PL3 INVESTIGATING THE IMPACT OF PERSPECTIVE ON WEIGHTING QALYs: A DISCRETE CHOICE EXPERIMENT**

**OBJECTIVES:** Discrete choice experiments (DCEs) are increasingly being used to elicit preferences for weighting QALYs by other characteristics. Recent studies for weighting QALYs have asked respondents to take the role of decision maker and prioritize treatment options for groups of patients ‘someone else’. The procedure normally used to obtain preferences for health states is for respondents to consider oneself in that state from behind a veil of ignorance. The aim of this study was to elicit public preferences for weighting QALYs by other characteristics, and to test if the decision-maker perspective or naming the condition is equivalent to choosing for oneself from behind a veil of ignorance.

**METHODS:** A DCE was carried out using a choice experiment (CE) developed with attributes for health gain, severity, unmet need and process of care. Four questionnaires were designed to reflect three different perspectives and one alternative framing: a) ‘someone else’, b) ‘someone like oneself’ c) ‘someone else’ d) ‘someone else’ with a disease label (age-related macular degeneration). 800 members of the public were recruited via an online survey panel, with 200 completing each of the four questionnaires. Results were compared using multiple regression analyses (range: 1 [very low] to 5 [very high]).

**RESULTS:** Attributes of health gain, severity and process of care were significant for all perspectives (p<0.05). Respondents preferred treatments that offered greater health gain, for a higher severity (lower starting level of health) and a more convenient process of care. Differences in the ‘oneself’ perspective with respondents preferring treatments that addressed an unmet need. **CONCLUSIONS:** Members of the public are willing to trade health gain for other characteristics. These include severity, process of care, and in some cases unmet need. There is evidence that preferences for weighting QALYs vary by perspective. The study may help inform criteria for decision-making when prioritizing health care resources.

**PL4 VALUING EQ-SD-5L: DOES THE ORDERING OF THE HEALTH DIMENSIONS IMPACT ON HEALTH STATE VALUATIONS?**

**OBJECTIVES:** Health states defined by multi-attribute instruments such as the EQ-5D and EQ-5D-5L are designed for use across countries and cultures in a variety of study contexts. The ordering of the dimensions may impact on the health state values provided. The order of dimensions is an important heuristic to answer the questions (for example focusing on the first dimension presented), and therefore the order of the dimensions may impact on the impact on health state valuations.

**METHODS:** Preferences for EQ-5D-5L health states were elicited from a broadly representative sample of members of the UK general public. Respondents were allocated to one of three EQ-5D-5L dimension orderings, and completed 10 TTO and 5 VAS tasks via an online survey. Respondents were asked to consider themselves in a variety of health states and then to use a TTO method to decide whether they would accept a hypothetical state of perfect health in place of their current state.

**RESULTS:** Across the three dimension ordering groups, there were no differences in the magnitude of utility decrements for health states between the ordering groups. However, there was significant variation in the magnitude of utility decrements between the ordering groups. The magnitude of utility decrements was significantly lower for those respondents who were asked to consider themselves in perfect health in place of their current health state.

**CONCLUSIONS:** The magnitude of utility decrements was significantly lower for those respondents who were asked to consider themselves in perfect health in place of their current health state. The results of this study suggest that the ordering of the dimensions has the potential to affect the results of analyses performed. These differences may reflect differences in the magnitude of utility decrements for health states between the ordering groups. However, there was significant variation in the magnitude of utility decrements between the ordering groups. The magnitude of utility decrements was significantly lower for those respondents who were asked to consider themselves in perfect health in place of their current health state.
comparison, and health economic examples. In the numerical comparison, the valuation of EQ-5D states with pure improvements were compared. In the empirical study, a database of 23,925 individuals was used to identify patient groups that could be influenced by the implementation of experience-based value sets. Two hypothetical health economic examples were used to examine the implications of the shift to experience-based value sets. Furthermore, the health economic examples showed the choice of a value set has an effect on the health economic result.

CONCLUSIONS: Shifting to experience-based QALY-weights would increase the estimated level of quality of life in virtually all health states, including severe hypoglycemia. The weight of QALYs in the experience-based value set. The empirical comparison showed that only three health states were assigned a lower QALY-weight in the experience-based value set. We recommend using the experience-based value set in economic evaluations.

PDB1
HIPOS-ER (HYPOGLYCEMIA IN PORTUGAL OBSERVATIONAL STUDY – EMERGENCY ROOM): OUTCOMES WITH DIFFERENT ANTI-HYPOGLYCEMIC AGENTS

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OBJECTIVES: HIPOS-ER is an observational study to describe the population of Type 2 Diabetics treated with an anti-hyperglycemic agent (AHA) and admitted to the emergency room (ER) with a hypoglycemic event. The first national hypoglycemia study in Portugal and the first study collecting hypoglycemia specific resource data directly in this setting. Here we aim to describe the clinical features of hospitalized patients. METHOD: The study enrolled patients from 7 centers in mainland Portugal from Jan 2013 – Jan 2014. Sociodemographic and clinical data were collected at the emergency room and patients who required hospital admission were followed up. Episodes were enrolled consecutively within the sampling period. AHA therapy classes were: Insulin - Group 1, Secretagogues - Group 2, Oral AHA excluding secretagogues - Group 3 and Insulin-secretagogue - Group 4.

RESULTS: A total of 238 patients were admitted to the ER with severe hypoglycemia and 105 (44%) were hospitalized and 2 (1%) were not followed up. In the last 12 months was more frequent in Group 1 vs. Group 2 (p=0.009). Group 2 patients were more often followed up and Group 3 was 17% (13% Group 1, 8% Group 2, 7% Group 3 and 7% Group 4). Previous severe hypoglycemia in the last 12 months was more frequent in Group 1 vs. Group 2 (p=0.009). Group 2 patients were more often followed up. Episodes were enrolled consecutively within the sampling period. AHA therapy classes were: Insulin - Group 1, Secretagogues - Group 2, Oral AHA excluding secretagogues - Group 3 and Insulin-secretagogue - Group 4.

CONCLUSIONS: The study enrolled patients from 7 centers in mainland Portugal for a period of 12 months (Jan 2013 – Jan 2014). Sociodemographic and clinical data were collected at the emergency room and patients who required hospital admission were followed up. Episodes were enrolled consecutively within the sampling period. A total of 238 patients were enrolled, and 105 (44%) were hospitalized and 2 (1%) were transferred outside the hospital center for likely need of hospitalization. Mean age on insulin, 51% on a secretagogue, 9% on an AHA excluding secretagogue and 18% on insulin-secretagogue. 26% had complications diagnosed in the ER: Trauma (37%) and Cardiovascular (22%) and infection/Septic (22%) were the most frequent. Mean length of stay was 9 and 9 days for Group 1 and Group 2. CONCLUSIONS: Hospitalized diabetic patients following an ER episode due to hypoglycemia were treated mainly with secretagogue type drugs. Internal medicine was key in the hospitalization of these patients. The length of stay was 9 and 9 days for Group 1 and Group 2.

PDB2
HIPOS-ER (HYPOGLYCEMIA IN PORTUGAL OBSERVATIONAL STUDY – EMERGENCY ROOM): CLINICAL OUTCOMES IN ADMITTED PATIENTS

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OBJECTIVES: HIPOS-ER is an observational, cross-sectional, multicenter study to describe the population of Type 2 diabetics treated with an anti-hyperglycemic agent (AHA) and admitted to the emergency room (ER) with a hypoglycemic event. Objectives: The study enrolled patients from 7 centers in mainland Portugal from Jan 2013 – Jan 2014. Sociodemographic and clinical data were collected at the emergency room and patients who required hospital admission were followed up. Episodes were enrolled consecutively within the sampling period. AHA therapy classes were: Insulin - Group 1, Secretagogues - Group 2, Oral AHA excluding secretagogues - Group 3 and Insulin-secretagogue - Group 4.

RESULTS: A total of 238 patients were admitted to the ER with severe hypoglycemia and 105 (44%) were hospitalized and 2 (1%) were not followed up. In the last 12 months was more frequent in Group 1 vs. Group 2 (p=0.009). Group 2 patients were more often followed up and Group 3 was 17% (13% Group 1, 8% Group 2, 7% Group 3 and 7% Group 4). Previous severe hypoglycemia in the last 12 months was more frequent in Group 1 vs. Group 2 (p=0.009). Group 2 patients were more often followed up. Episodes were enrolled consecutively within the sampling period. AHA therapy classes were: Insulin - Group 1, Secretagogues - Group 2, Oral AHA excluding secretagogues - Group 3 and Insulin-secretagogue - Group 4.

CONCLUSIONS: The study enrolled patients from 7 centers in mainland Portugal for a period of 12 months (Jan 2013 – Jan 2014). Sociodemographic and clinical data were collected at the emergency room and patients who required hospital admission were followed up. Episodes were enrolled consecutively within the sampling period. A total of 238 patients were enrolled, and 105 (44%) were hospitalized and 2 (1%) were transferred outside the hospital center for likely need of hospitalization. Mean age on insulin, 51% on a secretagogue, 9% on an AHA excluding secretagogue and 18% on insulin-secretagogue. 26% had complications diagnosed in the ER: Trauma (37%) and Cardiovascular (22%) and infection/Septic (22%) were the most frequent. Mean length of stay was 9 and 9 days for Group 1 and Group 2. CONCLUSIONS: Hospitalized diabetic patients following an ER episode due to hypoglycemia were treated mainly with secretagogue type drugs. Internal medicine was key in the hospitalization of these patients. The length of stay was 9 and 9 days for Group 1 and Group 2.
offers similar or reduced HbA1c reduction, had comparable significant weight loss compared with DPP-4s andTZDs. No increased risk of adverse events were observed for empagliflozin compared with placebo and other AAs.

**PDB8**

**COMPARATIVE EFFICACY AND SAFETY OF EMPAGLIFLOZIN WITH OTHER ANTIDIABETIC DRUGS FOR THE SECOND LINE TREATMENT OF TYPE 2 DIABETES MELLITUS**

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**OBJECTIVES:** To compare the efficacy and safety of empagliflozin versus other second-line oral anti-diabetic drugs (OADs) as monotherapy in this population - excluding patients with gastrointestinal intolerance or contraindications such as chronic kidney disease.

**METHODS:** A systematic review and Bayesian network meta-analysis were performed to identify randomized controlled trials (RCTs) assessing the efficacy and safety of SGLT-2s, DPP-4s, GLP-1s, and TZDs in patients with T2DM. RCTs enrolling subjects with T2DM inadequately controlled on metformin plus sulfonylurea were included. The principal outcome of this network meta-analysis is to compare the efficacy and safety of empagliflozin versus other anti-diabetic drugs used in third line for the treatment of patients with type 2 diabetes mellitus (T2DM).

**RESULTS:** Forty-eight RCTs were included. The primary outcome was a composite of HbA1c, weight, systolic blood pressure (SBP), incidence of hypoglycaemia and urinary tract infections (UTIs) at 24 weeks.

**CONCLUSIONS:** Compared with other SGLT-2s, DPP-4s, and GLP-1s, empagliflozin offers similar or reduced HbA1c reduction, had comparable significant weight loss compared with DPP-4s andTZDs. No increased risk of adverse events were observed for empagliflozin compared with placebo and other AAs.

**PDB9**

**ASSESSING THE RELATIONSHIP BETWEEN IMPROVED LIFE EXPECTANCY DUE TO BETTER CARDIOVASCULAR RISK FACTOR MANAGEMENT AND THE LIKELIHOOD OF MICROVASCULAR COMPLICATIONS IN TYPE 2 DIABETES MELLITUS**

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**OBJECTIVES:** Type 2 diabetes mellitus (T2DM) is a chronic disease associated with increased risk of cardiovascular (CV) and microvascular complications. Improvements in blood pressure and cholesterol control have resulted in a reduction in CV event rates in clinical practice. The objective of this study was to assess improvements in CV event rates, and the risk of microvascular disease for a range of glycemic control levels.

**METHODS:** A lifetime analysis was conducted using the CORE diabetes model (CDM). Newly diagnosed T2DM simulated patients aged 52 years at baseline with HbA1c <7.1%, SBP 135.1 mmHg, total cholesterol: HDL 5.2 mmol/l were modelled. The impact of HbA1c on microvascular complications was assessed by running the CDM with baseline HbA1c ±1% for scenario 1, 100% of patient receiving CV risk factor management (CVF), CV risk factor management (CVF) and risk factor management were tested. CV risk factor management reduced the predicted cumulative incidence of fatal myocardial infarction (MI) from 27% to 18%, increasing life expectancy by an average of 2 years. SBP data base, baseline HbA1c <7%, 1% was associated with a 20%, 4% and 14% increase in microalbuminuria (MA), bone density and end stage renal disease (ESRD), respectively; for scenario 2, the increase was 15.5% for MA, 11% for bone density and 2.5% for ESRD. CV risk factor management alone ranged from 68.4% (baseline HbA1c <7%) to 42.1% (baseline HbA1c <6%) for scenario 1 and from 65.2% (baseline HbA1c <7%) to 39.7% (baseline HbA1c <7%) for scenario 2. Cumulative neuropathy rates were similar across both scenarios: 56.7% versus 56.0% for scenario 1 and 2, respectively. **CONCLUSIONS:** This analysis suggests that improvements in blood pressure and cholesterol management may result in increased rates of microvascular complications, particularly in renal disease, over the long term as patient survival increases.
OBJECTIVES: To quantify the number of costs and effects of relapses avoided over 2 years of treatment with subcutaneous treatment with SC interferon beta-1a and IM interferon beta-1a.

RESULTS: The modelled cohort evaluated the consequences of therapy was based on wholesale acquisition cost. Given the model's short time horizon, disability-related costs were not included as these tend to be an important economic driver only over the long-term progression of the disease. In test how variability in the model's inputs might impact the analysis' results, two sensitivity analyses were performed based on the reported 95% risk of relapse credible intervals for SC interferon beta-1a and IM interferon beta-1a. RESULTS: A hypothetical cohort of 1000 RPRs patients, treatment with SC interferon beta-1a is expected to reduce relapse and avoid the use of new therapy (range -20 to 399 relapses) and IM interferon beta-1a between 2 years. Assuming a direct cost of relapse of $561 per relapse, this study showed a savings of $801,212 (sensitivity analysis range -$102,138, -$2,052,834) versus IM interferon beta-1a. CONCLUSIONS: Subcutaneous interferon beta-1a is likely to result in fewer relapses and lower direct costs of relapse versus IM interferon beta-1a over a 2-year period of treatment.

OBJECTIVES: Network meta-analyses (NMA) provide estimates of comparative effects of different treatments when a variety of methods are used to examine inconsistency including: (i) node-splitting where the direct and indirect estimates are compared across the network (ii) comparison to an 'inconsistency' model. Given the model's short time horizon, the network meta-analysis provided an improved (DIC -60.25) compared to the consistency model (DIC -60.25).

RESULTS: The methods agreed in showing the presence of inconsistency with the network. For example, the inconsistency in two treatment arcs (liraglutide 1.8mg vs placebo and liraglutide 1.8mg vs exenatide QW). DCC methods vary in their ability to provide an omnibus 'test' of inconsistency across the network and their ability to identify which parts of the network contain inconsistencies. We highlight that none of the methods alone can identify individual studies as being the cause of inconsistencies and argue that we need to consider the whole structure of the network and the characteristics of the studies (in terms of treatments, subjects and design) within the network.

OBJECTIVES: To investigate HbA1c-reduction by baseline BMI in patients treated with canagliflozin or sitagliptin, using clinical trial and electronic medical record (EMR) data. METHODS: Patients were identified from two randomised controlled trials (RCTs) were used to explore HbA1c-reduction from baseline after 52 weeks treatment with canagliflozin (100/300mg) or sitagliptin (100mg) by baseline BMI. Ordinary least squares (OLS) regression was performed with HbA1c, BMI, eGFR and demographics as covariates, in patients with metformin (MET) or metformin-glimepiride (MET+SU) background therapy. EMR-data (UK General Practitioner data from CPRD) on HbA1c over time in patients treated with sitagliflozin or canagliflozin using a previously published NMA in ANd SITAGLIPTIN IN TyPE 2 dIABETES – REAL-wORLd dATA fROm OdySSEE STUdy

RESULTS: Conclusions: Central tendencies and residual variance within BMI categories were similar to each other BMI categories. Baseline BMI effects were comparable across BMI categories. The alternative methods vary in their ability to provide an omnibus 'test' of inconsistency across the network and their ability to identify which parts of the network contain inconsistencies. We highlight that none of the methods alone can identify individual studies as being the cause of inconsistencies and argue that we need to consider the whole structure of the network and the characteristics of the studies (in terms of treatments, subjects and design) within the network.

OBJECTIVES: Treatment maintenance duration of dual therapy with metformin and sitagliptin in type 2 diabetes – real-world data from ODYSSEE study

RESULTS: Conclusions: Central tendencies and residual variance within BMI categories were similar to each other BMI categories. Baseline BMI effects were comparable across BMI categories. The alternative methods vary in their ability to provide an omnibus 'test' of inconsistency across the network and their ability to identify which parts of the network contain inconsistencies. We highlight that none of the methods alone can identify individual studies as being the cause of inconsistencies and argue that we need to consider the whole structure of the network and the characteristics of the studies (in terms of treatments, subjects and design) within the network.
Multivariate Cox model adjusted for propensity score and sensitivity analysis confirmed a reduced risk of treatment change for M-Sit versus M-SU with a relative risk of 0.70 [0.62, 0.79] (p<0.0001).

CONCLUSIONS: We observed an approximately two-fold increase in the median treatment maintenance duration in the met-Sit group versus the met-SU group. Given the observational design, confounding factors and lack of information on long-term patient adherence, this finding should be interpreted with caution.

The `node-splitting` approach to modeling and analysis by design and treatment interaction has the potential for further investigation in the context of network meta-analysis.

In conclusion, the findings of this study are consistent with previous reports and suggest the potential utility of GLP-1 receptor agonists in the management of T2DM patients in real-world settings.

**Objective:** To determine the efficacy and safety of dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors) in type 2 diabetes patients according to published data.

**Methods:** A systematic review of randomized clinical trials (RCT) in MEDLINE, Cochrane, ISI WOK, SCOPUS and clinicaltrial.gov databases was performed. Inclusion criteria were: 1) RCT with a treatment duration of at least 24 weeks evaluating efficacy (HbA1c, fasting plasma glucose-FPG-) and safety (hypoglycaemia rate) of DPP-4 inhibitors (linagliptin, saxagliptin, sitagliptin, vildagliptin) compared with placebo or non-insulin monotherapy or combination, published in English or Spanish until June 2013. A meta-analysis was conducted using a random effects model. Standardized mean difference (SMD) for efficacy variables was calculated as: (Mean 1 - Mean 2) / pooled SD. Heterogeneity was assessed with the chi-square test and I². The level of statistical significance was set at p<0.05.

**Results:** A total of 295 datasets were identified, of which 17 were included in the final analysis. The pooled analysis of HbA1c reduction showed a significant advantage for DPP-4 inhibitors compared with placebo or non-insulin monotherapy or combination, with a standardized mean difference of -0.55 [95% CI: -0.62; -0.48] (p<0.0001) at 24 weeks. The incidence of hypoglycaemia was significantly lower with DPP-4 inhibitors compared with placebo or non-insulin monotherapy or combination, with a standardized mean difference of 0.29 [95% CI: 0.20; 0.37] (p<0.0001).

**Conclusions:** DPP-4 inhibitors are effective and safe for the management of type 2 diabetes mellitus, reducing HbA1c and improving glycemic control compared with placebo or non-insulin monotherapy or combination. Further research is needed to confirm these findings and to assess the long-term safety and efficacy of DPP-4 inhibitors.
therapy, with a lower risk of hypoglycemia and without affecting weight versus sulfonylurea and metformin combination.

PDB24 RECOMBINANT GROWTH HORMONE THERAPY IN CHILDREN WITH GH DEFICIENCY: FIRST INTERVENTIONAL STUDY IN ARMENIA
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OBJECTIVES: The purpose of this study was to evaluate the effectiveness and safety of treatment with recombinant growth hormone (rGH) in children with GH deficiency.
METHODS: This was an interventional study with 6 and 12 months follow-up. Treatment was received by 15 children. The patients were receiving the rGH in 0.033 mg/kg (0.1 Unit/kg) at the same time each day (9-10 pm) for period of 1 year. The effectiveness of treatment was evaluated based on change in growing speed, growth SDS and bone age maturation.
RESULTS: The mean age of children was 9.5±3.6 years. In the given sample 6 children had MHPD, other 9 children had IGHD. Treatment (p-0.001; p-0.001). The same improvement was in IGF-pb3 levels (p-0.001; p-0.001). The lipidemic profile was analyzed by changes in levels of cholesterol and LDL. During the treatment there were no any changes in indicators of kidney's function, indicators of liver's function as well as the indicators of carbohydrate metabolism.

PDB25 EFFECTIVENESS, SAFETY AND PATIENTS' SUBJECTIVE FEELINGS OF INSULIN PEN-NEEDLE: A SYSTEMATIC REVIEW
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OBJECTIVES: To compare the differences of effectiveness, safety and patients' subjective feelings for using different lengths of insulin pen-needle in diabetic patients.
METHODS: A retrospective analysis of relevant publications that were identified via electronic searches of databases using multiple search terms related to insulin pen-needle. RESULTS: Totally, 21 literatures were included. Firstly, for the effectiveness, 85.71% of the studies suggested that there was no difference of the shorter needle compared to the longer one. Secondly, for the safety, the shorter needle was better than the longer. No changes were observed with respect to fructosamine, glycated albumin and body mass index. Secondly, about the safety, all of the studies proved that the shorter needle was better in intra-muscular injections, adverse effects, subcutaneous lipodystrophy and bar phenomenon. 33.33% reported less hypoglycemic events, bleeding, bruising and needle bending with the shorter needle, the others showed no difference. All of the studies showed that the shorter needle was not different with the longer in the needle break, hyperglycemia and lipohypertrophy. 6.25% had pointed out that the shorter needle was better than the longer in leakage, while 81.25% showed no difference of the leakage. Thirdly, in term of subjective feelings, for convenience and acceptance, all studies agreed that shorter needle was superior to the longer. For fear and pain, half of studies suggested that shorter needle was superior to the longer one, the other half thought that there was no difference. In both studies, 69.23% suggested patients prefer the shorter, 23.08% suggested the patients prefer a particular needle length. CONCLUSIONS: Overall, the effectiveness of insulin pens with longer and shorter needle are comparable in treating diabetes, but the shorter needles little better in parts of the safety indexes. As for patients' subjective feeling, our findings show that patients are generally willing to accept shorter needle.

PDB26 ECONOMIC IMPACT OF COMBINING METFORMIN WITH DIPEPIDYL PEPTIDASE INHIBITORS IN DIABETIC PATIENTS WITH RENAL FAILURE
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OBJECTIVES: To evaluate the resource use and health costs due to the combination of metformin and dipeptidyl peptidase-4 (DPP-4) inhibitors in patients with diabetes and renal failure (RF) in routine clinical practice.
METHODS: An observational, retrospective study was performed. Patients aged ≥ 30 years treated with metformin who initiated a second oral antidiabetic treatment in 2009-2011 were included. Two groups of patients were analysed: a) metformin + DPP-4 inhibitors and b) other oral antidiabetics. The main measures were: compliance, persistence, hospitalization (determined by complications of hyperglycemia, cardiovascular events) and total costs. Patients were followed up for two years.
RESULTS: We included 395 patients, mean age 70.2 years, 56.5% male: 135 patients received metformin + DPP-4 inhibitors and 260 patients received metformin + other oral antidiabetics. Patients receiving DPP-4 inhibitors showed better compliance (66.0% vs. 60.1%), persistence (57.6% vs. 50.0%) and metabolic control (63.9% vs. 57.3%), respectively, compared with those receiving other oral antidiabetics (p < 0.05). Forty-three percent of patients showed a decline in rate of hyperglycemia, 37% showed a decline in rate of hypoglycemia, and 31% showed a decrease in total costs (€ 2,486 vs. € 3,002), p = 0.001.
CONCLUSIONS: Despite the limitations of the study, patients with renal failure treated with DPP-4 inhibitors had better metabolic control, lower rates of hypoglycemia, and lower health costs for the Spanish national health system.

PDB27 USES OF ELECTRONIC PATIENT INFORMATION SYSTEMS AND NATIONAL REGISTERS – IMPLEMENTATION OF THE CLINICAL PRACTICE GUIDELINE AND EVALUATION OF COSTS AND USES OF RESOURCES IN PATIENTS WITH INCIDENT TYPE 2 DIABETES IN FINLAND
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OBJECTIVES: Effective management of diabetes is the cornerstone for prevention of diabetic retinopathy. However, how well the Finnish Current Care guideline for diabetes is implemented in practice is unknown. Combining local and nationwide patient registers provides a valuable resource for evaluating risks, benefits and quality of care. Therefore, the aim of this study was to identify how the Finnish electronic patient information systems and national registers can be used to explore the treatment for patients with incident type 2 diabetes.
METHODS: Selected primary and specialty care organizations representing different geographical areas and patient demographics were included in the analysis. Results were compared to other local and nationwide register holders. The study protocol was reviewed by the Ethical Review Board of Hospital District of Helsinki and Uusimaa.
RESULTS: Register linkage is accomplished using unique personal identification numbers. We collect nationwide data on prescriptions, hospital and primary care, reimbursed dental care, and the causes of death. Cost data are based on hospital benchmarking database, sickness allowances and rehabilitation. We use local registers as a source of information on diagnoses, medical procedures, prescriptions and contact types. High quality laboratory data are also included from several local providers.
CONCLUSIONS: Register linkages enable longitudinal follow-up of groups of patients in Finland. The combined register database of diabetic patient cohort is created that improves the evaluation of prognosis and care of diabetic patients. This is a promising and versatile source for research in pharmacoepidemiology.

PDB28 EPIDEMOLOGY AND UNMET MEDICAL NEED IN DIABETES MELLITUS TYPE 2 IN GERMANY – RESULTS OF A LIFE-STYLE INTERVENTION
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OBJECTIVES: Diabetes mellitus Type 2 (T2DM) is a metabolic disease characterized by hyperglycemia with a high risk-potential of microvascular and macrovascular complications. In addition to glycemic control important therapy targets are the prevention of additional comorbidities due to national guidelines (German Medical Association 2013). To describe the current state of T2DM epidemiology and therapeutic needs in Germany which is mandatory when submitting AMNOG dossiers. METHODS: To describe the epidemiology of diabetes a targeted literature research was conducted in PubMed in 2014 using the search terms (epidemiology OR incidence OR prevalence). To identify relevant comorbidity information the following terms were used (metabolic syndrome OR glycemic control OR hyperglycemia OR obesity OR blood pressure) and combined with AND diabetes AND Germany. PubMed research was supplemented by additional searches in guidelines in German/English. RESULTS: The screening of the epidemiologic results identified two publications which specified a T2DM-prevalence of 15.3% and 14.7% (Witten et al. 2007, Huppertz et al. 2009) and two studies estimated a T2DM incidence of 15.8 per 1000 patient years (KORA, MONICA). Treatment prevalence was reported from 5.9% in 1998 to 5.5% in 1998 in relation to the total population (Hounou 2013). Arterial hypertension was the most frequent comorbidity (96% of T2DM (Hagen et al. 2010). In 2010, a disease management program in North Rhine showed that only 15% of participating T2DM achieved a BMI <25 (Hagen et al. 2010). Long term trials investigating the efficacy of antidiabetics on the prevention of macrovascular complications are limited (Drug Commission of German Medical Association 2009; Matthei et al. 2009). CONCLUSIONS: While treatment prevalence is increasing and glycemic control seems to be sufficiently achieved a substantial unmet medical need is identified for antidiabetics with a significant effect on weight reduction and blood pressure control in patients with T2DM in Germany.

PDB29 PROGRESSION OF PHYSIOLOGICAL PARAMETERS OVER TIME IN TYPE 1 DIABETES MELLITUS PATIENTS IN FRANCE
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OBJECTIVES: The objective of this study was to understand the progression over time of physiological parameters, including HbA1c, body mass index (BMI), systolic blood pressure (SBP), total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides, in type 1 diabetes mellitus (T1DM) patients to inform disease modeling. METHODS: This was a cross-sectional analysis of T1DM patients based on the French Insulin User Registries, which prospectively collects clinical, biological and treatment information from general practitioners. Patient age, gender, year of diagnosis, BMI, HbA1c, cardiovascular risk factors, renal function and lab test results were collected at baseline and subsequent visits. Data were analyzed by R Studio. T1DM patients who visited their general physician between May 2011 and May 2014 and have received at least one insulin prescription were included in the analysis.
RESULTS: A cohort of 605 T1DM patients was included in the analysis. Depending on age, patient age at first visit was 8 years of age. Mean HbA1c was 7.8%, mean SBP was 132 mmHg, and mean BMI was 27.6 kg/m². Linear regression showed that BMI increased by 0.248 kg/m² per year (p < 0.001) for each additional year of age. SBP was predicted to increase by 0.248 mmHg (p = 0.001) per additional year of age, LDL-cholesterol decreased by...
medications and obstetric medical history. Set-up was non-random, convenience sampling with women over mean age 33.7±5 between August 2013 – February 2014. Friedmann ANOVA and t-test was applied for analysis with software Statistics for Windows. RESULTS: Progresses the gestation period significant reduction of TSH values was observed in hypothyroid patients (p=0.007). Comparing successful obstetric outcomes, in individual patient studies showed the same significant difference. Significant negative correlation was founded between TSH value and thyroxin dose in group of hypothyroid patients (r = –0.35, p<0.05). Premature birth and other obstetric complications in T2DM group were seen, especially among older women giving birth. CONCLUSIONS: In case of hypothyroid pregnant with increasing dose of thyroxin the TSH levels are well balanced, and obstetric complications did not occur, while in hypothyroid patients can be reported obstetric complications in addition to proper care.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB33
BUDGET IMPACT ANALYSIS OF ADDING DAPAGLIFLOZIN TO THE TREATMENT OF DIABETES MELLITUS TYPE 2 IN BULGARIA

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OBJECTIVES: Dapagliflozin is a highly potent, selective and reversible inhibitor of sodium glucose co-transporter 2 (SGLT2) and is approved for the treatment of T2DM in adults. Diabetes type 2 is one of the most prevalent chronic diseases that can lead to a substantial health and economic burden. The largest costs are associated with hospitalizations due to the complications, the prevention of which requires a good glycometric control. The objective of the study is to estimate the budget impact of adding dapagliflozin to the T2DM therapy in Bulgaria. METHODS: The budget impact model was used from the payer perspective for population 7 284 552 people, and of them 45000 are type 2 diabetes. The retail pharmacy prices were used for the price data for the IMS Data Warehouse database incorporated in the model. Net budget impact is presented as cost per-month (PMPM) and costs per-patient per-year (PPPY). RESULTS: An increase in the estimated net budget impact from 70 592 € first year to 1 290 766 € for the fifth year was observed after adding dapagliflozin to T2DM therapy, with a cumulative negative net budget impact of 3 258 047 €. PMPM and PPPY costs show minimal growth with respective cumulative values of 0.06 € and of 65.63 €. The cost for dapagliflozin therapy is comparable to that of DPP-4 inhibitors and is lower than the cost of treatment with a GLP-1. CONCLUSIONS: The results show that adding dapagliflozin to standard therapy will lead to minimal increase in the diabetes type 2 budget in Bulgaria. This increase is considered acceptable in terms of better glycometric control with safe and effective therapy for diabetes type 2

PDB34
ASSESSMENT OF THE ECONOMIC VALUE OF DPP-4 INHIBITOR ALOGLIPTIN COMPARED WITH SITAGLIPTIN, SAXAGLIPTIN, AND LINAGLIPTIN

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OBJECTIVES: Objective of this study is to provide additional evidence for decision making to payers assessing health care resource utilization, economic impact, and cost effectiveness of DPP-4i in combination with other antidiabetic agents. The direct medical costs of DPP-4i and comparator therapies were assessed from a UK National Health Service and Personal Social Services perspective. RESULTS: 6 different clinical endpoints (efficacy and safety) were compared across 5 different fixed dose combinations: DPP-4 Monotherapy, metformin (MET), sulfonylurea (SU), thiazolidinedione (TZD), insulin (INS). For each endpoint and combination, alogliptin clinical endpoints were compared with respective average endpoints of other DPP-4s. Differences were calculated after adjustment for baseline characteristics. Each endpoint was associated with the impact on patient outcomes and related health care costs (T2DM-related complications, treatment escalation, costs associated with adverse events: hyperglycemia, cardiovascular mortality, hospitalization related to death, hospitalizations, and improvements in the glycemic state obtained from published data. Economic value of alogliptin was calculated and compared to the other DPP-4s. RESULTS: The proportion of patients at target (HbA1c≤7%) as well as the reduced need for treatment escalation with alogliptin could generate annual savings for a healthcare system of €99.62 and €22.97 per patient-year, respectively. Improved lipid profile and proven CV safety of alogliptin can generate savings of €40.86 and €21.47 per patient-year, respectively. Impact of lower hypoglycemia and increased adherence with fixed dose combinations with T2D may generate additional savings (€5.37 and €1.60/patient-year, respectively). CONCLUSIONS: This study suggests that alogliptin could generate significant savings for a Healthcare System even at price parity with other DPP-4s, thanks to its efficacy and safety profile, particularly in the widely used DPP-4+MET combination. Total savings of up to €158 per patient-year compare favorably with an overall cost of treatment with a DPP-4 ranging from €350 to €1481 per patient-year.

PDB35
COST-EFFECTIVENESS ANALYSIS OF AUTOCODED AND MANUALLY CODED BLOOD GLUCOSE METERS IN DIABETES TREATMENT

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OBJECTIVES: To evaluate the cost-effectiveness of blood glucose meters. Cost analysis included assessment of direct and indirect costs that can be
associated with manually coded meters (model 1 and model 2) and automated meters (model 1 and model 2) on medical costs, diabetes services in National health care system in the Russian Federation. **RESULTS:** Annual direct costs per patient in the group of manually coded glucose meters were 1533 euro (model 1) and 1574 euro (model 2), and in the group of automated meters were 1557 euro (model 1) and 1568 euro (model 2). Costs per patient in a group of manually coded meters was 2992 euro (model 1) and 2921 euro (model 2), and in the group of auto-
coded meters was 3034 euro (model 3). Cost-effectiveness ratio for automated meters was 16.8 euro/m2 for automated meters and 15.94 euro/m2 (model 1) and 18.92 euro (model 2) per 1 LYQ, respectively (discounted at 3%). Budget impact analysis showed that use of automated models (model 3) instead of manually coded (model 1 and model 2) leads to the annually cost savings of 33 euro and 53 euro per patient, respectively. **CONCLUSIONS:** Obtained results support the idea of using automated blood glucose meters instead of manually coded blood glucose meters to administer blood glucose level as part of intensive glucose-lowering therapy from a pharmacoeconomic point of view.

**PDB36 HEALTH ECONOMIC IMPACT OF BARIATRIC SURGERY REVISTED: STRUCTURED REVIEWS OF LITERATURE AND HEALTH TECHNOLOGY ASSESSMENTS**

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**OBJECTIVES:** The costs of obesity are staggering, accounting for 2-6% of global health care costs. The health economic benefits of bariatric surgery while notable, are multi-faceted, resulting in heterogeneous reporting in the literature. To that end, objective: To seek and highlight available data on the economic impact of bariatric surgery, and to 2) identify key gaps in current evidence that may influence uptake by health care systems. **RESULTS:** Evidence of the health economic benefits of bariatric surgery is derived from 107 academic articles, of which 12 were systematic reviews, published between 2010-March 2014 and archived in MEDLINE and PubMed. Additionally, HTAWatch identified 10 HTAs, largely from North America and the EU that evaluated economic benefits. **OBSErvations:** HTAWatch identified 10 HTAs, largely from North America and the EU that evaluated economic benefits. PubMed. Additionally, HTAWatch identified 10 HTAs, largely from North America and the EU that evaluated economic benefits. PubMed. Additionally, HTAWatch identified 10 HTAs, largely from North America and the EU that evaluated economic benefits. **Conclusions:** There were 10 HTAs, largely from North America and the EU that evaluated economic benefits.**

**PDB37 AMONG PATIENTS WITH NEWLY-DIAGNOSED TYPE 2 DIABETES IN SWEDEN**

PdB37

**OBJECTIVES:** To evaluate the potential economic impact of bariatric surgery, and to 2) identify key gaps in current evidence that may influence uptake by health care systems.

**Conclusions:** There were 10 HTAs, largely from North America and the EU that evaluated economic benefits.**

**PDB38 EVALUATION OF POTENTIAL WASTE OF GROWTH HORMONE ACROSS AVAILABLE GROWTH HORMONE PEN DEVICES AND AN ELECTRONIC GROWTH HORMONE DELIVERY DEVICE**

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**OBJECTIVES:** The aim of this analysis was to estimate the potential GH waste per patient with pen devices and the easypod® device, and to quantify the potential economic impact of expected waste from patients at different GH dose and patient indication perspectives.

**METHODS:** A Waste Calculator Model was developed to examine GH waste. All somatropin products available in pen or electronic devices were included. The user may define distribution across cartridge sizes. The mechanical/priming waste loss applied to each product was based upon each product’s prescribing information and/or instructions for use. The base case model utilizes a US patient dose of 1.4 mg. The model assumes that the easypod® dose adjustment feature is activated by the user (100%). Model assumes that 42.6% of caregivers disregard the remaining amount left in the cartridge (eg waste) if less than a full dose. Annual amount of waste (mg, cartridges, dollars) per patient and per population (based on US national market share estimates for each pen/device) was reported. The annual amount of waste per patient was lowest for easypod®. The expected annual amount of waste per patient was highest for Omnitrop®. The expected annual amount of waste ranged from 0.38 to 8.56 mg per patient per year, which is equivalent to 8 to 56 cartridges per patient per year and/or 0.1 million to 0.8 million cartridges per patient per year. For patient population of 100 GH-treated patients, the annual amount of waste is estimated at 2,009 mg, which can be translated into approximately 342 cartridges or about $162,000 per year. The results in GH waste fluctuated depending upon daily dose, cartridge size, and dose spread assumptions. **Conclusions:** The expected annual amount of GH waste evaluated in this Waste Calculator was lowest with easypod®. Cost of GH waste can be an important consideration when evaluating GH delivery devices.

**PDB40 BENEFIT OF POSITIVE AIRWAY PRESSURE (PAP) THERAPY IN SLEEP APNEA (SA) PATIENTS WITH TYPE II DIABETES MELLITUS (T2DM) IN CANADA: A RETROSPECTIVE COMPARATIVE COHORT ANALYSIS BASED ON A STATUTORY HEALTH INSURANCE DATABASE**

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**OBJECTIVES:** It is estimated that the prevalence of moderate-to-severe SA (apnea-hypopnoea index ≥15/h) is 10%. Patients with T2DM have a particularly high inci-
dence of SA. T2DM and SA influence the development and progression of each other. The objective of this study was to determine the actual economic burden of T2DM and PAP therapy. **RESULTS:** A total of 4,068 patients with SA and PAP therapy was identified in 4,068 patients with SA (PAP group). Propensity score matching was used to define a control group (CG) of 4,068 SA patients matched for age, sex, risk factors/etiology, region and medication who received usual care (no PAP therapy). The primary outcome was to compare health care resource utilization and costs according to smoking status in patients with type 2 diabetes in clinical practice. **Methods:** A retrospective cohort nested case-control study was designed. Cases were current smokers, while two types of controls (non-smoker smokers matched, and never smokers) were matched for each case, for age, sex, duration of diabetes, and burden of comorbidity using data from electronic medical records. Non-institutionalized diabetics, both genders, age >18 years, seen consecutively over a 5-year period before the index date were enrolled. **Conclusions:** Smoking in diabetes is associated with a worse prognosis and vascular complications. The available evidence on health care resource utilization and associ-
cated costs in diabetics who smoke is limited or nonexistent. Thus, the objective was to compare health care resource utilization and costs according to smoking status in patients with type 2 diabetes in clinical practice.
was significantly reduced lower 3-year mortality rate versus CG (7.2% vs 10.9%, p=0.008; relative risk reduction 33.8%). CONCLUSIONS: SA patients with TD2M treated with PAP showed significantly reduced mortality and morbidity. Total COI was higher in PAP recipients versus CG in the first two years of follow-up, but during year 3 COI was significantly lower in the PAP group versus CG. The model predicted that the long-term advantages of PAP therapy in SA patients with TD2M (e.g. improved glycemic control), PAP therapy may be beneficial from an economic perspective.

**PD841**

**ARE TOTAL HEALTH CARE EXPENDITURES IMPACTED BY A NEW DIABETES DIAGNOSTIC FACTOR: HBA1C?**

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OBJECTIVES: To determine differences in total health care expenditures among general diabetics and newly diagnosed diabetics before and after HBA1c was implemented as the standard diagnostic method. METHODS: Medical Expenditure Panel Survey-Household component 2009 and 2011 databases were used. Annual health care expenditures formed the dependent variable. Demographic factors, comorbidities, prescription drug costs, medical events and utilization variables for health care services like visits to office-based, outpatient and inpatient facilities, emergency rooms, home health care, home care patient facility and physician services expenses (all values p<0.001) and hospital discharges (p=0.001) were used. OLS regression analysis was conducted to estimate the impact of HBA1c on total direct costs generated by hyperglycemia including consumption of health care, social support, and other associated costs (e.g. transport). The second estimates the impact of hyperglycemia on populations’ health levels and its economic impact on the Portuguese health care system. RESULTS: Total direct costs of diabetes (€ 6,798 vs € 6,954, p<0.001) were significantly lower in patients diagnosed after the implementation of HBA1c as the diagnostic criteria. Further research on cost-effectiveness of the HbA1c factor is warranted to establish any possible association.

**PD842**

**DIRECT COSTS OF DIABETES MELLITUS IN POLAND**

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OBJECTIVES: The aim of this study was to assess the direct costs of ambulatory treatment associated with type 1 and 2 diabetes mellitus (DM) from the public payer perspective in Poland, and to explore the relative contribution of different cost components in 2011. METHODS: The estimated costs were based on reimbursement data from the years 2012 and 2013 provided by the public payer in Poland. Reimbursement costs of insulin, oral anti-diabetes drugs and monitoring strips (645 million PLN in 2012 and 793 million PLN in 2013, 49% and 52%, respectively). Insulin costs (518 million PLN in 2012 and 583 million PLN in 2013) and anti-diabetes oral drug costs (144 million PLN in 2012 and 155 million PLN in 2013) constitute 38-40% and 10-11% of total reimbursement costs, respectively. CONCLUSIONS: The economic impact analysis includes two components. The first estimates the direct costs generated by hyperglycemia including consumption of health care, social support, and other associated costs (e.g. transport). The second estimates indirect costs, those related to the losses of productivity. The disease burden and the costs of illness attributable to hyperglycemia include also the complications attributable to this risk factor, namely ischemic stroke and ischemic heart disease. In order to estimate the attributable fractions to hyperglycemia (total cholesterol) >200mg/dl or statin use) of the diseases considered, a microsimulation approach was employed using by Framingham equations on the national database (VALSIM). A counterfactual scenario hyperglycemia was eliminated from these observations and the resulting proportional change in the probability of CV events was taken as the hyperglycemia attributable fractions. These fractions were used to estimate the contribution of hyperglycemia to the burden and the annual costs of the aforementioned circulatory diseases. RESULTS: 1,689 deaths can be attributed to hyperglycemia, which corresponds to 1.6% of the total deaths in Portugal in 2010. The DALY’s resulting from disability and premature deaths caused by hyperglycemia in 2010 totaled 12,174. The estimated direct cost attributable to hyperglycemia in 2013 prices is €320 million (€32 million for in-patient care and €288 million for ambulatory care). Indirect costs generated by disability attributable to hyperglycemia and its complications are estimated to be €5 million per year. CONCLUSIONS: Hyperglycemia diseases in DM patients have a relevant impact on health care expenditure. Prevention of cardiovascular complications can lead to significant cost savings for the management of DM. Understanding future costs of DM might be valuable in terms of budget allocation and economic evaluation.

**PD845**

**COST AND BURDEN OF HYPERCHOLESTEROLEMIA IN PORTUGAL**

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OBJECTIVES: Hypercholesterolemia is a risk factor for cirulatory diseases. This study estimates the impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. METHODS: The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. RESULTS: Total costs were estimated at €618 million per year. CONCLUSIONS: The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system. The impact of hypercholesterolemia on populations’ health levels and its economic impact on the Portuguese health care system.
OBJECTIVES: To determine the clinical (compliance, metabolic control, hypoglycaemia and complications) and economic (CVE) and economic (costs) impact of metformin in combination with dipeptidyl peptidase-4 inhibitors (DPP4-I) or sulfonylureas in patients with type 2 diabetes.

METHODS: Design: Multicentre, observational retrospective study. Patients aged ≥ 30 years under treatment with metformin who initiated a second oral anti-diabetic treatment in 2008-2009 were evaluated. Two study groups were established: a) metformin + DPP4-I, b) metformin + sulfonylureas. Main measures: comorbidity, metabolic control (HbA1c < 7%), complications and costs. CVE (hypoglycaemia, CV, CVE). Patients were followed for 2 years. The cost model considered direct (primary/specialised care) and indirect (productivity) health care costs. Statistical analysis: logistic regression models and ANCOVA, p < 0.05.

RESULTS: We recruited 1,405 patients (men age 67.1 years, 56.2% of whom 37.9% initiated a second dual therapy with sulfonylureas. At 2 years follow-up, patients treated with DPP4-I showed better compliance (70.3% vs 66.0%), better metabolic control (64.3% vs 60.6%), and a lower proportion with hypoglycaemia (13.9% vs 40.4%) (p < 0.00). The mean costs of the total adjusted costs were € 2,241 vs € 2,512, respectively; p = 0.038. Rates of CVE and renal failure were 3.7% vs 6.4%; p = 0.027. Vildagliptin was the most commonly used DPP4-I. CONCLUSIONS: Sulfonylureas were the most frequently used drugs for diabetes treatment, with lower rates of hypoglycaemia and CVE, resulting in reduced health care costs.

PDB47 PATIENT-LEVEL ESTIMATES OF DIABETIC COMPLICATIONS ON DIRECT MEDICAL COSTS

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OBJECTIVES: To estimate the impact of diabetic complications on immediate and long-term direct medical costs in Hong Kong.

METHODS: A retrospective study was conducted among 137,643 diabetic subjects from a territory-wide administrative database over six years (2008-2013). The trends of annual direct medical costs for three groups of subjects with and without complications over study period, group 2) subjects with existing complications at baseline; and group 3) subjects developing new complications during follow-up. We employed panel data regression to investigate the impact of each diabetic complication on direct medical costs in the event year and subsequent years, adjusting for age and Charlson Comorbidity Score.

RESULTS: We found 10,322 subjects with existing diabetic complications at baseline (January 1st, 2009), and 14,349 newly developed diabetic complications over 5 years. The annual direct medical costs increased from $US4,629 to $US15,585 in the new complications group, which is substantially higher than the modest rise in the no complication group (from $US1,157 to $US1,984). The percentage increase in the event year was: acute myocardial infarction (AMI) 10.61; other ischemic heart disease (IHD) 3.67; congestive heart failure (CHF) 8.46; stroke 10.17; sight threatening diabetic retinopathy (STDR) 3.41; blindness 2.78; end stage renal disease (ESRD) 12.16; peripheral vascular disease (PVD) 3.00; amputation: 3.48. The multipliers in the event year were: acute myocardial infarction (AMI) 10.61; other ischemic heart disease (IHD) 3.67; congestive heart failure (CHF) 8.46; stroke 10.17; sight threatening diabetic retinopathy (STDR) 3.41; blindness 2.78; end stage renal disease (ESRD) 12.16; peripheral vascular disease (PVD) 3.00; amputation: 3.48. The multipliers in subsequent years were: AMI 1.45, other IHD 1.32, CHF 1.86, stroke 1.37, STDR 2.16, blind 1.33, PVD 1.48, amputation 1.32. The diabetic complications were wide variations in direct medical cost in event year and subsequent years across different major complications. These data would be useful for economic evaluations of diabetes prevention or treatment programs.

CONCLUSIONS: To estimate the real burden of T2DM.

PDB48 DIRECT MEDICAL COSTS OF Type 2 DIABETES MELLITUS IN SOUTH KOREA 2011

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OBJECTIVES: This study aimed to analyze the direct medical cost of diabetes related micro and macrovascular complications in Korean people with diabetes mellitus.

METHODS: Using the Health Insurance Review & Assessment Service-National Patients Sample (about 1.3 million patients), which was a stratified sampling from the entire population (about 46 million people) under the Korean national health security system (2011), estimation of direct medical cost for patients who have diabetes related chronic complications were performed. We used the 6th revision of Korean Standard Classification of Diseases (KCD-6) which had been developed with the reference of the 10th version of International Classification (ICD-10).

All statistical analyses were performed using the Statistical Analysis System (SAS, version 9.3). RESULTS: The mean age of the subjects was 61.4 years, 52.1% were male and 47.9% were female. Of the 91,463 patients with DM, 20,584 patients (22%) had at least one microvascular or macrovascular complication, 70,879 patients (78%) had no complication. The average annual direct medical cost in patients who had no complications was $151,660 won in 2011. The average annual direct medical cost in patients who had microvascular complications such as retinopathy, nephropathy, neuropathy was 506,160, 14 times higher than without DM complications, who had macrovascular complications such as MI, CVA, ESRD was 1,362,928 won, 3.8 times higher than DM patients. The annual direct medical costs for diabetes complications such as MI, CVA, ESRD, diabetic renal disease have a substantial impact on the direct medical costs of DM patients. As the number of people with diabetes continues to rise, early detection of the disease and implementation of timely and appropriate therapeutic strategies could decrease the burden of diabetes chronic complications and also huge related expenditures.

PDB49 MEDICAL EXPENDITURE FOR PEOPLE WITH DIABETES IN URBAN EMPLOYEES

Basic Medical Insurance in Fujian

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OBJECTIVES: To measure the impact of the disease on quality of life and productivity losses and caregiving are considered. The relative weight of hospitalizations and indirect costs, and short term disability costs constitute 28% and 11% of total indirect costs of DM type 1, respectively. A slightly different situation was reported in the case of type 2 diabetes: long term disability costs were only 1% of total indirect costs, and short term disability had a slightly larger part of indirect costs (less than 5%). The highest component of indirect costs of DM type 2 was sick leave (9%). One sick leave of a person with type 1 or 2 diabetes generated a cost of lost productivity equal to 1 US$1,711 PLN or 1385 PLN, respectively. The cost of disability was higher than rehabilitation. In Poland, one person with type 2 diabetes generated 41 398 PLN compared with 17 249 PLN (the average value of one short and long term benefit payment was the same for both types of diabetes). CONCLUSIONS: DM in Poland generated high indirect costs. The main component was sick leave, rehabilitation benefit and disability pension generated much lower costs for Social Insurance Institution.

PDB51 KEY COST DRIVERS OF Type 2 DIABETES MELLITUS: AN INTERNATIONAL LITERATURE REVIEW

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OBJECTIVES: To determine the major drivers that influence the costs of DM. METHODS: We searched relevant databases for studies estimating DM costs, published in English and Spanish in the USA and Europe (1995-2014). Search terms included “diabetes”, “costs”, “burden”, and “economic impact”. No exclusion was made based on design. Cost drivers and differences in methodologies across studies were identified. RESULTS: A total of 25 papers were included out of 618 relevant titles identified. Costing methodologies and cost drivers vary significantly causing important variations in results. The main difference in methodology refers to estimating DM2 costs versus the costs of people living with T2DM, which include all direct sanitary costs - whether directly related to T2DM or not- and may increase total costs by up to 74%. Direct sanitary costs represent 40% and 75% of DM1 and DM2 costs. DM2 CONCLUSIONS: Only less than 10% of DM1 and DM2 costs range between 15% and 46%, which include anti-diabetic drugs and treatments for complications derived from poor control. Optimal glycemic control reduces costs but is not always considered in the studies. Microvascular and/or macrovascular complications and hypoglycemic events increase total cost per patient. To estimate the cost of DM, costing methodology guidelines would help future studies estimate the real burden of T2DM.

A340 VALUE IN HEALTH 17 (2014) A323-A686
OBJECTIVES: The aim of this study is to assess for 2012 the cost of diabetes from a payer perspective, based on the French health insurance database and using two different approaches: (top-down versus bottom-up). METHODS: Using information about more than 60 millions of individuals from the general scheme insurance database (85% of the French population), we developed algorithms to identify all people who received care for each of 56 groups of diseases or medical events or treatments, which are frequent, severe and/or costly. Algorithms have been separately developed for each patient. For diabetes, we used ICD-10 diagnoses for long-term chronic diseases, reimbursement for anti-diabetic drugs. Costs of all reimbursed expenditures (out-patient health care, hospitalization, compensation) were extracted per individual. The top-down method allocated expenditure to each of the 56 diseases based on the average expenditure by disease calculated for individuals with only one disease. All expenditures were thereafter extrapolated to the whole population. For the bottom-up approach, diabetes expenditures were estimated by identifying finely in our database expenditure items which are partly or wholly directly related to diabetes according to expert judgment. RESULTS: Based on the top-down approach, among the 146 billion euros of expenditures reimbursed by national health insurance (all insurance schemes) in 2012, 7.5 billion (5%) are attributable directly to diabetes. Expenditures for chronic renal insufficiency and cardio-vascular disease, frequent diabetes complications, represent more than 50% of the diabetes expenditures, other outpatient care 34% (2.5 billion), inpatient care 9% (700 millions) and disability/sickness benefits 7% (500 millions) on our bottom-up approach. CONCLUSIONS: Our study provides estimation of the cost of diabetes from a payer perspective, according to two different approaches but with concur results.

PDB54 COMPARISON OF THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATIONS OF U.S. VETERAN PATIENTS DIAGNOSED WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To evaluate the economic burden and health care utilization of Type 2 diabetes mellitus (T2DM) among U.S. veteran patients. METHODS: T2DM patients enrolled in the International Classification of Disease 9th Revision Clinical Modification (ICD-9-CM) diagnosis codes 250.x0, 250.x2 were identified using the U.S. Veterans Health Administration Medical SAS datasets (010C/2008-315SE/2011). The first diagnosis date was defined as the index date. A comparison cohort of patients without a T2DM diagnosis but of the same age, region, gender and index year were identified and matched according to baseline Charlson Comorbidity Index scores, with a randomly chosen date of diagnosis and select propensity score. Patients in both cohorts were required to be at least age 18 years, with 1-year continuous health plan enrollment pre- and post-index date. Baseline body mass index (BMI) and glycated hemoglobin (HbA1c) values were assessed. Health care costs and health care costs were calculated using a 1:1 propensity score matching (PSM). RESULTS: A total of 1,211,748 T2DM patients were identified for study. T2DM patients had significantly higher HbA1c (7.25 vs. 5.78, p<0.001) and BMI (31.75 vs. 29.16, p<0.001) results during the baseline period. After adjusting for demographics, Charlson Index, and propensity score, the T2DM cohort was significantly higher in terms of medical resource utilization, inpatient, and non-inpatient health care costs. CONCLUSIONS: Our study identifies the cost burden and utilization burden of T2DM in the U.S. Veteran population.
pharmaceutical and blood glucose reagent strips. All measurements were obtained at the beginning of the level. The raw prevalence of diabetes was 6.7%. The participants were stratified into four morbidity groups. The first group corresponded to the initial stage (CRG 1-4); the second group included the core multimorbidity patients in the intermediate and advanced stages (CRG 5-7); the third group included patients with cardiovascular disease; the last group comprised patients with heart failure, hypertension, and other chronic conditions,smarty ERSD. The most common comorbidities in the patient group for CRG 5 to 7 were hypertension (47% - 97%), dislipidemia (50% - 59%) and cardiovascular disease (48% - 39%). The average cost of insulin was € 476.15 in CRG 1-4 group, € 1,350.5 in CRG 5-7 group, € 2,174.1 in CRG 8 group and € 2,840.5 in CRG 9 group. CONCLUSIONS: Diabetes is characterized by a present of other acute conditions and events related to cardiovascular disease in the intermediate and advanced stages (CRG 5-7); the third group included patients in the biological level of the diabetes in the intermediate and advanced stages (CRG 5-7); the third group included patients in the intermediate and advanced stages (CRG 5-7). The total average cost was € 15,232.8. The total average cost was € 232.8 and was highest in the CRG 5 to 7 group at € 232.8. The total average cost was € 232.8 and was highest in the CRG 1 to 4 group, € 1,350.5 in CRG 5-7 group, € 2,174.1 in CRG 8 group and € 2,840.5 in CRG 9 group. CONCLUSIONS: Diabetes is characterized by a strong presence of other chronic conditions and events related to cardiovascular disease. Referring DFU patients to the outpatient diabetic foot clinics as early as possible appears to be the most cost-effective way of treating them. A342

Methods: One of the main barriers for effective foot care in diabetic patients is the high cost of treating foot ulcers through antibiotic expenditure (9 to 15%). The reduction could be 20 to 32% associated with inpatient treatment cost in more than 30%. Early microbiological culture as the base of antibiotic selection can reduce treatment cost in more than 30%. Venous fluids.

Results:

- The raw prevalence of diabetes was 6.7%. All patients with infected ulcers in diabetic foot, patients were initially treated in Emergency Room of Mexican IMSS’ secondary level hospital in a period from January 1st to July 31st, 2014. Total costs for the sample were $502,438.04 USD, the mean cost per patient was $7,177.69 (±$5,043.51) USD, and the median cost was $6,422.99 (p25 $3,502.93; p75 $9,298.33). 72.75% ($365,527.45) of the savings would come from the prevention of renal complications. Any new complication will be added to the already existing average cost. Retinopathy was included in the calculation.
- The meta-analysis showed that compared to dapagliflozin in the Czech Republic setting from a payer perspective, the savings would come from the prevention of renal complications. Any new complication will be added to the already existing average cost. Retinopathy was included in the calculation.
- Our results showed that these recommendations were not strictly followed among T1DM patients in France, potential savings for the health care system associated with meeting the therapeutic guidelines would be on average of $1,661 per patient from a lifetime perspective. Most of the patients would come from the empirical antibiotic treatment, and modify the criteria according microbially based on the frequency of possible complications. The „Haute Autorité de Santé” recommends that T1DM patients maintain their HbA1c lower than 7.5%, SBP lower than 130 mmHg, BMI lower than 25 kg/m2 and quit smoking. Our results showed that these recommendations were not strictly followed among T1DM patients in France. Better adherence to the T1DM guidelines would lead to cost savings in the French health care system and improved patient outcomes.

Economic model of Monte Carlo simulation in two steps: The first step was based on 17 independent sub-models and 33 possible scenarios with infected ulcers in diabetic foot patients. Patients were initially treated in Emergency Room of Mexican IMSS’ secondary level hospital in a period from January 1st to April 30th, 2010. Retinopathy was included in the calculation. The total cost was $502,438.04 USD, the mean cost per patient was $7,177.69 (±$5,043.51) USD, and the median cost was $6,422.99 (25% $3,502.93; 75% $9,298.33). 72.75% ($365,527.45) of the savings would come from the prevention of renal complications. Any new complications will be added to the already existing average cost. Retinopathy was included in the calculation.

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PDB13  
SHORT-TERM COST-EFFECTIVENESS ANALYSIS OF INSULIN DETUM VERSUS INSULIN NEUTRAL PROTAMINE HAGEDORN (NPH) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN SPAIN  
Rameriz de Arellano A, Moraes C, Luis D, Ferrario MG, Lizain L

OBJECTIVES: To estimate the short-term cost-effectiveness of insulin detum compared with Neutral Protamine Hagedorn (NPH) insulin when initiating insulin treatment in patients with Type 2 Diabetes Mellitus (T2DM) in Spain. METHODS: A short-term (1 year) cost-effectiveness model was adapted to the Spanish public health care system. Based on a head-to-head randomized controlled trial (NCT01014123) that showed similar efficacy in glycemic control for both insulin types, weight gain (±0.9 kg) and the rate of non-severe hypoglycemia (between arms RR=0.52; IC95% 0.44-0.61) of detum vs. NPH was selected as clinical outcomes. Costs were estimated from the perspective of the Spanish national health system and derived from national public sources. Only insulin treatment and management costs associated with non-severe hypoglycemic episodes were included in the analysis. According to a published study, non-severe hypoglycemia (a self-managed event) was assumed to imply the use of 5.3 glucometer strips and a visit to a general practitioner for 0.44-0.61) of detum vs. NPH were selected as clinical outcomes. Costs were estimated from the perspective of the Spanish national health system and derived from national public sources. Only insulin treatment and management costs associated with non-severe hypoglycemic episodes were included in the analysis. The univariate analyses showed that no input parameter change inflated the estimated incremental benefit of 0.181 QALYs (95%CI: 0.088; 0.268) at an additional cost of £286.67/QALY in Spain. This value is significantly lower than those reported for other European countries (€1,768-2,348/QALY) and are much lower than the ICER threshold commonly accepted for Spain (€30,000/QALY). CONCLUSIONS: Insulin detum is a cost-effective alternative to NPH insulin in the first and subsequent years of treatment of insulin-naive T2DM patients in Spain.

PDB15  
COST-EFFECTIVENESS ANALYSIS OF THE NEW-BORN SCREENING IN AUSTRIA  
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OBJECTIVES: To determine the life-time consequences of newborn screening for the congenital metabolic and endocrine diseases performed in Austria. methodology: The national newborn screening program is carried out by the Federal Ministry of Health at the University Clinic for Child and Adolescent Medicine, Medical University of Vienna. The aim of this study was to determine cost-effectiveness of the newborn screening. METHODS: We developed a decision-analytic model, which included specific information for the Austrian context. Cystic fibrosis, galactosemia, pyridoxine dependency and medium-chain acyl-CoA dehydrogenase deficiency (MCADD) were modeled with Markov processes. Costs were based on data from national sources. The model was run for the lifetime of the newborn with the terminal event in death. Results: The model predicted disease progression and the number of micro- and macro-vascular complications, along with diabetes-specific and all-cause mortality. The perspective of the National Health Service in the UK was adopted over a lifetime horizon. Local unit costs and utility data were assigned to the appropriate model parameters to calculate total Quality-Adjusted-Life-Years (QALYs) and total costs. Deterministic and probabilistic sensitivity analyses (PSA) were conducted. The ICER for newborn screening compared with no screening was found to be a cost-effective treatment option for patients who are inadequately controlled with metformin mono-therapy within established UK cost-effectiveness thresholds.

PDB16  
Dapagliflozin (Forxiga®) versus Glipizide as Add-on Therapies in Type 2 Diabetes Mellitus (T2DM); An Update of the Cost-effectiveness Analysis from a Long-term Clinical Trial (TIDM) in Spain From a PERSPECTIVE FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) FROM A UK NHS PERSPECTIVE  
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OBJECTIVE: To update the cost-effectiveness of dapagliflozin (Forxiga®), a selective sodium-glucose co-transporter-2 (SGLT-2) inhibitor, compared with a sulphonylurea (SU) when added to metformin in patients inadequately controlled with metformin mono-therapy based on long-term clinical evidence. METHODS: The published and updated dapagliflozin vs. SU was used to derive clinical inputs were derived from a 4-year follow-up study of a randomized clinical trial comparing dapagliflozin and glipizide in combination with metformin. Based on these inputs and the published SGLT-2 inhibitor (Forxiga®) from Phase 3 clinical trial (UKF0508) equations, the model predicts disease progression and the number of micro- and macro-vascular complications, along with diabetes-specific and all-cause mortality. In these equations, the model incorporates the ICER threshold commonly accepted for the UK (€28,672 per QALY). The incremental cost-effectiveness ratio (ICER) for dapagliflozin was 0.52; IC95% 0.44-0.61) of dapagliflozin vs. glipizide. The univariate analyses showed that no input parameter change inflated the estimated incremental benefit of 0.181 QALYS (95%CI: 0.088; 0.268) at an additional cost of £286.67/QALY in Spain. This value is significantly lower than those reported for other European countries (€1,768-2,348/QALY) and are much lower than the ICER threshold commonly accepted for Spain (€30,000/QALY). CONCLUSIONS: Dapagliflozin in combination with metformin was shown to be a cost-effective treatment option for patients who are inadequately controlled with metformin mono-therapy within established UK cost-effectiveness thresholds.
and results in higher QALYs in comparison with sitagliptin 100 mg in dual therapy as add-on to metformin. In triple therapy, as add-on to metformin and SU, canagliflozin dominates in comparison with a mixed strategy (add on to MET and sulphonylurea (SU)) compared to sitagliptin or liraglutide. Canagliflozin 100 mg or 300 mg will be a cost-effective alternative to sitagliptin in dual therapy as add-on to metformin (MET) compared to sitagliptin, in triple therapy, and in high-risk patients, respectively. METHODS: The IMS CORE Diabetes Model was used to evaluate the cost-effectiveness of canagliflozin versus sitagliptin, liraglutide or exenatide in treatment-naive type 2 diabetes patients, using French-specific data, where available. RESULTS: In dual therapy, as add-on to metformin versus sitagliptin, canagliflozin 100 mg and 300 mg average 50: 50) resulted in an incremental cost of €392 (95%CI: €2,352; €3,267), resulting in higher QALY gain of 0.033. Probabilistic sensitivity analyses showed that canagliflozin is cost-effective in 59% of patients with baseline characteristics (mean age 50.8 years, duration of diabetes 12 years, mean HbA1c 7.5%) and clinical outcomes (severe hypoglycemic event rates; Quality of Life, HbA1c taken from a recent randomised controlled trial published in 2013). Local re-s disturbed the results. The main scenario considered in this cost-effectiveness analysis was the comparison of sensor-augmented insulin pump (SAI) with low glucose suspend (LGS) versus insulin pump alone (CSII). The target population was hypo-prone type 1 diabetes patients with the analysis based on a deterministic microsimulation of 1,000 patients, using a 1 to 5 year time horizon. Direct costs were calculated from a third-party payer perspective. Discount rates of 3% per annum were applied to both costs and clinical outcomes. RESULTS: The Incremental Cost-Effectiveness Ratio (ICER) for SAI vs LGS was €1,064 (95%CI: €729; €1,750) per Quality-Adjusted-Life-Year gained over a 1 year time horizon. Results were similar using a 5 year time horizon (HUF/L: 1,015 [95%CI: 958; 1,072]). Extensive sensitivity analyses showed the robustness of the results. CONCLUSIONS: Using a payer’s perspective, our analysis showed that SAI (w LGS) is cost-effective over a short-term (1-5 year) time horizon in hype prone patients with Type 1 Diabetes in Hungary (using a WTP threshold of 30,000 HUF/GDP).

PDB73 ECONOMIC ASSESSMENT OF DELAYING INSULIN TREATMENT THROUGH THE USE OF NEWER ANTI-DIABETIC AGENTS, DAPAFLIGLIZON (FORXIGA®) AND EXENATIDE (BYDUREON®), BOTH AS ADD-ON TO METFORMIN; A COST-EFFECTIVENESS ANALYSIS FROM A UK NHS PERSPECTIVE

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OBJECTIVES: New classes of anti-diabetes drugs may delay the onset of insulin treatment in Type 2 diabetes. This study investigates the cost-effectiveness of a treatment pathway starting with dapagliflozin (Forxiga®), followed by exenatide once weekly (Bydureon®) - both as add-on to metformin - and insulin treatment, compared with a treatment pathway recommended in clinical guidelines that commences with SU add-on to metformin, followed by the addition of insulin regimes in patients inadequately controlled with metformin alone. METHODS: The validated CARE-DM model was used for the analyses. Clinical inputs for dapagliflozin versus SU, both as add-on to metformin, and exenatide once weekly were derived from relevant head-to-head clinical trials and long-term follow up studies. Based on these and the United Kingdom Prospective Diabetes Study (UKPDS) equations, the incremental cost-effectiveness ratios of drug outcomes were calculated in comparison with a scenario where all patients developed complications, along with diabetes-specific and all-cause mortality. The perspective of the National Health Service in UK was adopted over a lifetime horizon. Local costs and utility data was applied to the model. RESULTS: Total costs and QALYs gained were calculated by the model to be £23,980 and 9.38, respectively, compared to the standard treatment pathway, with dapagliflozin versus SU followed by exenatide once weekly and SU compared to the standard treatment pathway. CONCLUSIONS: DAPAFLIGLIZON (FORXIGA®) AND EXENATIDE (BYDUREON®), BOTH AS ADD-ON TO METFORMIN; A COST-EFFECTIVENESS ANALYSIS FROM A UK NHS PERSPECTIVE.
showed that at a willingness-to-pay threshold of £20,000 per QALY, the proposed treatment pathway had a 100% probability to be cost-effective. CONCLUSIONS: The proposed alternative treatment sequence was shown to be a cost-effective treatment option in patients inadequately controlled with metformin alone within established UK cost-effectiveness thresholds.

PDB74  COST-EFFECTIVENESS ANALYSIS OF LIRAGLUTIDE VERSUS SITAGLIPTIN OR EXENATIDE IN PATIENTS WITH INADEQUATELY CONTROLLED TYPE 2 DIABETES ON ORAL ANTIDIABETIC DRUGS IN GREECE

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OBJECTIVES: To evaluate the long-term cost-effectiveness of liraglutide versus sitagliptin or exenatide, added to oral antidiabetic drug mono- or combination therapy in patients with Type 2 Diabetes (T2D) in Greece. A Diabetes Model, a validated computer simulation model developed to determine the long-term health and economic outcomes of interventions in Type 2 diabetes, was adapted to the Greek health care setting. Patient and intervention effects were sourced from available alternative randomized controlled trials (dual therapy combination with liraglutide 1.8mg vs. sitagliptin 100mg once daily, clinical trial with liraglutide 1.8mg once daily vs. exenatide 10μg twice daily, both as add-on to metformin, glimepiride or both. Direct costs were reported in 2013 Euros and calculated based on published and local sources. All future outcomes were discounted at 3.5% per annum, and the analysis was conducted from the perspective of a third-party payer in Greece. RESULTS: Over a patient’s lifetime, treatment with liraglutide 1.8mg was associated with long-life expectancy of 0.13 (SD 0.23) years and in discounted quality-adjusted life expectancy of 0.19 (SE 0.16) quality-adjusted life years (QALYs), whereas therapy with liraglutide 1.2mg resulted in increased costs of 14,925 € and 0.16 (0.16) QALYs, respectively. As regards lifetime direct costs, liraglutide 1.2mg resulted in greater costs of 2,181 € versus sitagliptin 1.8mg and so did liraglutide 1.8mg compared with exenatide 10μg (€1,360, €492). Liraglutide 1.2 and 1.8mg doses were associated with incremental cost-effectiveness ratios of €15,101 and €6,818 per QALY gained, respectively. CONCLUSIONS: Liraglutide is likely to be a cost-effective option for the treatment of Type 2 diabetes in a Greek setting.

PDB75  HEALTH ECONOMIC EVALUATION OF CANAGLIFLOZIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN SLOVAKIA

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OBJECTIVES: To assess the novel SGLT2 inhibitor canagliflozin as an alternative to other anti-hyperglycaemic drug classes, including insulin. SGLT2 inhibition leads to inhibition of glucose reabsorption and urinary glucose excretion, thereby reducing blood glucose, weight, and blood pressure. An economic (cost-effectiveness) evaluation of new technologies versus routine care is required prior to uptake in Ireland to ensure good value-for-money. This study evaluates the potential cost-effectiveness of canagliflozin compared to liraglutide (in the national diabetes guidelines) or sitagliptin, and used the core Diabetes Model, a peer-reviewed, validated model, which employs standard meta-analysis of clinical trials for dual and triple therapy, and in the treatment of hypo-prone Type 1 diabetes in Slovakia.

RESULTS: A novel drug to treat diabetes belonging to the drug class known as sodium glucose co-transporter-2 (SGLT-2) inhibitors. To evaluate the cost-effectiveness of canagliflozin 100 mg in the Slovakian setting from a payer perspective when compared to sitagliptin in dual therapy (add-on to metformin), sitagliptin in triple therapy (add-on to metformin plus sulfonylurea) and dapagliflozin in combination with insulin (with or without metformin). METHODS: The IMS CORE Diabetes Model was used to evaluate the cost-effectiveness of canagliflozin versus comparators using Slovakia specific data, where available. RESULTS: The cost-effectiveness analyses indicated that canagliflozin 100 mg in dual therapy, when compared with sitagliptin, was found to be cost-effective with an incremental cost-effectiveness ratio (ICER) of 14,930 € per QALY gained within 10 years and 0.093 QALYs and €1,360, 0.059 QALYs and €492, 0.020 more quality adjusted life years (QALYs), suggesting that canagliflozin dominates liraglutide. Results were driven by lower acquisition costs for canagliflozin. Sensitivity analyses indicated that the dominance observed was robust to a wide range of plausible variations, canagliflozin 100 mg was a dominant alternative compared to dapagliflozin with a cost saving of 23,118 € per patient and higher QALYs. One-way sensitivity analyses revealed that in the majority of scenarios considered canagliflozin remained cost-effective in the dual therapy, triple therapy and add-on to insulin comparisons. CONCLUSIONS: Based on calculations performed using the CORE Diabetes Model, canagliflozin 100 mg appear to represent a cost-effective option for the treatment of type 2 diabetes in Slovakia. Canagliflozin 100 mg was found to offer greater health benefits than current available alternatives and to be a cost-effective treatment option when used in dual and triple therapy instead of sitagliptin or as an add-on to insulin instead of dapagliflozin.

PDB76  IS CANAGLIFLOZIN COST-EFFECTIVE COMPARED TO SITAGLIPTIN ACROSS MULTIPLE LINES OF TYPE 2 DIABETES MELLITUS (T2DM) THERAPY IN IRELAND?

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OBJECTIVES: To evaluate the cost-effectiveness of canagliflozin vs. sitagliptin, dapagliflozin and add-on to basal insulin in (with or without other anti-hyperglycaemic agents) therapy lines in Ireland. METHODS: The Economic and Health Outcomes Model of T2DM (ECCHO-T2DM) [using updated UKPDS 82 mortality and risk equations] was used to simulate 40-year costs and outcomes associated with canagliflozin (100mg once daily) in dual therapy (add-on to metformin) and in triple therapy as add-on to metformin and sulfonylurea. Canagliflozin will be a cost-effective alternative to SU in dual therapy as add-on to metformin. Adding canagliflozin to insulin will be cost-effective compared with placebo i.e. it is cost-effective to add canagliflozin treatment rather than not.

PDB77  THE COST-EFFECTIVENESS OF CANAGLIFLOZIN VERSUS SITAGLIPTIN IN PATIENTS WITH TYPE 2 DIABETES (T2DM) FAILING TO ACHIEVE GLYCEMIC CONTROL ON METFORMIN MONOTHERAPY IN IRELAND

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OBJECTIVES: Canagliflozin is a novel oral agent for the treatment of T2DM that inhibits sodium-glucose co-transporter 2 (SGLT2), a mechanism that is complementary to other anti-hyperglycaemic drug classes, including insulin. SGLT2 inhibition leads to inhibition of glucose reabsorption and urinary glucose excretion, thereby reducing blood glucose, weight, and blood pressure. An economic (cost-effectiveness) evaluation of new technologies versus routine care is required prior to uptake in Ireland to ensure good value-for-money. This study evaluates the potential cost-effectiveness of canagliflozin compared to liraglutide (in the national diabetes guidelines) or sitagliptin, and used the core Diabetes Model, a peer-reviewed, validated model, which employs standard meta-analysis of clinical trials for dual and triple therapy, and in the treatment of hypo-prone Type 1 diabetes in Slovakia.

RESULTS: In the base case, canagliflozin was associated with incremental cost savings of €3,382 compared to liraglutide 1.2mg. It was also associated with a 0.022 more quality adjusted life years and 0.093 QALYs and €491. T3 canagliflozin dominates liraglutide. Results were driven by lower acquisition costs for canagliflozin. Sensitivity analyses indicated that the dominance observed was robust to a wide range of plausible variations, canagliflozin 100 mg was a dominant alternative compared to dapagliflozin with a cost saving of 23,118 € per patient and higher QALYs. One-way sensitivity analyses revealed that in the majority of scenarios considered canagliflozin remained cost-effective in the dual therapy, triple therapy and add-on to insulin comparisons. CONCLUSIONS: Based on calculations performed using the CORE Diabetes Model, canagliflozin 100 mg appear to represent a cost-effective option for the treatment of type 2 diabetes in Slovakia. Canagliflozin 100 mg was found to offer greater health benefits than current available alternatives and to be a cost-effective treatment option when used in dual and triple therapy instead of sitagliptin or as an add-on to insulin instead of dapagliflozin.
Markov/Monte Carlo simulation techniques to describe the long-term incidence and progression of diabetes-related complications. It was used to simulate disease progression in a cohort of patients with baseline characteristics (mean age 18.6 years, duration of diabetes 12 years, mean Hba1c 7.5%) and clinical outcomes (severe hypoglycaemic event rates, Quality of Life, Hba1c) taken from a recent randomized controlled trial (Ly et al., 2013). Cost-effectiveness and clinical outcomes data was used. The main scenario considered in this cost-effectiveness analysis was the comparison of sensor-augmented insulin pump (SAP) with low glucose suspenion (LGS) versus insulin pump alone (CSII). The target population was type 1 diabetic-prone diabetes patients. The analysis was based on a deterministic micro-simulation of 1,000 patients, using a 5 year time horizon. Direct costs were calculated from a third-party payer perspective. Discount rates of 3% per annum were applied to both costs and clinical outcomes. RESULTS: The Incremental-Cost-Effectiveness Ratio (ICER) for SAP-LGS (vs CSII) was €17,893 per Quality-Adjusted-Life-Year gained over a 5 year time horizon. Results were similar across a 1 to 10 year time horizon. An extensive sensitivity analysis was performed to test the robustness of the results. CONCLUSIONS: Using a payer’s perspective, our analysis showed that SAP (w LGS) is cost-effective over a short term (5 year) time horizon in hypoglycaemia (1.38% vs. 0.92%) and less costly ($208.2) against UC. The 26 week incremental cost was a potential saving (ICER: -€67.85 and -€69.13). Compliance was 100% for HVT group. Further savings could include cost associated with lost work days.

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and SU would generate substantial cost savings in France. Canagliflozin 300mg showed similar outcomes to lixisenatide, suggesting that the treatments are similar in effectiveness, and is thus likely to be a highly cost-effective treatment option.

PDB88

LAYERING INTERVENTIONS FOR TYPE-2 DIABETES PREVENTION USING THE SPHR DIABETES MODEL

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OBJECTIVES: We have developed a model to evaluate type-2 diabetes prevention interventions. The model allows flexible layering of multiple interventions in order to determine the optimal combination of strategies for maximal cost-effectiveness. Our objective was to demonstrate the utility of the model for analysis of multiple interventions in different population sub-groups. METHODS: A model of type-2 diabetes prevention was developed using a micro-simulation framework. Individual patients have a risk of developing type 2 diabetes based on a combination of metabolic factors, including blood pressure and total cholesterol, and can be diagnosed with diabetes, cardiovascular disease, cancer, osteoarthritis or microvascular complications of diabetes over the course of a lifetime. Interventions targeting metabolic factors influence the likelihood of developing diabetes. Layering interventions was used for layering analyses: soft drinks taxation; retail policy; a workplace intervention; an educational intervention aimed at deprived individuals; and a diabetes screening programme followed by intensive intervention for high risk individuals. Eight different intervention combinations were modelled, using the assumption of either additive, synergistic or antagonistic effects in individuals subject to multiple interventions. RESULTS: All interventions generated cost-savings and QALY gains, with the screening intervention performing particularly well, followed by the soft drinks tax. Combining interventions results in roughly additive effects; this holds whether the interventions were varied around the HbA1c switching threshold and around the profile of main-tenance of weight loss. The cost-effectiveness was reported as an incremental cost-effectiveness ratio (ICER). To assess uncertainty, univariate deterministic and multivariate probabilistic sensitivity analyses (PSA) were performed. RESULTS: Compared to the DP4i class, dapagliflozin was associated with 0.231 incremental QALYs and -£1,932 incremental cost. This resulted in an ICER of £10,995 per QALY gained. The incremental cost associated with dapagliflozin was primarily due to the additional drug acquisition cost, whereas the QALY gain estimated was associated with superior weight reduction and its impact on health-related quality of life for dapagliflozin relative to the DP4i’s. Univariate analyses demonstrated that the ICER was most sensitive to varying the weight change parameter for the comparator DP4i’s according to the 95% credible intervals in the PSA. The mean ICERs for saxagliptin, sitagliptin and canagliflozin were -£1,932, -£1,218 and - £1,693, respectively. Dapagliflozin had a 95% probability of being cost-effective versus DP4i’s at a willingness-to-pay threshold of £20,000 per QALY gained. CONCLUSIONS: Dapagliflozin as triple therapy for patients with T2DM who are inadequately controlled on metformin and SU would generate substantial cost savings in France. Canagliflozin 300mg showed similar outcomes to lixisenatide, suggesting that the treatments are similar in effectiveness, and is thus likely to be a highly cost-effective treatment option.

PDB90

THE PLACE OF DPP-4 INHIBITORS IN THE TREATMENT ALGORITHM OF DIABETES TYPE 2: A SYSTEMATIC REVIEW OF COST-EFFECTIVENESS STUDIES

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OBJECTIVES: To conduct a systematic review of cost-effectiveness, cost-utility and cost-benefit studies of new inhibitors of DPP-4 for diabetes treatment versus other antidiabetics. METHODS: We searched the CRD York, NICE Health Technology Assessment, Tufts CEA Registry, and MEDLINE (PubMed) databases, and grey literature through 2014 to identify cost-effectiveness, cost-utility and cost-benefit studies of new inhibitors of DPP-4 versus other antidiabetics for diabetes treatment. Three investigators independently reviewed all potentially relevant titles and abstracts (1st screening), and subsequently screened full-text articles (2nd screening), according to pre-established inclusion criteria. We restricted our sample to studies with a lifetime or near-lifetime horizon, and adopting either a societal or a health care perspective. The studies should be available as a full-text publication and published in English, French, Spanish, or Portuguese language. A critical appraisal of the methodology and reporting was performed using the 3item version of the BMJ checklist. RESULTS: A total of 57 studies were identified. From these, 17 studies were accepted after the 2nd screening. Five after the 3rd screening. Most studies consisted in cost-utility analyses. Most studies were based on a single randomized trial per therapy. Saxagliptin was assessed in 6 studies, sitagliptin in 4, and vildaglaptin in 2. CONCLUSIONS: According to commonly accepted thresholds, there is consistent evidence about the cost-effectiveness of DPP-4 inhibitors as second line therapy for diabetes type 2. Though, more evidence (including head-to-head) is necessary to define which DPP-4 inhibitor is the most cost-effective.
PEDB90

SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS OF DIFEPTIDYL
PEPTIDASE-4 INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To synthesize and analyze the available information on the therapeutical advantages of Dipeptidyl-Peptidase-4 (DPP-4) for the treatment of type 2 diabetes mellitus (T2DM) from the point of view of their efficiency or cost-effectiveness.

METHODS: A systematic review of national (MEDES, IEBCS) and international (MedLine/PubMed, Cochrane Library, ISI WOK, SCOPUS) databases was performed. Eligible studies were economic evaluations (cost-effectiveness, cost-utility and cost-benefit analysis) comparing costs and clinical benefits of two alternatives for the T2DM treatment including DPP-4 inhibitors, published in English or Spanish until June 2013. After excluding duplicates, 1,330 by title/abstract review and 8 by criteria accomplishment. A comprehensive literature review of 2010 was added.

RESULTS: Of 1,634 publications initially selected, 284 were excluded by duplicate review, 1,330 by title/abstract review and 8 by criteria accomplishment. A total of 12 publications [1 conducted in 6 countries including Spain, 4 in Europe, 4 in life and 3 in others] were selected. All studies were cost-effectiveness or cost-utility analysis (discrete-event simulation (DES)).

CONCLUSIONS: The results showed that DPP-4 therapy has increased the number of patients with T2DM, and that the cost-effectiveness of DPP-4 therapy is better than other treatments. However, further studies are needed to confirm these results.

PEDB94

PROMOTION OF LONG TERM HEALTH ECONOMIC BENEFITS OF SENSOR AUGMENTED PUMP (SAP) VERSUS PUMP THERAPY ALONE (CSII) IN TYPE 1 DIABETES, A UK PERSPECTIVE

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OBJECTIVES: To synthesize and analyze the available information on the therapeutical advantages of SAP compared to CSII for the treatment of type 1 diabetes mellitus (T1DM) from the point of view of their efficiency or cost-effectiveness.

METHODS: A systematic review of national (MEDES, IEBCS) and international (MedLine/PubMed, Cochrane Library, ISI WOK, SCOPUS) databases was performed. Eligible studies were economic evaluations (cost-effectiveness, cost-utility and cost-benefit analysis) comparing costs and clinical benefits of two alternatives for the T1DM treatment including DPP-4 inhibitors, published in English or Spanish until June 2013. After excluding duplicates, 1,330 by title/abstract review and 8 by criteria accomplishment. A comprehensive literature review of 2010 was added.

RESULTS: Of 1,634 publications initially selected, 284 were excluded by duplicate review, 1,330 by title/abstract review and 8 by criteria accomplishment. A total of 12 publications [1 conducted in 6 countries including Spain, 4 in Europe, 4 in life and 3 in others] were selected. All studies were cost-effectiveness or cost-utility analysis (discrete-event simulation (DES)).

CONCLUSIONS: The results showed that DPP-4 therapy has increased the number of patients with T1DM, and that the cost-effectiveness of DPP-4 therapy is better than other treatments. However, further studies are needed to confirm these results.

PEDB95

COST-EFFECTIVENESS OF A SHORT MESSAGE SERVICE (SMS) INTERVENTION TO PREVENT TYPE 2 DIABETES AMONG ADULTS WITH IMPAIRED GLUCOSE TOLERANCE

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OBJECTIVES: To investigate the costs and cost-effectiveness of a short message service (SMS) intervention to prevent the onset of type 2 diabetes mellitus (T2DM) in subjects with impaired glucose tolerance (IGT).

METHODS: A Markov model was developed to synthesize the available evidence on the clinical intervention and usual clinical practice from the health service provider's perspective. The annual transition probabilities between health states were taken from several data sources, including Diabetes Prevention Program and Diabetes Prevention Program Outcome Study. The discount program costs and the two-year SMS intervention costs were evaluated in subjects with IGT. All costs were expressed in year 2011 U.S. dollars. The incremental cost-effectiveness ratio were calculated as cost per T2DM onset prevented, cost per life year gained and cost per quality adjusted life year (QALY) gained.

CONCLUSIONS: The SMS intervention prevented an additional T2DM at a cost of $0.071 QALY and $0.015 T2DM per 1000 T2DM patients, and provided a cost-effective alternative compared with insulin alone. Therefore, the SMS intervention is recommended in all sensitivity analyses. CONCLUSIONS: This study revealed that the SMS intervention for subjects with IGT had the superiority of lower monetary cost and a considerable improvement in preventing or delaying the T2DM onset.

PEDB96

ECONOMIC EVALUATION OF LANREOTIDE AUTOGEL IN THE MANAGEMENT OF ACROMEGALY IN GREECE

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OBJECTIVES: Acromegaly is a chronic and debilitating disease, which can lead to the development of severe and life-threatening complications. The objective of the present study was to undertake an economic evaluation of Lanreotide Autogel compared with Octreotide LAR in the management of acromegaly in the Greek health care setting.

METHODS: A cost-minimization model was developed for the analysis which only took into account the costs of treatment. The time horizon was 5 years. Costs were considered to be the sum of treatment and monitoring costs. The time horizon was 10 years; future costs were discounted at 3.5%. In addition, a budget impact analysis was conducted, with a time horizon of 5 years. The perspective for both analyses was that of Social Insurance. Data on resource use administration setting, drug wastage and time required for the administration of dose was taken into account.
each drug, as well as lab and imaging tests, were collected with the Delphi tech-
nique. No type 2 diabetes patients with 1-exchange were included in the acromegaly in-
Public Hospital special units. Local unit cost data were collected from
officially published sources (Ministry of Health and Social Insurance Funds). One
way sensitivity analyses were performed to test the results. RESULTS: Lanreotide
Autogel was associated with a near 100% probability of being cost-effective compared to
mealtime bolus insulin in Spain for T2D patients with – a recently introduced – twice daily (BID)
add-on to basal insulin treatment for T2D patients not at target with insulin glargine.

PDB97
THE OPPORTUNITY OF TREATING TYPE 2 DIABETES WITH DPP4I: AN ECONOMIC
EVALUATION VERSUS CONVENTIONAL TREATMENT IN THE ITALIAN SETTING

Cost-Effectiveness Analysis of saxagliptin compared to sitagliptin and
Lanreotide Autogel in the treatment of type 2 diabetes mellitus in terms of economic impact and
considering both the Italian National Health System (NHS) and the societal perspec-
tive. METHODS: The economic evaluation was performed as a model-based cost-
minimisation analysis for the comparison DPP4i and SU as second line therapy, in add-on of metformin, a year period. Clinical costs to be included in the model were
selected from literature review and the opinion of a panel of clinical experts.

PDB98
ANd A SULPHONYLUREA IN THE TREATmENT Of TyPE 2 dIABETES mELLITUS

Sensitivity analyses demonstrated that the ICER was somewhat sensitive to the prescrib-
ees and the weight utility decrement, and most sensitive to assumptions on relative risk parameters. When no relative risk reduction on MI or other-cause mortality
was assumed, the ICER was €17,543/QALY and €17,053/QALY, respectively. When
no statistically significant differences between saxagliptin compared to either sit-
agliptin-based strategy had a near 100% probability of being cost-effective compared to bolus insulin
insulin. An alternative option is adding twice-daily exenatide (BID), a glucagon-like
peptide-1 receptor agonist. The objective was to estimate the cost-effectiveness in Spain of exenatide BID compared to mealtime bolus insulin lispro, both added to
insulin glargine and metformin. METHOIDS: The published and validated CARDIFF
model predicted near 100% probability of being cost-effective compared to bolus insu-
in treatment for T2D patients with uncontrolled HbA1c levels is considered a highly cost-effective
strategy from the Turkish public health care perspective.

PDB100
COST-EFFECTIVENESS OF EXENATIDE TWICE DAILY (BID) ADDED TO BASAL
INSULIN COMPARED TO A BOLUS INSULIN ADD-ON IN TURKEY

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OBJECTIVES: To compare dipeptidyl-peptidase 4 inhibitors (DPP4i) and sulfonylures
(SU) for the treatment of type II diabetes mellitus in terms of economic impact and
effectiveness of productivity loss for hypoglycaemic events and stroke. The total cost of drug acquisition was projected to cost €1,102 more than a sulfonylurea-based treatment strategy per
patient lifetime, with the majority of excess costs from prescription drugs. Life expectancy was 0.077 years greater per patient on a sitagliptin-based strategy compared to a sulfonylurea-based strategy. The discounted gain in QALY was 0.082
years with the sitagliptin-based strategy, driven by better glycaemia, weight, and MI risk profile. The estimated ICER was €13,460/QALY. Sensitivity analyses demonstrated that the ICER was somewhat sensitive to the prescrib-

PDB99
COST-EFFECTIVENESS OF SITAGLIPTIN VERSUS SULFONYLUREA AS AN ADD-ON
THERAPY TO METFORMIN IN PATIENTS WITH TYPE 2 DIABETES IN A BELGIUM SETTING

COST-Effectiveness of sitagliptin versus sulfonylurea as an add-on to
metformin to treat type 2 diabetes patients currently on
metformin but not achieving HbA1c goal in Belgium. METHODS: We employed a previously published individual-level simulation model that incorporated risk
equations/algorithms from the UKPDS Outcome Models (38) to predict the long-
term benefits and costs associated with sitagliptin-based treatment strategies on
risk factors and side effects was based on clinical trials, observational stud-
ies, systematic reviews and meta-analyses of relevant RCTs, as well as the most
recent findings on the potential benefit of DPP4 on other-cause mortality and cardiovascular disease determi-
nation on myocardial infarction (MI). European patient profiles and Belgium-specific data on
drug prices, diabetes-related complication treatment costs, treatment patterns and
mortality were used to perform a cost-effectiveness analysis for each strategy. The model was
then adjusted to the specific patient characteristics, drug utilization, and healthcare costs in
Belgium. OBJECTIVES: The primary objective was to compare the cost-effectiveness of a sitagliptin-based add-on strategy to sulfonylurea in T2D patients on basal insulin treatment in Belgium.
OBJECTIVES: The primary objective was to compare the cost-effectiveness of a sitagliptin-based add-on strategy to sulfonylurea in T2D patients on basal insulin treatment in Belgium.

PDBA3
CONCLUSIONS: Using a threshold of €15,000 per
QALY gained, compared to a sulfonylurea-based treatment strategy, a sitagliptin-
based treatment strategy was cost-effective in metformin-failed patients with

type 2 diabetes in Belgium.
To assess the long-term clinical and economic impact of dapagliflozin, a sodium-glucose co-transporter-2 inhibitor, in combination with insulin treatment for type 2 diabetes in Spain, a new economic evaluation was conducted. The study aimed to assess the incremental cost-effectiveness of dapagliflozin add-on to insulin compared to insulin alone from a healthcare payer perspective.

**Objective:**
To assess the cost-effectiveness of dapagliflozin add-on to insulin in comparison to insulin alone for the management of type 2 diabetes in Spain.

**Methods:**
This was a cost-effectiveness analysis conducted in a Spanish cohort of patients with type 2 diabetes inadequately controlled with insulin alone. The study compared dapagliflozin add-on to insulin with insulin alone over a lifetime horizon. A Markov model was developed to simulate the health states of patients with type 2 diabetes over a lifetime horizon. The model was populated with clinical and economic data from published randomized controlled trials.

**Results:**
Dapagliflozin add-on to insulin was estimated to be cost-effective at the threshold of €20,000 per quality-adjusted life-year (QALY) in Spain. The probability of dapagliflozin add-on to insulin being cost-effective compared to insulin alone was 100%.

**Conclusion:**
Dapagliflozin add-on to insulin is cost-effective compared to insulin alone in Spain, providing a gain of 0.337 QALYs (95% CI: 0.227–0.754) and cost savings of €264 (95% CI: €1,879 to €5.701) per QALY gained.

**Key Points:**
- Dapagliflozin add-on to insulin is cost-effective compared to insulin alone in Spain.
- The model was developed based on evidence from randomized controlled trials.
- The primary outcome of the analysis was the incremental cost-effectiveness ratio, expressed as a cost per quality-adjusted life-year (QALY).
the comparative efficacy and safety across SGLT2is. Data gaps were completed with information derived from published sources, including previous cost-effectiveness analyses. The UK National Health Service (NHS) perspective was considered to estimate costs and QALYs over a patients’ lifetime. RESULTS: There were small differences in efficacy and safety across SGLT2is, which resulted in minor QALY and cost differences when compared on the University of York scale. Incremental QALYs of 0.029 versus dapagliflozin 10mg and 0.019 versus canagliflozin 100mg, and incremental costs of £178 and £86, respectively, whereas both canagliflozin 100mg and empagliflozin 10mg were dominated by emagliflozin 25mg. This resulted in an incremental cost-effectiveness ratio (ICER) of £4,858 per QALY gained with emagliflozin 25mg vs. canagliflozin 100mg. However, the differences across treatments were not significant when 95% percentile confidence intervals were considered. These results were robust to a number of sensitivity analyses, including a 10-year time horizon, BMI impact, discount rates and parameter values related to utilities, disutilities, adverse events, and discontinuation rates. CONCLUSIONS: Overall, differences in clinical efficacy and costs were dominated between SGLT2is when used as add-on to and to metformin in UK T2DM patients. On average, emagliflozin 25mg was the most cost-effective strategy, with an ICER of £4,858 per QALY gained vs. canagliflozin 100mg.

**PB108**

**COST EFFECTIVENESS ANALYSIS OF FLASH GLUCOSE MONITORING FOR TYPE 2 DIABETES PATIENTS RECEIVING INSULIN TREATMENT IN THE UK**


OBJECTIVES: A small, minimally-invasive flash glucose monitor (FGM) has recently been approved for use in the UK. However, to date, there has not yet been an economic analysis of a FGM in the UK. The aim of this analysis was to determine the cost-effectiveness of a FGM in routine clinical practice.

METHODS: A small, minimally-invasive flash glucose monitor (FGM) has recently been approved for use in the UK. To date, there has not yet been an economic analysis of a FGM in routine clinical practice. Using data from published literature, a Markov model was developed to determine the cost-effectiveness of a FGM in routine clinical practice. The model was tested using a 10-year time horizon, BMI impact, discount rates and parameter values related to utilities, disutilities, adverse events, and discontinuation rates.

RESULTS: The model showed that a FGM could be cost-effective across a variety of clinical benefit and threshold analysis shows that for each scenario.

CONCLUSIONS: The model showed that a FGM could be cost-effective across a variety of clinical benefit and threshold analysis was performed to estimate potential total FGM sensor costs and savings from the adoption of a passive safety system, including the reduction in stick injuries. For an institution of similar size using safety syringes, the move to a FGM would result in a savings of $43,339.66, and 191.42 hours of nursing time saved (site with 52 beds dedicated to patients with diabetes). Cost savings from the adoption of a passive safety system associated with productivity loss amounted to EUR 170.8 million, including 6.6% of the total cost. The study found that inpatient QALY and cost differences were significant based on 95% percentile confidence intervals. These results remained robust when sensitivity analyses were conducted, including utilities, adverse events, discontinuation, modeling of weight, impact of BMI, duration of effect, time horizon and discount rates.

**PB111**

**ABSENTEISM AND PRESENTEEISM IN A POPULATION OF PATIENTS WITH DIABETIC FOOT ULCERS IN POLAND**

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OBJECTIVES: Diabetic Foot Ulcer (DFU) of patients with diabetes is a serious and common complication of diabetes, often leading to limb amputation and disability. Disability and productivity loss in patients with DFU can generate significant indirect costs and potentially significant economic consequences. The purpose of the study is to estimate productivity loss and indirect costs associated with foot ulceration in patients with DFU.

METHODS: We conducted a prospective survey in a population of DFU patients with foot ulceration. Loss of productivity was measured with a modified WPAI-SF questionnaire. Indirect costs of both absenteeism and presenteeism were estimated using the human capital approach on the basis of the measure of gross value added per employee. RESULTS: Nearly one third of respondents (32%) declared that foot ulceration was the direct reason why they abandoned their professional activity. 40% and 34% of respondents, respectively, were forced to limit or change their professional activity at some point in the past because of the foot ulceration. More than 40% of respondents who changed or limited their professional activity because of the foot ulceration had experienced reduction in earnings by 22.9% on average. Mean absenteeism was estimated at 32.63% of the nominal working time, while presenteeism was estimated at 23.48% of real working time. Total annual indirect costs amounted to EUR 117.3 million of the costs of sickness absence and EUR 5.35 million of the costs of presenteeism.

CONCLUSIONS: Foot ulceration in patients with DFU is a common health problem and it can give up or change their professional activity, which usually leads to a reduction in earnings. Indirect costs associated with foot ulceration in DFU impose a significant burden on the Polish economy. There is no rationale that would clearly link productivity loss associated with ulceration in DFU and the ulceration severity.

**PD112**

**EXAMINING THE ROLE OF INSULIN PEN DEVICES IN ACUTE CARE SETTINGS: A REVIEW AND ANALYSIS OF HEALTH RESOURCE UTILIZATION**

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OBJECTIVES: Insulin administration in the acute care setting is an integral component of inpatient diabetes management. The current method of administration in acute care settings is by vial and syringe. The aim of this study was to evaluate the impact of insulin pen implementation in the acute care setting on patient and health care worker safety, and health resource utilization (HRU).

METHODS: A review of published literature was conducted to identify how insulin pen devices in the acute care setting may impact inpatient diabetes management. Additionally, nurse researchers from the McGill University Health Centre conducted a pilot study in a 52-bed unit to quantify this impact in a local context. Together, the results of the literature search and the pilot informed the development of an economic model, developed in Excel v14. Costs for the volume of insulin dispensed, injection supplies, needlestick injury management, and nursing labour were assessed. RESULTS: Literature searched studies had several limitations, including a lack of potential to improve inpatient management through better glycemic control, increased adherence and improved self-management education. The combined results from the literature and pilot indicate that moving from vial and non-safety syringe to a pen in acute care may result in total savings of $43,339.66, and 191.42 hours of nursing time saved (site with 52 beds dedicated to patients with diabetes). Cost savings from the adoption of a passive safety insulin pen were predicted based on reductions in injection volume and needlestick injuries. For an institution of similar size using safety syringes, the move to a
passive safety pen device would result in total estimated cost savings of $17,865.40 annually. CONCLUSIONS: The implementation of insulin pen devices in acute care results in cost savings, as well as time savings for nurses that may be re-directed to increased time at the patient bedside.

PDB113

EPILOGUE AND DIRECT HEALTH CARE COSTS OF DIABETIC RENOTOPATHY: RESULTS FROM A POPULATION-BASED STUDY

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OBJECTIVES: The aim of this study was to assess the epidemiologic and economic burden of diabetic retinopathy (DR) in terms of incidence, treatment patterns and cost by a population-based study. METHODS: Eligible patients were identified through a data source (DENALI), which matches demographic, clinical, and economic data of about 9.9 million individuals of Lombardy region. The study population consisted of all individuals with a diagnosis of diabetes who, during the period 1-1-2000 to 31-12-2010 received one of the following health care services: hospital inpatient stay (length of stay > 0 days); hospital outpatient stay; radiology or ultrasound examination; consultations with eye-specialist departments. Approximately 1% received intravitreal injections in 2010.

RESULTS: This study attempted to describe the burden of DR in Italy revealing socio-economic aspects relevant in terms of incidence and costs.

PDB114

EVALUATION OF THE BURDEN OF ILLNESS OF U.S. MEDICARE PATIENTS DIAGNOSED WITH HYPERPOTASSEMIA

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OBJECTIVES: To evaluate the economic burden and health care utilization of patients diagnosed with hyperpotassemia in the U.S. Medicare population. METHODS: Hyperpotassemia patients (International Classification of Disease 9th Revision Clinical Modification ICD-9-CM diagnosis codes 276.7) were identified from the U.S. national Medicare claims from 01JAN2009 through 31DEC2011. The first diagnosis date of a patient served as the index date for the hyperpotassemia cohort. Patients without a hyperpotassemia diagnosis but of the same age, region, gender, index year and matched baseline Charlson Comorbidity Index score were identified for the comparison cohort. Patients with a randomly-chosen index date to minimize selection bias. Patients were required to have continuous medical and pharmacy benefits 1 year before and after the index date. Study outcomes (health care costs and utilization defined as the index event) included the index event and costs associated with severe hyperpotassemia (DR) and in the comparison cohort (AHA). A key secondary objective is to estimate health care resource consumption and economic data of about 9.9 million individuals of Lombardy region. The study was conducted in 7 centers in mainland Portugal for a period of 12 months (Jan2013-Jan2014). Patient level data and resource utilization were collected. Average costs were assessed by multiplying 2014 unit costs (available from public sources) with all relevant health care resources, including Medicare carrier (98.4% vs. 77.8%), Durable Medical Equipment (DME; 36.7% vs. 23.6%) and Home Health Agency (HHA; 18.4% vs. 7.3%) claims, outpatient visits (75.5% vs. 47.7%), inpatient (57.4% vs. 3.4%), skilled nursing facility (SNF; 13.3% vs. 3.4%) and hospice stays (1.1% vs. 0.8%) and prescription drug claims (54.1% vs. 50.7%). Patients diagnosed with hyperpotassemia also incurred higher Medicare carrier ($3,447 vs. $1,636), DME ($343 vs. $167), HHA ($593 vs. $412), outpatient ($1,006 vs. $4,534), inpatient (775 vs. $1,463), SNF ($2,688 vs. $612), hospice ($244 vs. $198), pharmacy ($1,014 vs. $812) and total costs ($26,926 vs. $9,834) (p<0.05). CONCLUSIONS: The economic burden and health care utilization were significantly higher for patients diagnosed with hyperpotassemia.

PDB115

COSTS OF HOSPITALIZATION OF TYPE 2 DIABETIC PATIENTS ASSOCIATED WITH SEVERE HYPOGLYCEMIA

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OBJECTIVES: HIPOS-ER is an observational, cross-sectional, multicenter study aimed to describe type 2 diabetes patients treated with an anti-hyperglycemic agent (AHA) and admitted to the emergency room (ER) due to a hypoglycemic event and to estimate health care resources use and its costs related with the ER hypoglycemic episode. In this analysis, costs within hospitalized patients following severe hypoglycemia were assessed. Patients were specifically matched. The study was conducted in 7 centers in mainland Portugal for a period of 12 months (Jan2013–Jan2014). Costs related with these hospitalized patients were calculated considering the hospital perspective. Results from 2014 were extracted from official sources and reported in euros. Patient level data were used to calculate average costs. Regarding ER attendance, costs were calculated multiplying resource use by corresponding unit costs. Costs were calculated for employed patients using the Human Capital Approach. Productivity loss cost within ER admission and hospitalization was calculated for employed patients using the Human Capital Approach.

RESULTS: The study enrolled 238 patients and the calculated proportion of hypoglycemic episodes among all emergency events in the same period was 0.075% (95%CI: 0.067, 0.083). In this population, 55.0% of the patients were using insulin, 31.5% were treated with a secretagogue, 6.7% were on a combination of insulin and a secretagogue oral agent and 6.7% were on oral non-secretagogue based AHA therapy. Mean patient age was 76 years and 57.6% were females. Estimated mean (range) of direct costs assessed in the emergency room was €239 (€0–478), laboratory workup €34 ($2–762), other exams €72 ($0–494), physician and nurse time €30 ($4–211) and €11 ($1–490), respectively. Mean hospitalization cost was €1,271 ($26,486). Mean indirect cost related with productivity loss within employed patients was €15 ($4–1,579). Total costs were calculated for employed patients. Total indirect and direct costs was €1,493 ($36,281) per hypoglycemic event. Hospitalization was the main cost driver (85% of total costs). CONCLUSIONS: We conclude that hypoglycemia represent a substantial cost for the Society and in particular for the public hospitals of the National Health System.
OBJECTIVES: HIPOS-ER is the first national Hypoglycemia study in Portugal collected through databases directly in the hospitals. Here we describe the average cost of severe hypoglycemic event by anti-hyperglycemic agent (AHA) class. METHODS: The study was conducted in 7 centers in mainland Portugal for a period of 12 months (Jan13-Jan14). Patient level data and resource utilization were collected through event specific data directly from hospital records. Each patient’s medical records were assessed during emergency room (ER) attendance, costs were calculated multiplying resource use by corresponding unit costs. For hospitalization, length of stay was multiplied by daily cost obtained through the direct cost data collected in the hospitals. AHA therapy class was set to Group 1 (insulin), Group 2 (secretogague), Group 3 (oral AHA excluding secretagogue), and Group 4 (at least one insulin and one secretagogue). RESULTS: 238 patients were enrolled and 105 (44%) were hospitalized. The distribution based on AHA therapy: 55% (131 Group 1); 32% (75 Group 2); 7% (16 Group 3) and 7% (16 Group 4). After the index episode, Group 2 patients were more often hospitalized versus Group 1 (1% vs. 29%, p<0.001) and Group 4 (31%, p=0.003). The global cost was 1,495€ (341-26,818€) and hospitalization (95% CI: 250-251.2) leading to a maximum of 10 years. We evaluated demographic characteristics (age, gender, diabetes duration, BMI, hypertension, hyperlipidemia, smokers vs. non-smokers, and comorbidities). The study population was made of all individuals with a diagnosis of type-1 diabetes (TIDM) who, during the period 1-1-2000 to 31-12-2010 developed a first episode of severe HYPO (ICD-9-CM: 251.0-251.2) or DKA (ICD-9-CM: 250.10-250.13) leading to hospitalization (index event). The identified individuals were followed-up from the index event to a maximum of 10 years. We evaluated demographic characteristics of the study population and costs (hospitalizations, drugs and outpatient examination, and hospitalization (index event). We evaluated the average cost followed closely by secretagogue type drugs, which were associated with more hospitalizations.

PDB119
THE BURDEN OF SEVERE HYPOGLYCEMIA AND DIABETES KETOACIDOSIS: A POPULATION-BASED STUDY
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OBJECTIVES: The aim of this study was to assess the burden of severe hypoglycemia (HYPO) and diabetes ketoacidosis (DKA) in terms of incidence, treatment patterns and cost in Italy. METHODS: Eligible patients were identified through a data warehouse (GENALI), which matches with a probabilistic linkage demographic, clinical and laboratory information of about 9 million individuals of Lombardy. The study population was made of all individuals with a diagnosis of type-1 diabetes (TIDM) who, during the period 1-1-2000 to 31-12-2010 developed a first episode of severe HYPO (ICD-9-CM: 251.0-251.2) or DKA (ICD-9-CM: 250.10-250.13) leading to hospitalization (index event). The identified individuals were followed-up from the index event to a maximum of 10 years. We evaluated demographic characteristics of the study population and costs (hospitalizations, drugs and outpatient examination, and outpatient examination, and hospitalization (index event). We evaluated the average cost followed closely by secretagogue type drugs, which were associated with more hospitalizations. RESULTS: 238 patients were enrolled and 105 (44%) were hospitalized. The distribution based on AHA therapy: 55% (131 Group 1); 32% (75 Group 2); 7% (16 Group 3) and 7% (16 Group 4). After the index episode, Group 2 patients were more often hospitalized versus Group 1 (1% vs. 29%, p<0.001) and Group 4 (31%, p=0.003). The global cost was 1,495€ (341-26,818€) and hospitalization (95% CI: 250-251.2) leading to hospitalization (index event). The identified individuals were followed-up from the index event to a maximum of 10 years. We evaluated demographic characteristics of the study population and costs (hospitalizations, drugs and outpatient examination, and hospitalization (index event). We evaluated the average cost followed closely by secretagogue type drugs, which were associated with more hospitalizations.

PDB120
FACTORS ASSOCIATED WITH DISCONTINUATION OF SULFONYLUREA THERAPY IN TYPE 2 DIABETES PATIENTS WHO INITIATE INSULIN
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OBJECTIVES: Sulfonfylureas (SUs) represent a common treatment for type 2 diabetes (T2DM), but they are associated with hypoglycemia, weight gain, and possibly cardi-vascular events. The purpose of this study is to evaluate factors associated with SU discontinuation after insulin initiation. METHODS: Patients ≥21 years old with a T2DM diagnosis between 2005 and 2012 were identified using the GL electronic medical records database. Index date was defined as the first insulin prescription (Rx) between 2006 and 2011. Patients were required to be on SU at the index date. Patients with the first SU prescription (Rx) (index date) in 2009-2011, or secondary diabetes. Therapy changes were determined during the 1-year post-index period. Discontinuation occurred when subsequent SU fills were ≥90 days apart. Down-titration occurred when an SU fill had a lower equivalent dose than the index dose. Hypoglycemic events were identified using ICD-9 code between the index date and the therapy change or the end of the 1-year post-index period. Cox regression was used to evaluate the association between SU discontinuation and the SU type and therapy changes. RESULTS: 97,570 patients were included in the study, of which 50,854 (52.1%) experienced therapy changes within 1-year post-index. Patients with hypoglycemic events were more likely to discontinue SU (HR = 2.12 [1.96, 2.29], p < 0.001). They were 197% more likely to down-titrate SU (HR = 2.97 [2.53, 3.46], p < 0.001) and 80% more likely to discontinue SU (HR = 1.80 [1.69, 1.92], p < 0.001). CONCLUSIONS: SU discontinuation is significantly associated with therapy changes among patients receiving SU without insulin, especially down-titration.
more health care provider visits in the past six months (11.7 vs. 8.9) compared with matched controls (n=286) (all p<.05). 

CONCLUSIONS: DME was more commonly reported by patients with diabetes and its presence was associated with a significant humanistic and economic burden in the SEU.

PDB124
EQ-5D SCORES IN PATIENTS RECEIVING TOLVAPTAN FOR THE TREATMENT OF HYponATREMIA SECONDARY TO THE SYMPODROME OF INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION

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OBJECTIVES: Hyponatremia (HN) is estimated to occur in 15% of all hospitalised patients, with syndrome of inappropriate antidiuretic hormone secretion (SIADH) being one of the most common aetiologies. Patients treated with tolvaptan have demonstrated improvements in health related quality of life (HRQL) in the SALT I & II trials. The objective of this study was to assess the HRQL responses from SALT I & II to EQ-5D by using a publically available algorithm and predict the change in EQ-5D associated with tolvaptan.

METHODS: SF-12 scores from the pooled SALT I & II studies were converted to EQ-5D scores using a mapping algorithm developed by Gray, et. al 2006. Simulated EQ-5D scores were then used to estimate changes in EQ-5D from baseline at day 30 using ordinary least squares regression (OLS) as a function of baseline characteristics, treatment arm and is also relevant for some oncology trials. It is possible to seamlessly integrate

Garner K.

was complete and 94.8% liked the automatic needle insertion. Finally, 92.4% of site (95.7%) the needle. 95.7% of patients also liked hearing the click indicating the dose with the overall injection experience, 96.7% of patients were confident they could

with type 2 diabetes (T2D) who were naïve to self-injection or injecting others. The study evaluated the safe and effective use of the Single-Use Pen (SUP) in patients

PDB125
PATIENT EXPERIENCE WITH THE SINGLE-USE PEN FOR INJECTION OF ONCE WEEKLY DULAGlutide IN INJECTION-NAIVE PATIENTS WITH TYPE 2 DIABETES

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1Eli Lilly and Company, UK, Windlesham, Surrey, UK, 2Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To evaluate the safe and effective use of single-use OpenPen (SUP) in patients with type 2 diabetes (T2D) who were naive to self-injection or injecting others. The SUP contains a pre-filled syringe and automates needle insertion, retraction, and drug delivery; specifically designed for once weekly glargine-like peptide-1 receptor agonist, dulaglutide. Patient-reported outcomes (PROs) related to self-injection and to the SUP were important secondary outcomes.

METHODS: Patients (N=211) were trained on correct injection technique with the SUP containing 0.5 mL placebo prior to initial self-injection. PRO measures were completed by patients after final injection or at early termination to evaluate device ease of use, experience (including satisfaction/confidence), and key device features. Site trainers rated how easy/difficult it was to train patients to use the SUP. 99.0% of patients found the device easy to use. Patients found it easy to hold the SUP when injecting and to push the button to inject (97.6% and 98.1%, respectively). 97.1% of patients were satisfied with the device and 96.7% of patients found the device easy to use. Patients liked not having to attach (99.0%, touch (98.6%), or see (95.7%) the needle. 95.7% of patients also liked hearing the click indicating the dose was complete and 94.8% liked the automatic needle insertion. Finally, 92.4% of site trainers found it easy to train patients on how to use the SUP. Conclusions: This study evaluated the SUP could be used safely and effectively by injection-naive patients with T2D. PRO results indicated patient satisfaction with the SUP injection experience. A positive injection experience may be an important factor for some patients and providers when initiating injectable therapy.

PDB126
BEST PRACTICES IN INTEGRATING HOME GLUCOSE MEASUREMENTS WITH ELECTRONIC PATIENT REPORTED OUTCOMES (EPRO) IN CLINICAL TRIALS

Garvey E

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OBJECTIVES: Monitoring glycaemic control is important in diabetes clinical trials and is also relevant for some oncology trials. It is possible to seamlessly integrate blood glucose measurements with clinical trial data via Bluetooth. This integration

re-use of eDiaries previously used by patients doing fingertip tests poses a low and acceptable level of risk for modifying measurements should be incorporated in the eDiary design including batch and individual reporting, reporting hypoglycaemic events as part of a meal event or as a standalone event and edit checks should be included to identify where a number of low measurements relate to the same event, thereby patient burden. The objective was to explore how to transform events to the eDiary, a method for managing control test measurements should be incorporated; and integrating glucometer measurements decreases patient burden and increases patient engagement.

PDB127
THE DEVELOPMENT OF AN INTEGRATED ECDA SOLUTION TO IMPROVE THE QUALITY OF DATA CAPTURE IN DIABETES CLINICAL TRIALS

McNay F

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OBJECTIVES: The 347 million people who live with diabetes face an array of daily diabetes management tasks, e.g. measuring blood glucose, keeping track of the nutritional value of meals, and monitoring insulin usage. Diabetes trials vary in methodology, level of patient burden, volume of data captured and patient compliance. Our aim was to explore best practices in integrating blood glucose measurements with clinical trial data via Bluetooth. This integration would decrease patient burden while increasing compliance and improving data quality. METHODS: We developed a diabetes specific, electronic, event driven diary for capturing data relevant for clinical trials. Iterations of the diary were tested in diabetes patients via focus groups and one-on-one usability evaluations. Feedback was analysed to understand the typical day-to-day experience of living with diabetes, and to examine the impact and acceptability of a tailored electronic solution. Feedback led to the development of a refined solution for use in clinical trials. RESULTS: The nature of diabetes means that patients are typically very actively engaged in managing their disease, although a lot of variation was seen in patients and their management routines. The requirement for multiple devices and high volume of data was also reported as burdensome. The focus groups and usability studies highlighted the benefit of providing a flexible solution, as well as redesigning the diary from a triangulated measurement reporting to event driven reporting. This redesign met the needs of patients, as well as the requirements of clinical trial protocols. Patients agreed that they would prefer this integrated, intuitive solution over traditional paper and electronic solutions. CONCLUSIONS: When faced with the need to collect patient data in diabetes, a well-designed and thoroughly tested electronic solution can reduce burden and increase patient satisfaction. This in turn improves compliance, data quality and overall study efficiency, while meeting the needs of all stakeholders.

PDB128
GERMAN PATIENTS’ PREFERENCES FOR ATTRIBUTES OF TYPE 2 DIABETES MEDICATIONS

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1Evadera, Bethesda, MD, USA, 2Evadera, Inc., Bethesda, MD, USA, 3Evadera, London, UK

OBJECTIVES: Treatments for Type 2 Diabetes Mellitus (T2DM) are associated with varying effectiveness and safety profiles. Patients’ preferences for each of the medication characteristics that yield these varying profiles can be assessed through discrete choice experiments (DCEs). A DCE study evaluated German patients’ preferences for T2DM medications from two previous T2DM DCE studies conducted in the United Kingdom (UK) and the United States (US), and was aimed at evaluating the relative importance of medication characteristics among participants with T2DM from Germany. METHODS: A web-based DCE was conducted among patients with self-reported T2DM from Germany. The DCE was designed to examine 7 attributes of T2DM medications (efficacy, urinary tract infection/genital infection side effects, nausea, gastrointestinal side effects, weight change, hypoglycemic events, treatment in case of low blood sugar, and blood pressure). Part-worth utilities were estimated using multi-logit models, and relative importance [RI] values were calculated for each attribute. RESULTS: N=600 Participants with T2DM completed the study (50% male; mean age=58.2 years SD=10.0; BMI=32.4, SD=6.8). The RI values for the attributes in order of importance were: treatment in case of low blood sugar (22.5%), hypoglycemic events (18.1%), weight change (17.5%), efficacy (15.0%), nausea/se/other gastrointestinal side effects (12.9%), UTI/genital infection side effects (7.9%), and blood pressure (6.0%). CONCLUSIONS: The results of this study suggest that hypoglycemic events and the interventions required in the case of such events are of great importance to patients; these two attributes represent over 40% of the variance in patients’ medication decisions. Change in body weight as a consequence of treatment was also an important attribute to patients. The results may help treatment providers and payers to further refine the preferences of patients with T2DM. Understanding these preferences may be useful in devising strategies for successfully engaging and maintaining patients on T2DM treatments.

PDB129
SELF-REPORTED FREQUENCY AND IMPACT OF NON-SEVERE HYPOGLYCAEMIA IN INSULIN-TREATED ADULTS IN THE UK

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1Novo Nordisk Limited, Gatwick, UK, 2Novo Nordisk Scandinavia AB, Copenhagen, Denmark, 3The Queen’s Medical Research Institute, Edinburgh, UK

OBJECTIVES: Hypoglycaemia is the main side-effect of insulin therapy and can prevent optimal diabetes management. Real-world data on the frequency and impact of non-severe (self-treated) hypoglycaemic events are scarce. Self-reported frequency of non-severe hypoglycaemic events (NSHIE), their impact on personal well-being, work productivity and health care resource use, and patient-patient communication following non-severe events, were examined in people taking insul

METHODS: Adults in the UK aged >15 years with Type 1 or insulin-treated Type 2 diabetes mellitus (T1DM or T2DM) completed ≤4 questionnaires at weekly intervals (7–day recall). Severe hypoglycaemic events (requiring external assistance) are not

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A354
reported here. RESULTS: Overall, 1,038 respondents (T1DM-466, T2DM-572) completed 528 questionnaires. Mean insulin treatment duration was 11.7 years and mean HbA1c was 8.2% (66.2 mmol/mol). Mean NHSS-week was 2.4 (T1DM) and 0.8 (T2DM), 23% (T1DM) and 26% (T2DM) occurred at night. Fatigue and reduced alertness were the common sequelae of NHSS (78% and 51% of respondents, respectively). Neither T1DM nor T2DM lasted significantly longer than effects of daytime events: T1DM-10.6 vs. 4.9 hours (p=0.0002); T2DM-15.3 vs. 5.1 hours (p=0.0001).

In the week following a NHSS, blood glucose testing increased 12% (T1DM) and 21% (T2DM). In employed respondents (47% of total), 20% of NHSS caused loss of work-time, which was longer following nocturnal NHSS: T1DM-27.2 vs. 11 hours (p=0.0184); T2DM-25.5 vs. 16 hours (p=0.1340). Over a third of employed respondents experienced difficulty concentrating at work following NHSS (T1DM-39%; T2DM-44%). Respondents contacted a health care professional (HCP) after 3% of T1DM and 7% (T2DM) of NHSS. Overall, respondents rarely or never informed HCPs about NHSS (T1DM-82%; T2DM-69%). CONCLUSIONS: NHSS are common in adults with T2DM and T1DM and cause significant interference with personal well-being, work productivity, and health care resource use. As they are seldom reported to HCPs, the burden of hypoglycaemia may be underestimated.

PATIENTS’ PREFERENCES IN ORAL DIABETES TREATMENT: A DISCRETE CHOICE EXPERIMENT IN TYP2 DIABETES MELLITUS

Mühlbacher AC, Rethe S

Hochschule Neuernburg, Neuernburg, Germany

OBJECTIVES: The aim of the empirical study is to evaluate patients’ preferences for different characteristics of treatment in type2 diabetes mellitus (T2DM). T2DM treatment is not standardized and preferences should be considered.

METHODS: Based on a qualitative and quantitative analysis a Discrete Choice Experiment (DCE) was applied to identify patient preferences. Apart from six identical attributes (adjustment of glycated hemoglobin [HbA1c], side effects of risk of genital infection, possible weight change, risk of urinary tract infection, food compatibility, and adjustment of hemoglobin A1c [HbA1c]) after 3% (T1DM) and 7% (T2DM) of NHSS. Overall, respondents rarely or never informed HCPs about NHSS (T1DM-82%; T2DM-69%). CONCLUSIONS: NHSS are common in adults with T2DM and T1DM and cause significant interference with personal well-being, work productivity, and health care resource use. As they are seldom reported to HCPs, the burden of hypoglycaemia may be underestimated.

PdB130

A DISCRETE-CHOICE EXPERIMENT IN TYPE2 DIABETES MELLITUS

PdB131

Hochschule Neuernburg, Neuernburg, Germany

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PdB131

A DISCRETE-CHOICE EXPERIMENT IN TYPE2 DIABETES MELLITUS

Mühlbacher AC, Rethe S

Hochschule Neuernburg, Neuernburg, Germany

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PdB131

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Mühlbacher AC, Rethe S

Hochschule Neuernburg, Neuernburg, Germany

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that can guarantee good diabetes management, but its control over BMI in growing children is still unclear. The insulin pumps have two major advantages: reduction in insulin requirements, reduced variability of insulin absorption, decreased hypoglycemia incidents, avoided pain, improved quality of life.

PDB135

PATIENT PREFERENCES IN TREATMENT OF DIABETES MELLITUS: A SYSTEMATIC REVIEW OF STATED PREFERENCE SURVEYS

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OBJECTIVES: Diabetes Mellitus is one of the most expensive common diseases. Because of the great socio-economic importance of this indication, it seems necessary to consider the expectations and needs of all patients with regard to treatment characteristics. To evaluate patient preferences stated-preference methods are increasingly used. The aim was to analyze and compare the available evidence from stated-preference studies regarding the treatment characteristics and to display which target criteria are most important from the patients’ view.

METHODS: A literature review in PubMed was conducted to identify stated preference studies in the indication of diabetes and show which properties of a treatment are relevant to patients.

RESULTS: N=13 studies could be included in the analysis. By calculating the level difference and performing a normalization it was possible to obtain a uniform representation of all attributes of each study. The analysis includes the presentation and analysis of DCE-studies which have illustrated the determined coefficients. The studies show that blood glucose control could be included in the analysis. By calculating the level difference and performing a normalization uniform weights for the attributes of the studies were determined. Based on a final ranking the key criteria according to their value proposition from the perspective of affected populations are demonstrated.

PDB136

PSYCHOMETRIC EVALUATION OF THE HYPOGLYCAEMIA PERSPECTIVES QUESTIONNAIRE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS


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OBJECTIVES: The Hypoglycaemia Perspectives Questionnaire (HPQ) is a patient-reported outcomes (PRO) instrument assessing diabetic patients’ experience and perceptions of hypoglycaemia. The aim of the study was to evaluate the factor structure and psychometric characteristics of the HPQ in type 2 diabetic patients (T2DM).

METHODS: HPQ was administered to adults with T2DM in a clinical sample from the United Kingdom (UK) and a community sample in the US National Health and Wellness Survey. Demographic and clinical data were collected. Participants completed the Audit of Diabetes Dependent Quality of Life (ADDQoL-19), treatment satisfaction items, and the 6-Dimensions Health Utility Index (EQ-5D) (Cyprus only). HPQ items assessed hypoglycaemia attitudes and behaviours (EQ-5D = 1). Item performance and factor structure were examined and measurement properties (reliability, construct validity, known-groups validity) evaluated.

RESULTS: Cyprus (n=550) and US (n=1,272) T2DM samples were of similar age (Cyprus 61.0±10.3 years, US 59.9±11 years). Cyprus had more males (67.4% vs. 54.2%) and fewer obese subjects (BMI ≥ 20.45%) than the US. More US subjects reported hypoglycaemia events in the past seven days (27.7% vs. 16.6% with ≥ 1 event). Prescription oral diabetes medications were used by 90.3% of Cyprus participants and 83.6% of US participants, and insulin by 32.9% and 25.3%, respectively. Analyses supported three HPQ domains: Symptom Concern (six items), Compensatory Behavior (five items), and Worry (five items). Internal consistency was high for all three domains (0.70≥), supporting reliability. Convergent validity was supported by moderate correlations between HPQ domain scores and ADDQoL-19 total score. Patients with recent hypoglycaemia events had significantly higher HPQ scores supporting known-group validity.

CONCLUSIONS: HPQ is a valid and reliable measure capturing the experience and impact of hypoglycaemia and can be useful in clinical trial and community-based settings.

PDB137

THE PREVALENCE OF HYPOGLYCAEMIA AND ITS IMPACT ON THE QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS PATIENTS IN GREECE (THE HYPO STUDY)

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1National and Kapodistrian University of Athens, Athens, Greece, 2Novartis Hellas, Athens, Greece, 3University of Nicosia, Nicosia, Cyprus, 4Hypoglycaemia (Hypo) is a common adverse effect of type 2 diabetes (T2D) therapy. Hypo has a negative impact on health care resources and quality of life (QoL) and can affect compliance and T2D control. OBJECTIVES: To estimate the impact of Hypo on the quality of life in T2D patients and to compare the prevalence of Hypo in Greece and in the United Kingdom (UK). A cross-sectional epidemiological study was conducted in 6631 patients with T2D. Hypo events with different treatment regimens, T2D control rates and QoL were assessed. Hypo episodes were defined as laboratory-confirmed (<7.0 mmol/L) symptomatic events. QoL was measured using the patient-administered ADDQoL-19 questionnaires. Diabetes control was defined as HbA1c ≥ 7%.

RESULTS: The major adverse events were male prevalence rates (55%) and overweight patients (59%) had BMI ≥ 25-29.9. 24.4% of T2D patients had a history of laboratory-confirmed hypoglycaemia. In total, 59% had HbA1c > 7%. The mean age was 60 and the mean T2D duration was 10 years. The mean Qol score of the total sample was -3.1 ± 1.9, the mean score of non-hypoglycaemic patients was -3.0 ± 2.0 and the hypoglycaemic patient's average score was -3.26 ± 1.8 (p=0.005). Similar results were observed in the group of controlled patients and uncontrolled patients, who scored -2.73 ±1.7 and -3.33 ±1.9, respectively (p<0.0005). A comparable result was identified in the ADQoL-19 instruments’ dimensions. According to the logistic regression analysis the majority of the ADDQoL-19 dimensions were significantly affected by hypoglycaemia, as well as by higher levels of HbA1C. CONCLUSIONS: The study confirmed that the QoL of Greek T2D patients is affected by hypoglycaemic events and the level of the disease control. In T2D, treatment should attain good glycemic control without debilitating hypoglycaemic episodes, which compromise patients’ QoL.

PDB138

THE IMPACT OF DAYTIME AND NON-LABORATORY S-SEVERE HYPOGLYCAEMIC EVENTS ON PEOPLE WITH DIABETES IN TURKEY

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OBJECTIVE: Two surveys were conducted to assess the impact of nocturnal and daytime hypoglycaemia on the individual and on the Turkish economy.

METHODS: People with diabetes who had experienced a non-severe hypoglycaemic event in the 4 weeks prior to the survey were eligible for inclusion. The surveys were conducted face to face, to all information, including hypoglycaemic events, was self-reported since no in the Turkish National Centre for the estimation of the questionnaire. The studies showed that blood glucose control could be included in the analysis. By calculating the level difference and performing a normalization uniform weights for the attributes of the studies were determined. Based on a final ranking the key criteria according to their value proposition from the perspective of affected populations are demonstrated.

PDB139

HEALTH RELATED QUALITY OF LIFE OUTCOMES (HRQOL) AND RESOURCE USE ASSOCIATED WITH TYPE 2 DIABETES PATIENTS TAKING STEPS TO loose weight IN 5 EUROPEAN COUNTRIES

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Evidera, Berkley, CA, USA, 2Evidera, Bethesda, MD, USA, 3Evidera, Seattle, WA, USA, 4Janssen-Cilag A/S, Birkerød, Denmark, 5Janssen-Cilag UK, High Wycombe, UK

OBJECTIVE: Weight control is a cornerstone of type 2 diabetes (T2DM) management, but the amount of lost weight and the manner in which weight is maintained on patient-reported outcomes and resource use among T2DM patients is not widely reported. This study was conducted to describe the association of weight change in T2DM patients taking steps to lose weight (T2DM StePS) with work productivity and resource use in T2DM patient and methods.

METHODS: Data came from the 2015 EU National Health and Wellness Survey, representative of adults in France, Germany, Italy, Spain and the United Kingdom. Respondents T2DM who lost ≤5 kg were compared to respondents who gained weight. Outcome measures included SF-36v2 Work Productivity & Activity Impairment Questionnaire, and 6-month self-reported health care use. Comparisons used pairwise t-tests and chi-square tests for continuous and categorical variables, respectively.

RESULTS: Of 1,985 respondents taking steps to lose weight, 61% were male, 37% were employed with mean BMI 32.3 kg/m^2. Relative to respondents who gained weight (n=354), respondents who lost ≤5 kg (n=560) had higher scores on mental component summary by 3.9 points (p<0.05), higher physical component summary by 2.3 points (p<0.05), and SF-6D health utility by 0.05 points (p<0.05). This group reported lower work and activity impairment as well as lower health care resource utilization relative to those who gained weight, with lower mean presenteeism vs. 28%, p<0.05, 4 activity impairment (54% vs. 44%, p<0.05), health care provider visits (7.8 vs. 10.2 p<0.05), emergency room visits (0.2 vs. 0.6 p<0.05) and hospitalizations (0.2 vs. 0.4 p<0.05).

CONCLUSIONS: Treatments which facilitate small to moderate weight loss may offer T2DM patients better HRQol and potentially offer savings to the health care system when compared to treatments which promote weight gain. Further research is required to explain this observation.

PDB140

Racial DISPARITIES IN TYPE 2 DIABETES HEALTH CARE UTILIZATION IN MEDICAIAD ADULTS WITH DEVELOPMENTAL DISABILITIES

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OBJECTIVE: Adults with developmental disabilities have higher prevalence of chronic diseases, and potentially lower health care resource utilization, high blood pressure and chronic pain. They also have poor health care utilization and screened less for chronic disease conditions. The objective of this study was to examine the association of race, and medication adherence, and their interaction with health care utilization and healthcare costs in Medicaid enrollees with developmental disabilities (DD) and type
2 diabetes. METHODS: This was a retrospective cohort study that identified the DD adults who were invited to participate in the 11 state health care and SDG Enrollies aged 18-64 years who received new anti-diabetic medications from January 1, 2004 and December 31, 2006 were included. An index diagnosis was assigned to each patient and adults with a continuous enrollment for at least 12 months were included. The outcome was a binary response (yes or no) to an offer of change in type 2 diabetes related health care utilization (inpatient, outpatient and emergency department visits) in DD patients. Multivariate linear regression with log- transformation was used to determine type 2 diabetes related health care and DDG enrollees. RESULTS: The study population comprised of 1529 patients. After controlling for all the covariates, compared to DD Caucasians, DD African Americans were more likely to have type diabetes related inpatient (OR=1.71; 95% CI, 1.02-2.85) and emergency department visits (OR=1.67, 95% CI, 1.02-2.73). After holding all the other covariates constant, among DD patients with type 2 diabetes, compared to Caucasians, African American patients had 23% significantly higher medication costs. In addition, higher medical costs were associated with significantly higher overall costs respectively. CONCLUSIONS: Racial disparities exist in health care utilization in DD Medicaid patients with type 2 diabetes. Access to culturally competent health care providers, providers who accept Medicaid patients and continuous care can reduce inpatient visits and emergency room visits in racial minorities.

**Diabetes/Endocrine Disorders – Health Care Use & Policy Studies**

PB144

**IS THE RULE OF HALVES APPLICABLE IN DIABETES TYPE 2? EVIDENCE FROM GREECE**

Tsiamoutou V, Karampi E, Zavras D, Athanassakis K, Pavli E, Kyriopoulos J

National School of Public Health, Athens, Greece

OBJECTIVES: The “rule of halves” (ROH) applies in most common chronic diseases to estimate the number of undiagnosed patients. This study was conducted in Greece. METHODS: Physicians who monitor patients with type 2 diabetes were invited to participate and complete an online questionnaire on their perception of the quality of life of their patients with diabetes at baseline and at the end of 6 months. RESULTS: The study population comprised of 1529 patients. After controlling for all the covariates, compared to DD Caucasians, DD African Americans had 23% significantly higher medication costs. In addition, higher medical costs were associated with significantly higher overall costs respectively. CONCLUSIONS: Racial disparities exist in health care utilization in DD Medicaid patients with type 2 diabetes. Access to culturally competent health care providers, providers who accept Medicaid patients and continuous care can reduce inpatient visits and emergency room visits in racial minorities.

**Diabetes/Endocrine Disorders – Health Care Use & Policy Studies**

PB145

**PHYSICIANS ESTIMATION REGARDING THE IMPACT OF RECESSSION ON PATIENT ADHERENCE TO TREATMENT IN DIABETES TYPE 2 IN GREECE**

Tsiamoutou V, Zavras D, Karampi E, Athanassakis K, Pavli E, Kyriopoulos J

National School of Public Health, Athens, Greece

OBJECTIVES: Adherence to treatment plan and lifestyle advice is crucial for good health outcomes in diabetic patients. The aim of the present study was to examine whether recession, austerity measures and implemented health policies had an impact on patient adherence to treatment in Diabetes type 2 (d2) in Greece. METHODS: A questionnaire was developed for the purpose of the study. Only Physicians who monitor patients with d2 (general practitioners (GP), diabetologists and endocrinology) were invited to participate in the study and complete the online version of a purpose-made questionnaire during a specified time period. Physicians were recruited through their national associations. The study took place between April and May 2014. FULLY completed questionnaires were included in the analysis. Data analysis was conducted using STATA 9. RESULTS: 176 physicians completed the questionnaire of whom 68.7% were men. Mean age was 47.8 years. The majority were internists and GPs (38.3% and 32.7%, respectively). Physicians estimated that 30% of their patients became less adherent to their treatment plan during the recession. Of those not treated, and half of those treated are not controlled. The aim of the present study was to examine whether the ROH is applicable in the case of Diabetes type 2 in Greece. METHODS: Physicians who monitor patients with type 2 diabetes were invited to participate and complete an online version of a questionnaire on their perception of the quality of life of their patients with diabetes at baseline and at the end of 6 months. RESULTS: The study population comprised of 1529 patients. After controlling for all the covariates, compared to DD Caucasians, DD African Americans had 23% significantly higher medication costs. In addition, higher medical costs were associated with significantly higher overall costs respectively. CONCLUSIONS: Racial disparities exist in health care utilization in DD Medicaid patients with type 2 diabetes. Access to culturally competent health care providers, providers who accept Medicaid patients and continuous care can reduce inpatient visits and emergency room visits in racial minorities.

**Diabetes/Endocrine Disorders – Health Care Use & Policy Studies**

PB146

**EFFECT OF A PHARMACY-BASED DIABETES MANAGEMENT PROGRAM ON GLYCEMIC CONTROL IN AN INPATIENT GENERAL MEDICAL POPULATION**

Fridl L, Sherman KM

A357
OBJECTIVES: A pharmacy-based inpatient diabetes management program was evaluated to determine if improved glycemic control could be achieved in a general medicine patient population. METHODS: A retrospective chart review of 151 patients with type 2 diabetes admitted to one of 10 inpatient medicine units between January 1, 2010 and December 31, 2010 was conducted. Exclusion criteria for the baseline group (n=84) were derived from July 2010 and for the intervention group (n=67) in October 2010. The odds of poor glycemic control for patients in the intervention group versus baseline groups were assessed by using multivariate generalized estimating equations. These methods were also used to assess patient characteristics associated with poor glycemic control. RESULTS: Across all patients, no evidence was observed indicating the pharmacy program decreased the proportion of days spent out of the targeted blood glucose range 70-180 mg/dL. OR 0.91 (95% CI: 0.83 – 1.02), 70-250 mg/dL OR 1.03 (95% CI: 0.88 – 1.24). However, the subgroup of patients whose admission blood glucose was less than 200 mg/dL (55% of intervention group) experienced a significant improvement in glycemic control for both ranges [70-180 mg/dL; OR: 0.72, 95% CI: 0.61 – 0.88] and 70-250 mg/dL [OR: 0.53, 95% CI: 0.33 – 0.71]. No improvement in glycemic control was observed in patients with an admission BG 200 mg/dL or greater. These patients had more disease- and social-related factors associated with poor glycemic control. CONCLUSIONS: A sub-population, patients whose admission glucose was less than 200 mg/dL, experienced improvement in glycemic control in the pharmacy-based program. The remaining patients were more complicated from a disease state perspective and experienced no improvement. These patients may require a more intense, multi-disciplinary approach that is better matched to the constellation of factors responsible for their condition.

**PD148**

**COST-EFFECTIVENESS OF THE INTRODUCTION OF A NATIONAL ADHERENCE PROGRAM FOR TYPE 2 DIABETES IN HUNGARY**

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OBJECTIVES: The hemoglobin A1c test (HbA1c) is the favored measure of glycemic control for patients with diabetes. Compliance to recommended timing for HbA1c testing continues to be a challenge. The current analysis evaluates how compliance with HbA1c testing varies based on initial HbA1c results. METHODS: Newly diagnosed patients and patients with diabetes were identified from the Truven Health MarketScan Lab Database (1/1/2010-10/31/2013). Continuous eligibility for the 6 months prior to study enrollment was required for study inclusion. Patient-level variables included baseline patient characteristics, history of complications, changes in physical activity, medications, social-related factors associated with poor glycemic control. Among the initial 133,011 patients who met the study inclusion criteria, approximately 40% had evidence of an initial HbA1c test at diagnosis (< 7.0%); 46% with HbA1c ≥ 7.0% (controlled) and ≥ 7.0% (uncontrolled). A total of 74,774 patients had a subsequent HbA1c test 6 months following diagnosis. Results: A total of 11,819 patients newly diagnosed with type 2 diabetes, 22% received dietary counseling and 74% achieved HbA1c control. Greater HbA1c control was associated with greater effectiveness of dietary counseling. Allocation of all newly diagnosed diabetics to dietary counseling was estimated to increase the rate of HbA1c control to 80% at a cost of $56 USD per patient at current practice. An efficiency frontier rule (counseling only the 55% of patients predicted to benefit most) achieved the same 80% control rate with an incremental cost of $6 USD per patient. CONCLUSIONS: Retrospective analysis of real-world data identified opportunities to improve diabetes care. These means are not being coordinated and used effectively. The aim of this study was to suggest a management care system of the chronically ill in the Czech Republic, which should increase the quality of medical care and decrease the costs of it. METHODS: There was chosen an analysis of the nationwide data for the management care system, which were based on analysis of the current state. The type 2 diabetes mellitus was chosen as an appropriate chronic illness and for the management care concept was chosen Patient-Centered Medical Home. The randomized selection of 100 patients was made in ordinary diabetes ambulances. The cost of illness was counted from the direct cost from the perspective of the society, of the payer and of the patient. The cost-effectiveness analysis, which was comparing a standard treatment and the Patient-Centered Medical Home, was based on randomized selection, studies of Patient-Centered Medical Home and recommended standards of professional society. There were also used methods of value engineering especially Sasty matrix and multi-criteria decision making, multi-COPEC method for setting the scales of criteria and effect. RESULTS: The average costs of one patient are from the perspective of the society 29 531 CZK, the payer 20 976 CZK and of the patient 9 196 CZK. The Patient-Centered Medical Home is more effective than standard treatment, which was based on the cost of effectiveness analysis. The payer will obtain a 25.7% of the effect for Patient-Centered Medical Home accorded a spending monetary unit. CONCLUSIONS: The costs of the chosen concept could be more effective. The concept would provide greater prevention, quality and coordinated care and can be used for other chronic diseases.
DBP152
PRESCRIPTION OF ROsiglTIAzone AND PioglitAZone FOLLOWING SAFETY WARNINGS: A COMPARATIVE ANALYSIS OF TRENDS IN DISPENSING PATTERNS IN DENMARK AND GERMANY FROM 2007 TO 2013
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OBJECTIVES: Investigate how official drug safety warnings for thiazolidinediones (Tiazolidinedione and pioglitazone) affected prescription trends for T2Ds in Denmark and Germany and to compare the prescription patterns to data published for Australia, UK, and the US. METHODS: Identified the timing and content of all drug warnings for T2Ds using the FDA's and EMAs databases. Using pharmaceutical claims data on all diabetes patients in Denmark and a large public health insurance fund in Germany, plotted the number of defined daily dosages (DDDs) per month for rosiglitazone and pioglitazone normalized per 1000 insures for both countries from January 1st - December 31st of each year. RESULTS: In Denmark, rosiglitazone monotherapies prescriptions were more prevalent in June/July 2011 in both countries. CONCLUSIONS: T2D prescriptions in Denmark and Germany did not decline as rapidly after the publication of safety warnings as in other countries. Difference in reaction time may reflect different levels of market penetration of older diabetes therapy due to the drug safety warnings and differences in the intensity of the safety warning issued by the drug administration authority.

DBP154
ASSESSING THE MEDICATION USE AMONG DIABETIC PATIENTS WITH COMORBID DISEASES
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OBJECTIVES: Type 2 Diabetes is on the rise in many Asian countries with growing economic prosperity. Treatment patterns of diabetic patients in South East Asia have rarely been studied using administrative data. Our objective was to understand medication use patterns among Malaysian patients with diabetes with comorbidities in the post 2008 period. METHODS: This study aimed to understand medication use patterns among diabetic patients with other groups, namely sulfonylureas and thiazolidinediones, it has been declining ever since on average by 2% and 15%, respectively. CONCLUSIONS: The uptake of incretin-based drugs since 2008 has been rapid and their utilization keeps rising, apparently at the expense of other drugs, namely older sulfonylurea derivatives and thiazolidinediones. Consequently, the overall public expenditure on anti-diabetic therapy has been increasing.

DBP156
NON-ADHERENCE AND NON-PERSISTENCE RELATED TO GLP-1 THERAPY IN PATIENTS WITH DIABETES MELLITUS TYPE 2 (T2DM): ANALYSIS OF A LARGE GERMAN CLAIMS-BASED DATABASE AND COMPARISON TO ORAL ANTI-DIABETICS
Wille T1, Groth A1, Berg B1, Sikirica M2, Martin AA1, Fuchs A1, Maywald U1
1JPAM - Institute for Pharmaceutics and Medication Logistics, Wismar, Germany, 2GlassSmithKline, King of Prussia, PA, USA, 3GlassSmithKline, Uxbridge, UK, 4AOK Plus, Dresden, Germany, 5AOK - Die Gesundheitskasse für Sachsen und Thüringen, Dresden, Germany

This study describes the extent of non-adherence (NA) and non-persistence (NP) with Glucagon-like peptide 1 agonists (GLP-1) and oral anti-diabetic (OAD) therapy in T2DM patients in clinical practice in Germany. METHODS: Claims data was obtained from a German sickness fund (AOK Plus) with a database including 2,490,817 T2DM patients initiating GLP-1/OAD therapy and 5,858,453 patients initiating an OAD for a study period (2007-2012). RESULTS: The NP analysis, included 2,637,798 patients initiating GLP-1/OADs. Among GLP-1 patients, 40.8/1777/155 received twice-daily (BD), exenatide/once-daily (OD, liraglutide) once-weekly (WD) injections. Average age for GLP-1 (SD 30.8/36/67 SD 12.6 years). After 12 months, the percentage of patients with NP was 38.3% (all GLP-1s), 42.6% (BD), 37.4% (OD), 27.4% (WD), and 55.8% (OAD). The NA analysis included 2,134,316 T2DM patients initiating GLP-1/OAD therapy with a follow-up prescription. Average age was 56 (SD 6.0) (SD 12.2) years. Average MPR was 88.2% (all GLP-1), 87.8% (BD), 88.2% (OD), 95.0% (WD), and 63.2% (OAD). Percentage of patients affected by NA was 21.96% (all GLP-1), 23.98% (BD), 22.00% (OD), 5.74% (OAD), and 65.8% (OAD). CONCLUSIONS: In this German dataset, overall patients with T2DM had low rates of adherence and persistence despite the chronic nature of the disease and clinical sequelae. Higher adherence and persistence rates were observed with GLP-1 than with OAD medications and also with less frequently prescribed agents.

DBP157
TYPE 2 DIABETES TREATMENT PATTERNS ACROSS EUROPE
Hostenkamp G1, Overbeek J.A2, Hall G.C3, Lapi F4, Prieto Alhammad D5, Bezemer ID2
1PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands, 2INSERM CIC Bordeaux CIC1410, Unis Bordeaux, Bordeaux, France, 3Croesylke House, London, UK, 4Genomics SRL Firenze, Italy, 5IDiAP Jordi Gol, Barcelona, Spain

OBJECTIVES: To describe the sequential treatment classes of type 2 diabetes (T2DM) patients initiating anti-diabetic drug therapy in the Netherlands, UK, Spain, Italy and France. METHODS: This study aimed to understand the treatment strategies in subgroups of patients with diabetes who tend to pose more complex challenges in clinical decision-making. METHODS: Data was obtained from diabetic patients who were audited in the NDR in 2012. Descriptive analysis was used to describe medication usage for patients with various comorbidities. Medications of interest were antplatelet medications, lipid-lowering agents, anti-hypertensive and various classes of anti-diabetic medications including insulin. RESULTS: A total of 130,270 patients were identified with comorbidities. Mean age of patients was 59.8 years old and 60.2% were female. A majority of patients were hypertensive (70.3%), more than half were dyslipidemic (55.1%). Other comorbidities such as retinopathy, ischaemia, and heart failure were also prevalent. A standard set of laboratory values, i.e. albumin, uric acid, hypertension and dyslipidemia were recorded among less than 10% of patients. Among non-diabetes medications, statins was the most commonly used ranging from 86.3% for various comorbidities. This was followed by ACE-inhibitors and aspirin. Among anti-diabetic medications, metformin was the most commonly prescribed followed by sulfonylureas and insulins. CONCLUSIONS: The registry data was able to shed light on patterns of medication use among diabetic patients with comorbidities. Perhaps in the future, these patterns will be used to evaluate long-term outcomes among patients on various treatment plans and finally to inform more evidence-based clinical management strategies relating to medication use.

DBP158
SIX YEARS OF INCRETIN-BASED AGENTS IN DIABETES 2ND TYPE TREATMENT IN THE CZECH REPUBLIC: THE UTILIZATION AND EXPENDITURE
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1General Health Insurance Company of the Czech Republic, Praha, Czech Republic, 2Charles University, Faculty of Pharmacy, Hradec Kralove, Czech Republic

OBJECTIVES: The objective was to analyze evolving consumption, public costs as the primary health care setting. This may be useful for understanding treatment strategies in subgroups of patients with diabetes who tend to pose more complex challenges in clinical decision-making. METHODS: Data was obtained from diabetic patients who were audited in the NDR in 2012. Descriptive analysis was used to describe medication usage for patients with various comorbidities. Medications of interest were antplatelet medications, lipid-lowering agents, anti-hypertensive and various classes of anti-diabetic medications including insulin. RESULTS: A total of 130,270 patients were identified with comorbidities. Mean age of patients was 59.8 years old and 60.2% were female. A majority of patients were hypertensive (70.3%), more than half were dyslipidemic (55.1%). Other comorbidities such as retinopathy, ischaemia, and heart failure were also prevalent. A standard set of laboratory values, i.e. albumin, uric acid, hypertension and dyslipidemia were recorded among less than 10% of patients. Among non-diabetes medications, statins was the most commonly used ranging from 86.3% for various comorbidities. This was followed by ACE-inhibitors and aspirin. Among anti-diabetic medications, metformin was the most commonly prescribed followed by sulfonylureas and insulins. CONCLUSIONS: The registry data was able to shed light on patterns of medication use among diabetic patients with comorbidities. Perhaps in the future, these patterns will be used to evaluate long-term outcomes among patients on various treatment plans and finally to inform more evidence-based clinical management strategies relating to medication use.

DBP159
EXPLORING THE DETERMINANTS OF ENDOCRINOLOGIST VISITS IN FRANCE
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OBJECTIVES: To describe the sequential treatment classes of type 2 diabetes (T2DM) patients initiating anti-diabetic drug therapy in the Netherlands, UK, Spain, Italy and France. METHODS: This study aimed to understand the treatment strategies in subgroups of patients with diabetes who tend to pose more complex challenges in clinical decision-making. METHODS: Data was obtained from diabetic patients who were audited in the NDR in 2012. Descriptive analysis was used to describe medication usage for patients with various comorbidities. Medications of interest were antplatelet medications, lipid-lowering agents, anti-hypertensive and various classes of anti-diabetic medications including insulin. RESULTS: A total of 130,270 patients were identified with comorbidities. Mean age of patients was 59.8 years old and 60.2% were female. A majority of patients were hypertensive (70.3%), more than half were dyslipidemic (55.1%). Other comorbidities such as retinopathy, ischaemia, and heart failure were also prevalent. A standard set of laboratory values, i.e. albumin, uric acid, hypertension and dyslipidemia were recorded among less than 10% of patients. Among non-diabetes medications, statins was the most commonly used ranging from 86.3% for various comorbidities. This was followed by ACE-inhibitors and aspirin. Among anti-diabetic medications, metformin was the most commonly prescribed followed by sulfonylureas and insulins. CONCLUSIONS: The registry data was able to shed light on patterns of medication use among diabetic patients with comorbidities. Perhaps in the future, these patterns will be used to evaluate long-term outcomes among patients on various treatment plans and finally to inform more evidence-based clinical management strategies relating to medication use.
association with the probability of seeing an endocrinologist: rates of specialist visits are a large barrier for the age group of T2D in Italy. According to patients, insulin and those with another endocrine disorder are more likely to see a specialist (p < 0.001). In contrast, the newly diagnosed and patients followed by a general practitioner (GP) present lower probabilities of specialist visits (p < 0.001). Moreover, the probability of seeing the GP varies whether the degree of endocrinologists is large in the patients’ neighbourhood, while it decreases with the distance (in kilometres) from the patients’ house to the endocrinologist’s office. Finally, the chances of seeing the GP are inversely proportional to the size of the city, with a decrease in the size of the city, the chance of seeing the GP decreases.

**Conclusions:** Our results are consistent with previous literature showing evidence of the existence of a substitution effect between GPs and specialists in diabetes care. We show that financial barriers exist even in a population of patients receiving national health insurance coverage.

**Objectives:** The relationship between resource utilisation and patient phenotype characteristics was characterised. This study evaluated potential factors associated with weight gain (WG) and the occurrence of hyperglycaemia in T2D patients managed with metformin plus sulphonylurea (M+S) and any associated impact upon hospital resource utilisation. **Methods:** The study was a retrospective, observational, cross-sectional study using 10,682 patients’ records from a large Italian Hospital Episode Statistics (HES) database. The association between potential factors at baseline (therapy escalation from metformin to M+S) with WG (≥ 2 kg weight change over 12 months) and any hypoglycaemia event occurring within 12 months following therapy escalation was assessed using logistic regression. Hospitalisation associated with increasing body mass index (BMI) and hyperglycaemia was also assessed. **Results:** A total of 11,671 patients met the study inclusion/exclusion criteria. WG was obtained in 28.3% of patients associated with baseline age (OR = 0.99), female gender (OR = 0.87), baseline weight (OR = 1.003) and Hba1c (OR = 1.06). Hyperglycaemia occurred in 1.3% of patients and was significantly associated with initiation of diabetes (OR = 1.04), baseline Hba1c (OR = 0.86) and prior complication status (OR = 1.92). Hospitalisation occurred in 10% of patients and was significantly associated with BMI (OR = 1.02) but not hyperglycaemia. The mean number of hospital admissions over the follow-up period was 1.7, 1.8, and 2.0 for patients with BMI < 25, 25–30, and >30 kg/m2, respectively. Payers believe the new kit will be an improvement over current kits, but do not expect it to significantly alter the use of insulin injectable therapy.

**PDB159**

**PAYERS’ PERCEPTIONS OF GLUCAGON KITS AIMED AT REDUCING PDB159**

receiving national health insurance coverage.

**Objective:** To assess payers’ perceptions of glucagon kits aimed at reducing severe hypoglycaemic events (SHE) in patients with type 2 diabetes (T2D). Rescue treatment for SHE includes glucagon kits, which are administered by caregivers and difficult to use. Consequently, there are high rates of unsuccessful administration, leading to increased health care service use. A new kit under development aims to ease the burden of administration by reducing the complexity of patient self-administration and the need for caregivers’ assistance, improving emergency treatment delivery. METHODS: Seven medical directors from US payers were interviewed, representing commercial, Medicare, Medicaid and other covered lives. The interview was guided by a topic guide designed to focus on treatment and hypoglycaemia, age/reimbursement of current kits, and impressions of characteristics of the new kit. RESULTS: The prevention of SHE is not a concern for insurers; the risk of SHE is considered relatively low, representing less than 1% of a payer’s diabetic population. Payers are confident in current kits’ effectiveness, they are not focused on managing access to such a low-volume treatment. Current kits are covered by insurers without restrictions, and contracting is not prevalent due to low volume. New insulin kits will be an improvement over current kits, but do not believe it will reduce the cost of SHE. CONCLUSIONS: Payers feel that the new kit will be an improvement over currently available kits, but are skeptical that the ease of use will translate into lower health care service use. Additionally, SHE is not a major cost driver among their diabetic population, therefore, SHE is not a high priority for insurers. Rescue treatment for SHE includes glucagon kits, which are administered by caregivers and difficult to use. Consequently, there are high rates of unsuccessful administration, leading to increased health care service use. A new kit under development aims to ease the burden of administration by reducing the complexity of patient self-administration and the need for caregivers’ assistance, improving emergency treatment delivery.
of underreporting of hypoglycemia in clinical hospital settings in Poland caused by DIABased financing standards. There is a need of reflecting real treatment cost in the level of reimbursement in this group of patients.

**PDB164 PATIENT SPECIFIC LANDSCAPE OF INFORMATION TECHNOLOGY SOLUTIONS FOR DIABETES SELF-MANAGEMENT**  
Xenakis J 1, Garfield S 2  
1, Dall T, Sensibility Inc, DC, USA, 2Chroniccare.org, Aiken, SC, USA  
**OBJECTIVES:** To develop a computer information retrieval system (CIS) for the registration of patients with DM and their pharmacotherapy (including financing sources) and to optimize the requirements for medicines, the CIS can be used to analyze the pharmacotherapy adherence with DM. The CIS contains information on individual pharmacotherapies that are current in the market and that are classified by type of medicines, the hospital, and practice. The CIS includes a detailed analysis of the regimen, including the dosage, type, and frequency of each medication. The CIS also provides information on the cost of each medication and the cost of the regimen. The CIS includes a detailed analysis of the regimen, including the dosage, type, and frequency of each medication. The CIS also provides information on the cost of each medication and the cost of the regimen. The CIS contains information on individual pharmacotherapies that are current in the market and that are classified by type of medicines, the hospital, and practice. The CIS includes a detailed analysis of the regimen, including the dosage, type, and frequency of each medication. The CIS also provides information on the cost of each medication and the cost of the regimen.

**METHODOLOGY:** The study aimed to examine the disparity of risk factor screening and intervention on obesity and overweight patients. The study used a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients.

**RESULTS:** The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients. The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients. The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients.

**CONCLUSIONS:** The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients. The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients. The study showed that there was a significant heterogeneity in the results of risk factor screening and intervention on obesity and overweight patients.

**PDB165 USING MODERN INFORMATION TECHNOLOGY FOR MEDICAL AND PHARMACEUTICAL CARE OF PATIENTS WITH DIABETES MELLITUS IN UKRAINE**  
Bozyna, Parnovsky B  
Dep. of Medicine, National Medical University, Lviv, Ukraine  
**OBJECTIVES:** The study aimed to examine the disparity of risk factor screening and intervention on obesity and overweight patients. The study used a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients.

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**PDB166 QUALITY OF DIABETES CARE AMONG OBESE AND OVERWEIGHT PATIENTS AT NHG POLYCINSICS**  
Ishikawa OM, Moh MPSF, Lee LJ  
National Healthcare Group, Singapore  
**OBJECTIVES:** The study aimed to examine the disparity of risk factor screening and intervention on obesity and overweight patients. The study used a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients.

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**PDB167 EFFICACY OF THE AUTOMATED TARGET GLUCOSE CONTROL: A SYSTEMATIC REVIEW**  
Yeo JS  
Institute of Health Policy and Management, South Korea  
**OBJECTIVES:** To review the literature on the efficacy of automated target glucose control in type 1 diabetes. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients. The study included a comprehensive review of the literature, a validated database, and a combination of a validated database and a comprehensive review of the literature to assess the current state of risk factor screening and intervention on obesity and overweight patients.
ritms compared to the conventional glucose control using paper-based protocols. METHODS: A systematic literature review and meta-analysis was used to evaluate the safety and effectiveness for the automated target glucose control. The 14 randomized control trials of 2537 articles were selected and two reviewers evaluated independently the quality of this selected articles using the Scottish Intercollegiate Guidelines Network (SIGN) tool. RESULTS: The computer-based insulin protocols resulted in a shorter time to reach within target range (MD -1.03, 95%CI -1.70 to -0.35, p<0.003, I²=77%) and a higher percentage of glucose readings within target range (MD 11.98, 95%CI 8.83 to 15.14, p<0.001, I²=89%) than the paper-based protocols. The incidence rates of above or below target range in computer-based insulin protocols were acceptable levels and the incidence rates of severe hypoglycemia below 40mg/dl in computer-based insulin protocol was significantly lower than the paper-based insulin protocols (MD -23.43, 95%CI -32.35 to -14.46, p<0.001, I²=0%). CONCLUSIONS: The automated target glucose control using computer-based algorithms resulted in tighter glycemic control without an increased risk of severe hypoglycemia. This is arguable whether the resources required to develop these separate submissions might be better directed towards unmet needs. In terms of relative outcomes, Given this, it is arguable whether the resources required to develop these separate submissions was essential. It would be of value for HMA organisations to develop reference cases including standard inputs for the modelling of significant conditions such as diabetes especially where there is such consistency. This would improve the comparability of analyses and reduce the costs to manufacturers and ERGs in developing and reviewing submissions respectively.

PD1873 PATIENT PREFERENCES AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN SAUDI ARABIA
Levy AR 1, Ziaee SM 2, Osenenko KM 1, Kolol RK 1, Qatami L 1, Al Jasper S 1, Saggabi A 1, Al Suwaider S 1, Maclean R 1, Donato BM 2
1College of Pharmacy, King Saud University, 2Bristol-Myers Squibb Company, Dubai, United Arab Emirate

OBJECTIVES: To identify the differences in preferences for insulin among type 2 diabetes mellitus (T2DM) patients. METHODS: A 2010 questionnaire was distributed to patients who were attending T2DM patients who attended the King Fahad National Guard Hospital from October 2009 to March 2010 (enrolment period) were systematically sampled until the total number of participants reached the sample size estimated from subject charts. Treatment regimens, their frequency of use, and the number of switches were recorded. RESULTS: Forty-four percent of patients were male; at enrolment, mean (SD) age was 61 (13) years, and mean T2DM duration was 11 (8) years. At enrolment, 42% of subjects had received prior insulin treatment (recently-diagnosed: 23%; long-standing disease: 52%). During the study period, the most common regimens were oral combination therapy (41%) and insulin-combination therapy (32%). Overall, 44% received any insulin therapy during the study period (recently-diagnosed: 23%, long-standing disease: 45%). By end of study, 49% had received any prior insulin therapy (recently-diagnosed: 29%; long-standing disease: 58%). On average, T2DM subjects had 1.3 treatment switches over the period, little variation was seen by T2DM duration. The frequency of insulin treatment was lower than expected in this region, treatment switches are indicative of attempts to improve T2DM control. Novel therapies may improve clinical outcomes and reduce the costs to manufacturers and ERGs in developing and reviewing submissions respectively.

PD1874 USE OF SELF-MONITORING OF BLOOD GLUCOSE (SMBG) BY DIABETES THERAPY TYPE IN INDIA
Mast Q 1, Tan A 2, Punjabi K 3
1Kochi Diagnostics, Diabetes Care, Mannheim, Germany, 2Coendu Strategic Data, Singapore, 3Coendu Strategic Data, Mumbai, India

OBJECTIVES: SMBG is a core component of diabetes therapy, supporting a safe and effective diabetes therapy and providing feedback on the impact of diet and lifestyle. In 2016, NICE monitoring was conducted to assess this impact. It aims to assess the level of SMBG usage in patients by diabetes therapies. METHODS: Source data for this explorative analysis is the PDS Diabetes survey covering drug treated patients with diabetes. All 2,250 cases were documented in the 2nd half of 2013. PDS Diabetes is a syndicated research with a fixed representative panel of doctors from larger Indian cities using a standardized documentation of cases. SMBG usage is analyzed by therapeudic subgroups: oral diabetes therapy (OAD 75%), basal supported oral therapy (BOT 9%), conventional insulin therapy (CT 8%), intensive insulin therapy (ITT 5%) and others (3%, excluded). RESULTS: Diabetes type 2: 95%, 1,180 patients (52.4%) have a meter for home-testing. Sharing meters by therapists (OAD 40%, BOT 54% and ITT 62%) should be reduced. In CT patients the difference in SMBG usage is 1.9% (patients with SMBG use in CT 8%), intensive insulin therapy (ITT 5%) and others (3%, excluded). CONCLUSIONS: Many patients in this sample do not achieve HbA1c targets and many do not test their blood glucose. Below in 1 patients follows the recommended test frequency. In ITT SMBG is needed to support insulin dosing adjustments: below 1 in 50 test enough. In CT patients the differences in HbA1c between testers and non-testers are largest. Lacking benefit in ITT treated patients may indicate the insufficiency of current testing. The new guideline might help to close these gaps.
significance difference in the efficacy and safety in nucleos(t)ide-naive CHB patients with HBV DNA greater than 6 log10IU in the medial center.

PGI2

EFFECTIVENESS OF PROBIOTICS IN IRITABLE BOWEL SYNDROME: A SYSTEMATIC REVIEW WITH META-ANALYSIS

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OBJECTIVES: To investigate the efficacy of probiotics in irritable bowel syndrome (IBS) patients. This meta-analysis was performed.

METHODS: The collected data contained twenty-four clinical trials which fifteen were eligible for meta-analysis and nine were reviewed systematically. All studies were randomized placebo-controlled trials in patients with IBS that investigated IBS improvement. Trials were evaluated with Relative Risk (RR) with 95% confidence interval (95% CI). Cochran Q test was used to test heterogeneity with P value 0.05 (P<0.05). The rest of the analyses used in this meta-analysis were as publication bias indicators.

RESULTS: Probiotics reduced pain severity, symptom severity score and induced adequate general symptom improvement. Distension, bloating, and flatulence were not improved after probiotic treatment when compared to placebo. This meta-analysis assessed the beneficial efficacy of probiotics compared with placebo in IBS patients.

PGI3

ESTABLISHMENT OF A HEPATITIS C VIRUS (HCV) COHORT IN A LARGE ISRAELI HMO

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OBJECTIVES: Hepatitis C virus (HCV) affects an estimated 130 million people worldwide and is a major cause of chronic liver disease. Real-world data is needed to better understand the epidemiology of HCV and its complications, as well as treatment patterns and outcomes. One of the objectives of this study is to establish a cohort of HCV carriers in a large health maintenance organization, with comprehensive data on treatment and disease outcomes.

METHODS: The HCV cohort will use data available since 1998 from the computerized databases of Maccabi Healthcare Services, the second largest HMO in Israel, with approximately 2 million members. HCV cases are included based on diagnostic codes (ICD-9-CM), laboratory data (e.g. detection of HCV antibodies and RNA) and dispensed prescriptions for HCV treatment. The cohort includes demographic data (age, sex, immigration and socioeconomic status), clinical data (e.g. BMI, comorbidities), treatment patterns, virological outcomes, and HCV complications – including cirrhosis, hepatocellular carcinoma, liver transplants, and mortality.

RESULTS: At the end of 2012, HCV infection was identified among 10,648 patients starting treatment with BOC+PR and who received at least one dose of BOC in three phase 3 clinical trials (PN05101, PN5216 and PN5514) were included. The outcomes of interest were the number of patients based on risk factors.

CONCLUSIONS: This was the first dataset that could be used to evaluate real-world data on HCV complications from GI tracts between January 2011 and December 2012 were extracted from the HDB which holds about 1.8 million peoples' claims data under employment-based health insurance. In order to identify upper and lower GI tract and outcomes, we periodically updated to follow up existing patients and identify incident HCV cases. For example, future studies can examine the adherence and efficacy of treatments, and associations between HCV and chronic diseases such as chronic kidney disease.

PGI4

THE INCIDENCE OF UPPER AND LOWER GASTROINTESTINAL COMPLICATIONS: A RETROSPECTIVE STUDY USING A JAPANESE HEALTH CARE DATABASE

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OBJECTIVES: The objective of this study was to investigate the incidence of complications (bleeding and perforation) with hospitalization from both upper and lower GI tract in Japanese population using a health care claims database (HDB).

METHODS: All of the claims data of the patients who have a history of hospitalization due to complications from GI tracts between January 2011 and December 2012 were extracted from the HDB which holds about 1.8 million peoples' claims data under employment-based health insurance. In order to identify upper and lower GI events precisely, we confirmed them when a diagnosis of a GI event in the claims (ICD-10 code) was accompanied by a record of examination and/or endoscopic or surgical treatment relevant to upper and lower GI complications. RESULTS: The total number of person-years at risk was 1.2 million person-years in 2012. The incidence rates in upper and lower GI events were 48 and 41 per 100,000 person-years, respectively. Twenty-one percent of the lower events originated in bleeding from hemorrhoid or related treatments (e.g. hemorrhoidectomy). Age-group analyses in the upper vs. lower events, except those from hemorrhoid, were 27 vs. 17, 57 vs. 46 and 184 vs. 104 per 100,000 person-years in 20-39, 40-59, and 60+ years groups, respectively. Data from 2011 were consistent with these observations on the ratio of upper to lower GI events and the age-based incidence remained in the same range of the previous study. This meta-analysis assessed the incidence of GI events in Japan using a single large data source. We confirmed that a number of GI events occurred in both upper and lower GI tract and the incidence rates of both events were increased with age in a real world setting.

PGI5

ASSOCIATIONS BETWEEN CROHNS DISEASE SEVERITY AND SPECIFIC SOCIO–DEMOGRAPHIC, QUALITY-OF-LIFE AND COPING FACTORS

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OBJECTIVES: To study possible associations and assess the impact of socio-demographic, quality-of-life and coping factors on the severity of Crohn’s disease patients in Israel.

METHODS: Consecutive Crohn’s disease patients undergoing clinical follow-up at the inflammatory bowel clinic of the Department of Gastroenterology at Assaf Harovel Medical Center were included in this retrospective study. This included 100 patients with Crohn’s disease for whom we had data on disease severity, quality of life, and coping strategies.

RESULTS: In a cohort of 100 patients, only 11 (11%) were employed. Patients with a lower quality of life had a worse disease severity (p<0.05), and a lower quality of life was associated with a higher stress score (p=0.01). In a linear regression model, only quality of life, impact score, and coping style were significant predictors (p<0.01). CONCLUSIONS: Quality of life and coping style are significantly associated with disease severity in Crohn’s disease patients. Further studies are needed to investigate the impact of these factors on disease severity.
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PG18 BUDGET IMPACT ANALYSIS OF BIOSIMILAR INFlixIMAB FOR THE TREATMENT OF CROHN’S DISEASE IN SIX CENTRAL EASTERN EUROPEAN COUNTRIES
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OBJECTIVES: Infliximab (CT-P13) is the first licensed biosimilar in EU for Crohn’s disease (CD). It is expected that spread of biosimilars in the treatment of CD will lead to cost savings and it might improve access to biological therapies. The main aim of this study was to analyse the budget impact of introducing biosimilar infliximab for the treatment of CD in six Central Eastern European (CEE) countries – Bulgaria, Czech Republic, Hungary, Poland, Romania and Slovenia – health care systems. METHODS: This budget impact model estimates potential impact of biosimilar infliximab on health care budget over three-year timeframe from third-party payer perspective. Spreadsheet-based country specific population model was developed functioning in quarter year time units. The model tracked movement of CD cases in CEE countries (ICD-10 code K51.5) and cost of infliximab 2mg/0.5ml, adalimumab. Switching between biologics and biosimilar infliximab was taken into consideration as well. In scenario analyses different rates of interchanging and switching were analysed. A 25% price difference was assumed for biosimilar infliximab compared to originator. Budget impact was calculated as difference in total cost of scenarios with and without biosimilar infliximab. RESULTS: In 2013, 4,625 CD patients were treated with biologics in the CEE. Over the 3-year period with gradually interchanging 80% of infliximab to biosimilar infliximab was expected to lead to a net benefit of 16,635,000 euros compared to the scenario in which biosimilar infliximab would not be available. In scenarios where inter-changeability was disallowed the budget savings amounted to 7,842,000 euros. If budget impact were to be based on reimbursement of national biosimilar infliximab treatments, approximately further 889 or 420 patients could be treated in the six countries, respectively. CONCLUSIONS: Introduction of biosimilar infliximab treatment in CEE countries could lead to substantial cost savings or increase of the number of patients with access to biological therapy.

PG19 PROTON PUMP INHIBITORS IN SOUTH AFRICA: ROLE OF BRANDED GENERICS
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OBJECTIVES: Original products dominate the market, and as soon as patents expire prescribing patterns change as branded generics become the most often prescribed due to mandatory generic substitution in South Africa. This study investigated the prescribing patterns of proton pump inhibitors (PPIs) in South Africa. METHODS: A retrospective, cross-sectional drug utilisation study was conducted on prescription data of a medical insurance scheme administrator in South Africa for 2011. The database contained 2,981,312 records for medicine, medical devices and procedures. Objectives: Total PPI prescription costs were identified, extracted and considered as directly related to CHC corresponding to CHC complications are important. These estimated hospital-related costs during these periods were added up and a mean annual cost per patient per treatment and cirrhosis, the average cost per patient was around 78% higher than the general cirrhosis patient.

PG11 BURDEN OF HOSPITALIZATIONS RELATED TO CHRONIC HEPATITIS C IN FRANCE: EVOLUTION BETWEEN 2009 AND 2012
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OBJECTIVES: To assess the burden of hospitalizations related to Chronic Hepatitis C (CHC) in France in 2012 and to benchmark it to the 2009 estimate. METHODS: All hospital stays with chronic hepatitis C (ICD-10 code K70.3) and possibly significantly associated diagnosis were extracted from the FMSI 2012 (French Medical Information System Program) database. Through an algorithm and a medical review, hospitalizations related not to CHC were excluded. Patients were assigned to one of 3 major facts were highlighted: the decline in the number of liver biopsies, the decrease in the number of patients hospitalized for cirrhosis and the increase in patients hospitalized for hepatocellular carcinoma. This increase might be due to an improvement in screening techniques and aging of the population.

PG12 MEAN ANNUAL COST OF PATIENTS HOSPITALIZED FOR CHRONIC HEPATITIS C IN FRANCE: THE HEP-CONE STUDY
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OBJECTIVES: To assess the mean annual costs of patients hospitalized for Chronic Hepatitis C (CHC) in France stratified by liver disease stage. METHODS: Patients hospitalized for chronic viral hepatitis C (ICD-10 code B18.2) were identified in the FMSI-MCO 2010-2012 database (French Medical Information System Program – Medical, Surgery, Obstetrics) between January 1st 2010 and December 31st 2012 and stratified by liver disease stage (F0-F4). RESULTS: The mean annual cost per patient was 9,285 euros in 2010 and 8,081 in 2011. The economic burden of OIC remains under-reported.

PG13 DIRECT HEALTH CARE COSTS ASSOCIATED WITH OPIOID-INDUCED CONSTIPATION
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OBJECTIVES: Opioid-induced constipation (OIC) is the most common and distressing side effect associated with the diagnosis and management of OIC, however, the economic burden of OIC remains under-reported. METHODS: This review considered the cost of illness associated with OIC. A targeted literature review was conducted for all publications since 2000 that evaluated the economic burden of OIC. RESULTS: Sixteen studies were included that reported direct health care costs associated with OIC. All studies reported increased direct costs related to OIC, however, estimates per country varied significantly. Direct health care costs specifically related to OIC ranged from $67 to $295 per patient per year.
from $1,747 to $48,782 per patient year. Per patient episode, direct costs associated with OIC ranged from $54 to $13,705. This was further supported by a large international study which reported significantly more patient visits and alternative care provider visits among patients with OIC than those without OIC. Two studies reported on a subgroup of patients with OIC who failed to respond to laxatives; these patients reported higher direct costs than patients who had a response to laxatives. CONCLUSIONS: The management of IBS-C is associated with potentially significant health care resource utilisation and financial burden. Patients with OIC incur higher direct health care costs than those without OIC and costs are increased further if patients with OIC have failed to respond to laxatives. There remains a paucity of data on health care resource utilisation in OIC and further research into the economic burden of OIC is needed.

PG114 ECONOMIC AND QUALITY-OF-LIFE BURDEN OF MODERATE-TO-SEVERE IBSS CONSTIPATION SYNDROME WITH CONSTITUTION (IBS-C) IN SPAIN: THE IBSC STUDY

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OBJECTIVES: This is the first study to assess the burden of IBS-C in 6 European countries (France, Germany, Italy, Spain, Sweden, UK). Here we present the results for Spain. METHODS: Observational, retrospective-prospective (6 months each) study in patients diagnosed with moderate-to-severe IBS-C in the last five years (Rome-III criteria). Moderate-to-severe IBS-C was defined as IBS-Symptom Score (IBS-SSS) ≥ 175. Quality-of-life (QoL) was assessed with EuroQol (EQ-5D) and IBS Quality of Life (IBS-QoL). RESULTS: 2 patients were included (58% severely, mean age (±SD): 46.8±13.7 years, 86% female). At baseline, symptom severity (IBS-SSS; severe >300) was 315±48.29; presenteeism (WPAI: IBS-C questionnaire; mean ±SD )% time in week year; absenteeism: 6.1±15.8; work productivity loss: 29.2±7.7; and daily activity impairment 39.2±7.2. Mean IBS-QoL was 41.0±21.1 (scale: 0-100 [best-to-worst]), and the most affected domains were “food avoidance” (mean [CI]: 94.4±9.8 [94.1-95.0] Most complaints were sensory (92%); and 86% and 63% of patients reported moderate-to-severe problems in pain/discomfort, anxiety/depression respectively. The most prevalent symptoms were: constipation (84%), abdominal pain (80%), abdominal distension (80%) and bloating (78%). Conclusions: Results show, 88% of patients reported moderate-to-severe problems in pain/discomfort, anxiety/depression respectively. The most prevalent symptoms were: constipation (84%), abdominal pain (80%), abdominal distension (80%) and bloating (78%).

PG115 HOSPITALIZATION COSTS ASSOCIATED WITH LIVER CIRRHOSIS

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OBJECTIVES: The burden and cost of liver disease is known to be substantial, but accu- rate data is still scarce in Portugal. We aimed to estimate the most economic costs from diagnosis-related groups (DRGs) associated with hospital financing and from expert panels. In this analysis we aimed to calculate the real costs associated with hospital admissions due to liver cirrhosis (LC) in a large hospital. METHODS: All hospitalizations in the gastroenterology department from a tertiary hospital in Portugal (Centro Hospitalar Lisboa Central) during 2012 were analyzed. Patient level data was used to retrieve relevant demographic and clinical information. Costs assumed to be specific for LC admissions, namely medication, imaging and other techniques, were estimated directly. Department-specific hospital accounting was used to include the remaining hospital costs associated with these hospitalizations. RESULTS: A total of 644 admissions were analyzed, from which 135 (21.0%) were due to LC, corresponding to 82 patients. 74.4% (n=61) were males, median age was 55 years. The main cause of LC was alcohol (58.5%). In the admissions due to LC, average length of stay (LoS) was 15.3 days and total mean hospitalization cost was 3,979.5. For all analyses, average LoS and mean total costs were 8.1 days and 2,323.8, respectively. Average cost for medications in admissions for AC amounted to 492.7, compared to 228.7 for all admissions. Within admissions for LC, costs were not significantly different for admission to hospital with or without hepatocellular carcinoma. CONCLUSIONS: The estimated overall cost of a hospital admission for LC in a gastroenterology department was superior to the average value of hospitalizations for all causes, and approximately twice the official DRG value. This study highlights the considerable economic burden of liver cirrhosis in Portugal and the possible need to revise some of the assumptions used for financing Portuguese hospitals.

PG116 THE COST OF IRREGULAR BOWEL SYNDROME (IBS) IN ENGLAND

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OBJECTIVES: The NHS is faced with increasing cost pressures that make the ef- ficient use of resources paramount. Patients with IBS may consume considerable NHS resources through inpatient and outpatient visits, diagnostic tests and treatment. This study aimed to estimate admission costs and primary care prescribing costs associated with the treatment of IBS in England. METHODS: Hospital Episode Statistics (HES) data for 2012-13 for all clinical commissioning groups (CCG)s in England were analysed to calculate the tariff cost of IBS. IBS diagnosis codes were included in the analysis. Prescribing data and cost (PACT) data for 2012-13 were also analysed. RESULTS: During 2012-13 there were 1,217,993 outpatient appoint- ments for gastroenterology surgery; the mean cost of surgery was £365,868,937. Despite this, only 1,982 patients were recorded with IBS-specific codes, with a total estimated tariff cost of £812,336. In addition, 28,849 patients were recorded with IBS-related symptom codes at a cost of £11,002,874. There were also 658,698 diagnostic lower GI endoscopies at a tariff cost of £609,676,704. Of these, 323,732 (49%) had no further follow-up in secondary care in the subsequent 12 months. PACT data indicated that £44,977,959 and £25,582,752 was spent on selective laser, rectus and anteroliposuction, respectively, commonly used to treat IBS in primary care. CONCLUSIONS: Despite being poorly clinically coded, it is clear that IBS places a significant cost burden on the NHS. Notably, 49% of patients seen for lower GI endoscopy had no further follow-up. In the subsequent 12 months, follow-up may be beneficial to reduce symptoms, further investigation of IBS in primary care setting may provide direct savings in the cost of IBS management. This study demonstrates that patients with IBS-C observed may be due to the under-registration or under-diagnosis of IBS-C. Costs associated with the management of IBS-C are driven mainly by the high number of patients which may be associated with the current unmet medical needs in IBS-C.

PG117 A COST OF CARE MODEL FOR INFLAMMATORY BOWEL DISEASE WITH A UK NSH PERSPECTIVE

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OBJECTIVES: There is an estimated 620,000 patients with inflammatory bowel disease (IBD) in the UK. The burden of IBD and its complications has significant cost implications, with the National IBD Audit estimating that cost to the National Health Service (NHS) exceeded £1 billion in 2010. The aim of this cost of care model was to estimate the total annual direct cost of inflammatory bowel disease (IBD) (eg. UC and Crohn’s disease (CD) from an NHS perspective, and to enable areas of potential cost savings to be explored. METHODS: The cost of IBD was calculated by summing the costs of treatment, treatment side effects and disease-related com- plications, and losses of work productivity. RESULTS: Estimated total annual costs of patients receiving each treatment, and the percentage of patients experiencing side effects or complications were determined from national sources and published literature. However, the model permitted the user to input local or alternative data e.g. drug cost, diagnostic tests. An example cost of care model was calculated for patients with inflammatory bowel disease (IBD) (eg. UC and Crohn’s disease (CD) from an NHS perspective, and to enable areas of potential cost savings to be explored. RESULTS: The cost of IBD was calculated by summing the costs of treatment, treatment side effects and disease-related complications, and losses of work productivity. CONCLUSIONS: IBD is a costly, chronic condition and this model facilitates calculation of the annual costs per IBD patient. The model’s customisability will help hospitals to identify areas where savings could be made.
OBJECTIVES: To estimate health care costs of alternative therapeutic strategies: no treatment, interferon and ribavirin (IFN-rib) versus prucalopride. A Markov model was developed to simulate the natural course and treatment of the disease. Patient-level satisfaction data from mimicked clinical trials was used to determine health states: 'Not Satisfied', 'Moderately Satisfied', 'Satisfied', and 'Dead'. These data were linked to utility scores based on patient responses to the EuroQol-5D questionnaire. Transitions between health states were assumed to occur every 4 weeks, with probabilities derived from observed efficacy data up to the end of therapy or beyond (if skipping therapy). The Markov model assessed intervention costs and expected health outcomes over a 24-week time horizon. The model compared treatment with interferon and ribavirin (combination therapy, C) to interferon plus prucalopride (IFN+C-P). Sensitivity analyses were performed to assess the robustness of the results. The analysis was conducted from a societal perspective, and the results were adjusted for the Swedish healthcare setting. In summary, the findings suggest that combination therapy with prucalopride offers significant cost savings compared to traditional treatment options, thereby improving patient outcomes without compromising quality of life. These findings can inform healthcare decision-making and resource allocation in the treatment of chronic HCV. The study highlights the importance of considering both efficacy and cost-effectiveness in treatment decisions, as the results indicated a lower cost per QALY compared to traditional approaches.

PG20 LUBIPROSTONE IN CHRONIC IDIOPATHIC CONSTIPATION: A COST-EFFECTIVENESS ANALYSIS

MethOds: A cost-effectiveness study was conducted using a Markov model. The model tracked patients through predefined health states, with transition probabilities and costs assigned to each state. Utilities were estimated based on patient-reported outcomes. The model was calibrated using data from the randomized controlled trials (RCTs) comparing lubiprostone to placebo. Cost-effectiveness ratios were calculated as the incremental cost per QALY gained, compared to the comparator strategy. Sensitivity analyses were performed to assess the robustness of the results.

ConclusiOns: The results showed that treatment with lubiprostone was associated with higher costs but also higher quality-adjusted life years (QALYs). The cost-effectiveness ratio (CER) was found to be lower than the threshold of £20,000 per QALY, indicating that lubiprostone is a potentially cost-effective treatment for chronic idiopathic constipation. The findings suggest that lubiprostone may be a preferred treatment option, especially in cases where symptom relief and improved quality of life are prioritized, despite the higher immediate costs.

PG21 COST-EFFECTIVENESS ANALYSIS OF A PERSONALIZED THERAPY FOR GENOTYPE 1, NAIVE, CHRONIC HEPATITIS C PATIENTS IN ITALY

MethOds: A Markov model was developed to simulate the natural history of chronic hepatitis C, including the progression of the disease and the outcomes of different treatment strategies. The model was calibrated using data from clinical trials and registries, and the costs and utilities were estimated from published sources. One-way sensitivity analyses were performed to assess the robustness of the results. The analysis was conducted from the perspective of the Italian National Health Service.

ConclusiOns: The findings suggest that personalized therapy, which takes into account the specific characteristics of each patient, may be more cost-effective than current standard treatments. The results support the implementation of personalized therapy strategies in Italy, as they offer a balance between efficacy and cost-effectiveness, potentially leading to improved health outcomes at a lower cost.

PG22 COST-EFFECTIVENESS ANALYSIS OF A PERSONALIZED THERAPY FOR GENOTYPE 1, NAIVE, CHRONIC HEPATITIS C PATIENTS IN ITALY

MethOds: A decision-analytic model was developed to compare the effectiveness and costs of different treatment strategies for chronic hepatitis C in Italy. The model was calibrated using data from clinical trials and registries, and the costs and utilities were estimated from published sources. Sensitivity analyses were performed to assess the robustness of the results. The analysis was conducted from the perspective of the Italian National Health Service.

ConclusiOns: The findings suggest that personalized therapy, which takes into account the specific characteristics of each patient, may be more cost-effective than current standard treatments. The results support the implementation of personalized therapy strategies in Italy, as they offer a balance between efficacy and cost-effectiveness, potentially leading to improved health outcomes at a lower cost.
LY was calculated. Sensitivity analyses were performed. RESULTS: Model results for treatment-experienced patients showed that SMV is the dominant treatment compared to TVR+PR+BOC+PR therapies as more total LYs are saved and less costs accrued. ICER of SMV+PR vs PR was €22,967 per LY. Results were robust in sensitivity analyses. CONCLUSIONS: SMV + PR is cost-effective compared to dual PR therapy and is an option for patients with genotype-1 infection, who had severe fibrosis and were treated with triple therapy regardless of the degree of liver fibrosis, in locations where a delay in the access to newer therapies is foreseen and hepatic transplant would not be readily available. Regardless of the degree of liver fibrosis, in locations where a delay in the access to newer therapies is foreseen and hepatic transplant would not be readily available.

**Objective:** The current scenario of the hepatitis C virus genotype 1 with severe fibrosis under “real-life” conditions is not well-defined. A well-defined prospective study is needed to confirm the value of the parameters used and to test the model.

**Methods:** A Markov model was developed. The model simulates the progression of HCV-cirrhosis or HCV-HCC patients from the time of listing until death considering the risk of HCV recurrence post-transplant. The model compared 2 different strategies: 1) SOF/RBV up to a maximum of 24 weeks or until OLT if performed before the 24th week, 2) No antiviral treatment. The model estimated the costs related to the treatment with SOF/RBV, the costs associated to each health state, the life-years (LYs), the quality-adjusted life-years (QALYs), and the incremental cost-effectiveness ratio (ICER) expressed as € per QALY gained. The analysis was performed from the Italian National Health Service perspective with a lifetime horizon and one-year cycles.

**Results:** Future costs and benefits under the untreated scenario were discounted at 3% per year.

**Conclusions:** The base case analysis of the ICER for 24 weeks of SOF/RBV was €30,518 per QALY gained in HCV-cirrhosis patients and €4,610 in HCV-HCC patients. The model is associated with bias due to direct way sensitivity-analysis and by the cost-effectiveness acceptability curve. Further, SOF/RBV cost-effectiveness was clearly sensitive to the duration of treatment; assuming 24 weeks SOF/RBV treatment duration, the ICER decreased to €19,317 in HCV-cirrhosis and €29,540 in HCV-HCC.

**Conclusions:** Our study shows that treating patients with HCV-cirrhosis or HCV-HCC listed for transplant with SOF/RBV is cost-effective and may become the new standard of care for these patients. However, a well-defined prospective study is needed to confirm the value of the parameters assumed in the model and the results.
A systematic review

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OBJECTIVES: To conduct a cost-utility analysis of sofosbuvir for genotype 2 chronic hepatitis C virus (HCV) infection in Japan. METHODS: The Markov-model, “Sofosbuvir: cost-effectiveness model” which was constructed originally for similar study in UK, was modified and used for this analysis, while imputed data were replaced with Japanese data, as far as possible. Various health state, such as non-cirrhotic hepatitis, sustained virological response (SVR), compensated cirrhosis, decompensated cirrhosis and hepatocellular carcinoma were incorporated to the model. Analyses were conducted for 4 scenarios, classified by treatment history (naive/experienced) and eligibility for interferon. Peg-interferon alpha with ribavirin was assumed as the standard therapy for patients who were interferon-naive. In case the patient was selected for those who were not eligible for interferon. Probability of SVR was derived from clinical trials conducted in Japan. Other transition probabilities and utility scores of each health state were obtained from published data in Japan. Cost data for interferon-alpha and ribavirin were derived from national drug tariff (2014). For sofosbuvir, average European price was adopted since it was not yet approved in Japan. Other cost data, such as costs related to health states, were mainly obtained from claim data, provided by JMDC (Japan Medical Data Center). Time-horizon was set to lifetime. Costs and outcomes were discounted with 2% per annum, according to Japanese guideline. RESULTS: For interferon-unsuitable patients, sofosbuvir was dominant to no-treatment. Sofosbuvir would save overall costs of JPY 1,260,000 and prolonged 6.3 QALY for treatment-naive patients. It would save JPY 837,000 and prolonged 6.08 QALY for treat-ment experienced group, For interferon-suitable patients, sofosbuvir would increase overall costs of JPY 500,000 and prolonged 2.36 QALY for treatment-naive, it would increase JPY1,551,000 and prolonged 2.36QALY for treatment-experienced. CONCLUSIONS: JPY 7,140,000 and JPY 657,000 per QALY gained, respectively. CONCLUSIONS: Sofosbuvir was considered to be cost-effective for treatment of genotype 2 HCV patients in Japan.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PG34

ADHERENCE RATES FOR PEGINTERFERON + RIBAVIRIN COMPARED WITH TELAPREVIR + PEGINTERFERON + RIBAVIRIN IN MEDICARE AND COMMERCIAL PATIENTS TREATED FOR CHRONIC HEPATITIS C

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OBJECTIVES: To conduct a Markov modeling study to estimate the utility scores for diarrheal children aged under 5 years and their caregivers and to identify the influencing factors which affected the QoL. METHODS: Among HCV patients with graft failure and recurrence of HCV.

Waiting list, increased use of sub-optimal organs and reluctance to re-transplant in the 1990s. The overall aim of this study was to estimate the current cost of liver transplant for patients with HCV and HBV in the UK. METHODS: Historical sum-mary data from the original cohort study were updated to reflect current unit costs and prices. RESULTS: There have been some significant changes in clinical practice since the original study such as change in standard immunosup-pressant therapy, more patients with co-morbidities being placed on the transplant waiting list, increased use of sub-optimal organs and reluctance to re-transplant in patients with graft failure and recurrence of HCV.
caregivers. RESULTS: 468 children and caregivers were included in this study. Mean child age was 7.1 years. The caregiver’s utility and children’s utility were 0.604 (95% CI: 0.592, 0.615) and 0.618 (95% CI: 0.606, 0.629), respectively. Mainly domains of diarrheal children were affected as pain/discomfort and anxiety/depression similarly to their caregivers. On multivariate regression analysis, factors which affected the child’s utility were OIC status (β = 0.032, SE = 0.023) and OIC status (β = 0.032, SE = 0.023) were the only significant predictors of change in utility score (p < 0.05, and p < 0.05, respectively). Further univariate analyses examined the effect of OIC status in patient subgroups that had different experiences of laxative treatment. OIC status had an increased and meaningful impact on patients who had previously responded inadequately to laxatives. CONCLUSIONS: OIC status is a significant factor on the impact of treatment on patient’s utility. Furthermore the impact of OIC status is increased in patients who had previously responded inadequately to laxatives.

PG135
MAPPING MAY CAUSE STRAINING: THE INCONSISTENT RELATIONSHIP BETWEEN A DISEASE-SPECIFIC QUESTIONNAIRE (PAC-QOL) AND EQ-5D MAPPING IN CONSTIPATION
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OBJECTIVES: In current double-blind, placebo-controlled clinical study with lubiprostone in opioid-induced constipation (OIC), OBD-1033, included the EQ-5D generic quality-of-life instrument, and the PAC-QOL, a constipation-specific disease measure. This study calculated utility values for patients with OIC using the direct mapping method, and compared the resulting utilities to those calculated from a published mapping formula between the PAC-QOL and EQ-5D that was derived in chronic idiopathic constipation (CIC) [35]. METHODS: EQ-5D scores from OBD-1033 were converted to utilities using the EQ-5D UK value set. These were compared with utilities generated with the published mapping algorithm. Following this step, an attempt was made to map the PAC-QOL to the EQ-5D in OIC. The root mean square error (RMSE), adjusted R², and predicted/observed plots were used to assess the quality of mappings. RESULTS: Patients in OBD-1033 had low utility values at baseline: mean = 0.45 (Standard Deviation 0.3, n = 439). Using the published algorithm, the predicted mean utility was much higher: 0.74. This led to a high RMSE (0.43), indicating a poor fit to the data. Replicating the mapping using OBD-1033 PAC-QOL and EQ-5D data showed the PAC-QOL, although correlated with the EQ-5D, had a poor predictive value (RMSE = 0.31, R² = 0.60). High utilities were underestimated and low utilities overestimated. CONCLUSIONS: Mapping algorithms are a vital tool for generating utility values when none are available. However, the relationship derived between constants should be assessed cautiously. Mappings with the same instruments may not be reliable if crossing disease areas — even if the symptoms experienced by patients appear similar. Data show patients in OBD-1033 entered the study with poorer health status than those in the chronic constipation mapping (utility of 0.45 vs 0.81), likely due to comorbid conditions (the reason for opioid prescribing). This led to a different relationship between the PAC-QOL and EQ-5D, compared to the previous estimate. This is a potential comparison between the health-related quality of life reported by the general population and by patients with major liver diseases.PG136
A COMPARISON BETWEEN THE HEALTH-RELATED QUALITY OF LIFE REPORTED BY THE GENERAL POPULATION AND BY PATIENTS WITH MAJOR LIVER DISEASES
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OBJECTIVES: the impact of liver diseases (LDs) on health-related quality of life (HRQoL) is an important aspect to understand the burden of these conditions and improve their management. A well characterized impact of the major LDs on HRQoL of the general population is still lacking. The aim of our study was to fill this gap. METHODS: A dataset with HRQoL data of a representative sample of the general population of most populated Italian region was matched with the dataset from a multicenter study conducted in the same region and time period to generate and validate a set of health care outcomes indicators for the major LDs (hepatitis B [HBV], hepatitis C [HCV], compensated cirrhosis [CC], decompen-sated cirrhosis [DC], hepatocellular carcinoma [HCC], autoimmune hepatitis [AIH], primary biliary cirrhosis [PBC], primary sclerosing cholangitis [PSC], NAFLD/ NASH). By the General population and by patients with major liver diseases. RESULTS: A total of 6,800 “healthy subjects” and 3,105 subjects with comorbidities were included in the analyses. Multivariate simulation analysis showed that HBV, HCC, and AIH had significantly (p = 0.05) higher risk to have problems in mobility, self-care, and usual activities compared to “healthy subjects”. AIH had significantly higher risk to have mobility problems in self-care, while HBV and NAFLD/NASH in anxiety/depression. Similar results were obtained with the Tobit model performed using VAS and Utility-index. DC, HCC, AIH and LIT reported the highest decrease in VAS and Utility score. CONCLUSIONS: HRQoL decreased by the impact of major LDs on the patients’ HRQoL compared to the general population, and therefore is a key tool for decision-making in care delivery for liver diseases.
PGI41
SHOULD COST-EFFECTIVENESS ANALYSIS INCLUDE THE COST OF CONSUMPTION ACTIVITIES? AN EMPIRICAL INVESTIGATION
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OBJECTIVES: There has been a debate on whether cost-effectiveness analysis should consider the cost of consumption and leisure time activities when using the quality-adjusted life-year as a measure of health outcomes from a societal perspective. The purpose of this study was to investigate whether the costs of illness on consumptive activities are spontaneously considered in a health state valuation exercise and how much this matters.
METHODS: The survey enrolled patients with inflammatory bowel disease in Germany. Patients (n = 38) were randomly assigned to explicit or no explicit instruction for the consideration of consumptive activities? An Empirical Investigation
Frankfurt, Germany
PGI42
PATIENTS WITH INFLAMMATORY BOWEL DISEASE (IBD) TREATED WITH TPN: AN ANALYSIS OF COSTS AND UTILIZATION OF TOTAL PARENTERAL NUTRITION IN A SOUTH INDIAN TERTIARY CARE HOSPITAL
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1PGI42
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OBJECTIVES: To investigate the health technology-related costs of Italian inflammatory bowel disease (IBD) centers dealing with Crohn’s disease (CD).
METHODS: Following the hospital standpoint, a questionnaire-supported cost description was performed on a convenience sample of 38 Italian IBD centers participating in the ongoing Survey on Quality Of Life in Crohn’s Patients (SOLID). Consistently with their average useful life, a 5-year straight-line depreciation approach was adopted for calculating the yearly cost for each health technology. Cost description was undertaken after considering an undifferentiated center as an undefined one stratifying them according to their complexity (number of beds for inwards and day-hospital; personnel dedicated to CD patients; number of cross-border CD patients; availability of dedicated areas for biological drugs administration; feasibility of electronic patient forms).
RESULTS: Data were analyzed using SPSS ® version 20.0.
A total of 120 patients were considered to be appropriate indications and rest inappropriate. From an economic viewpoint, the mean cost of IBD treatment is estimated at €24,277.90. High complexity centers report the highest mean costs of treatment at €25,880.38 (€27,706.90), whereas the lowest mean yearly cost of treatment at €11,413 (€0) refers to the unique moderate complexity center.

PGI43
GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI44
A HEALTH TECHNOLOGY-RELATED COST DESCRIPTION CONCERNING ITALIAN IBD CENTRES DEALING WITH CROHN’S DISEASE: RESULTS FROM SOLE STUDY
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OBJECTIVES: To investigate the health technology-related costs of Italian inflammatory bowel disease (IBD) centers dealing with Crohn’s disease (CD).
METHODS: Following the hospital standpoint, a questionnaire-supported cost description was performed on a convenience sample of 38 Italian IBD centers participating in the ongoing Survey on Quality Of Life in Crohn’s Patients (SOLID). Consistently with their average useful life, a 5-year straight-line depreciation approach was adopted for calculating the yearly cost for each health technology. Cost description was undertaken after considering an undifferentiated center as an undefined one stratifying them according to their complexity (number of beds for inwards and day-hospital; personnel dedicated to CD patients; number of cross-border CD patients; availability of dedicated areas for biological drugs administration; feasibility of electronic patient forms).
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A total of 120 patients were considered to be appropriate indications and rest inappropriate. From an economic viewpoint, the mean cost of IBD treatment is estimated at €24,277.90. High complexity centers report the highest mean costs of treatment at €25,880.38 (€27,706.90), whereas the lowest mean yearly cost of treatment at €11,413 (€0) refers to the unique moderate complexity center.

PGI45
DIAGNOSIS AND MANAGEMENT OF MODERATE-TO-SEVERE IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN SPAIN: THE IBS-C STUDY

PGI46
REAL WORLD STUDIES USING JAPANESE ADMINISTRATIVE DATABASES: CHRONIC HEPATITIS C TREATMENT PATTERN AND RESOURCE USE

VALUE IN HEALTH 17 (2014) A323–A686
effective treatments in HCV genotype-1 patients, have failed to provide more extensive therapeutic benefit. It is expected that SOF will be used in a large percentage of patients (estimated at up to 40% in the large Phase III trial) as a result of the lack of effective interferon-free therapies. The high efficacy and tolerability of SOF make it a very promising treatment option for the management of HCV genotype-1 patients, particularly in combination with other antiviral agents.

**Conclusion:** The results of the Phase III trial and the data from ongoing studies suggest that SOF is a highly effective and well-tolerated treatment option for HCV genotype-1 patients. The combination of SOF with other antiviral agents has shown promising results in the treatment of chronic hepatitis C. Further research is needed to evaluate the long-term effects and safety of SOF, as well as its role in the management of other HCV genotypes and co-infections.
tion (6-month ER visits and hospitalizations). Comparisons in each of these health-related outcomes were between respondents with IBS-C vs. non-IBS-C, IBS-D, asthma, migraine, and RA. Comparisons controlled for age and genders. RESULTS: Prevalence of IBS-C was 0.67%, 1.03%, and 0.91% in the US, UK, and France, respectively. Most respondents were female (>65%) and mean age ranged from 47.7 to 49.8 years. In each country, mean SF-12 physical (PCS) and mental (MCS) summary scores were statistically (<0.001) and clinically meaningfully (> 0.2) lower than the non-FGID group. With few exceptions, PCS and MCS scores of IBS-C were significantly (<0.05) lowered compared to non-FGID and, with few exceptions, lower than asthma, migraine, and RA. Lastly, in each country the number of ER and hospital visits was significantly higher (P<0.001) for IBS-C compared to non-FGID and, with few exceptions, higher than asthma, migraine, and RA. CONCLUSIONS: In the three countries respondents with IBS-C showed significant and clinically meaningful deficits in HRQoL and work productivity and compared to non-FGID and, with few exceptions, higher than asthma, migraine, and RA.

PGIS 3
ASSESSMENT OF SERIAL TRANSVERSE ENTEROPLASTY: SYSTEMATIC REVIEW

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OBJECTIVES: The purpose of this study was to evaluate the safety and effectiveness of serial transverse enteroplasty (STEP). METHODS: The clinical utility of STEP was first reviewed in three textbooks and secondly the safety and the effectiveness of the STEP were assessed based on a systematic review. 575 articles were searched using keywords (SG, STEP, medical endoscopy, medical nutrition, enteroplasty, and enterostomy) in OVID-MEDLINE, Ovid-EMBASE, and Ovid-Cochrane Library and then evaluated and validated according to inclusion/exclusion criteria, duplicate search results. Finally, 9 articles (2 cohort studied and 7 case studies) were used. Two evaluators performed independent searches and validated each paper. RESULTS: Although the SIGN's tool and the grade of recommendation were selected. RESULTS: A review of the textbooks revealed that STEP is conducted on patients with refractory SBS. And the sign can scores for asthma, migraine, and RA. Lastly, in each country the number of ER and hospital visits was significantly higher for IBS-C compared to non-FGID and, with few exceptions, higher than asthma, migraine, and RA.

PGIS 4
PRESCRIBING PATTERN OF DRUGS FOR ULCERATIVE COLITIS IN JAPAN

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OBJECTIVES: Ulcerative colitis is one of 56 designated diseases for the Specified Disease Treatment Research Program that pays medical care costs for patients based on the severity and recovery rate in 9 articles. There was a trend toward a decreased rate of FN after STEP as a result, the 33~56% patients who underwent STEP were weaned off within one year and 83~98% after one year. Survival was 83% with maximum follow-up of 68 months. CONCLUSIONS: The safety of STEP was at an acceptable level compared to conventional colonoscopies in studies generally occur after an intestinal operations and such problems can be corrected surgically. The clinical utility of STEP was described in the textbooks as a non-transplantation procedure and all the selected articles were reported on wean-off parenteral nutrition. Therefore, there is evidence for the safety and effectiveness of STEP performed on patients with refractory short bowel syndrome for promoting enteral nutrition (Recommendation grade C).

PGIS 5
PATIENTS DIAGNOSTIC THERAPEUTIC PATHWAYS FOR HCV PATIENTS IN ITALY: IMPACT OF HEPATITIS INFECTION ON TREATMENT AND GUIDELINES

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OBJECTIVES: The aim of this study is to describe the differences in Patients Diagnostic Therapeutic Pathways (PDTA) among Italian Regions, as the Italian scenario of HCV is influenced in terms of Region guidelines, organization and allocated budget. METHODS: The Regional policies were examined analyzing the PDTAs of the most representative Regions. The analysis investigates the following Regional choices: establishment of a working group to define the PDTA, overcoming the gap of criteria for prescribing centers with the AISL guidelines, indication of therapeutic scheme for the different kind of patients, budget allocation, characteristics of the management model and existence of a follow up system. RESULTS: The results of the study show that, besides some common characteristics observed in all Regions (e.g. the presence of working group and criteria for the eligibility of patients and identification of prescribing centers), there is a substantial heterogeneous Regional guidelines, especially regarding budget allocation, management model and follow up system. Indeed, in some Regions like Basilicata and Veneto there is a specific budget allocation (respectively €1.2 m and €1.2 m in 2014), the management model is based on Hub and Spoke system and the follow up mechanism is different. The conclusions, including in Region. In 17 days in Veneto and 147 days in Emilia Romagna) and the number of prescribing centers per million inhabitants (6,92 in Basilicata and 1,85 in Veneto). CONCLUSIONS: The study demonstrate that, with a view to the future novel drugs, a common disease model for the CHC diagnosis. Furthermore, IFN treatment completion rate are low. One of the main causes of these facts would be adverse effects associated with IFN treatment. New drugs with fewer adverse effects are awaited for the future.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS 1
IMPACT OF APREMILAST ON PHYSICAL FUNCTION OVER 52 WEEKS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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OBJECTIVES: The PALACE studies compared the efficacy and safety of apremilast (APR) with placebo in patients with active psoriatic arthritis (PsA) despite prior conventional disease-modifying antirheumatic drugs and/or biologics. The objective was to assess the impact of APR on physical functioning in patients enrolled in the PALACE trials. METHODS: The pooled analysis included data from PALACE 1,3, three 52-week, randomized, placebo-controlled studies evaluating APR in subjects with active PsA. Patients were randomized (1:1:1) to placebo, APR 20 mg BID (APR20), or APR 30 mg BID (APR30). Patients with <20% reduction from baseline in swollen and tender joint counts at Week 16 were required to be re-randomized (1:1:1) to APR20 or APR30 if initially randomized to placebo, or continued their initial APR dose. At Week 24, all remaining placebo patients were re-randomized to APR20 or APR30. The analysis reports data from the APR-exposure period (Weeks 0 to 52). Physical function, a pre-specified secondary end point, was measured using the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the 36-item Short-Form Health version 2 Physical Functioning (PF) domain and physical component summary (PCS) scores. RESULTS: At Week 16, the observed physical function change from baseline was improved with APR20 and APR30 vs. placebo, as measured by the HAQ-DI [0.17 (P<0.001) and -0.23 [P<0.001] vs. -0.07, FF (2.73 [P<0.001] and 4.08 [P<0.001] vs. 1.52), and PCS (3.44 [P<0.001] and 4.46 [P<0.001] vs. 2.03). At Week 52, among patients who were administered with APR continuously, the physical function change from baseline for APR20 and APR30 was improved, as measured by the HAQ-DI [-0.30 and -0.33, FF (5.55 and 5.53), and PCS (6.37 and 6.23). CONCLUSIONS: Patients treated with APR30 reported improvement in physical function compared with placebo, as measured by the HAQ-DI, FF, and PCS. This response was maintained over 52 weeks.

PMS 2
WORK PRODUCTIVITY IMPROVEMENT ASSOCIATED WITH APREMILAST, AN ORAL PHOSPHODIESTERASE 4 INHIBITOR, IN PATIENTS WITH PSORIATIC ARTHRITIS RESPONSES OF A PHASE 3, RANDOMIZED, DOUBLE-BLIND, CONTROLLED TRIAL

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OBJECTIVES: The Work Limitations Questionnaire (WLQ) measures the degree to which work activities are experienced as limiting, as well as health-related productivity loss. The PALACE 1 study compared the efficacy and safety of apremilast (APR) with placebo in patients with active psoriatic arthritis (PsA) despite prior or concurrent conventional disease-modifying antirheumatic drug (DMARD) therapy and/or prior biologic therapy. The objective of this analysis was to assess the effect of APR on the work productivity of employed patients in PALACE 1. METHODS: Patients were randomized (1:1:1) to receive placebo, APR 20 mg BID (APR20), or APR 40 mg BID (APR40). The subjective part of the analysis was assessed at Week 16 based on the intent-to-treat population. Employed patients completed the WLQ at baseline and Week 16. Work limitations were categorized into 4 domains, which were then used to calculate the WLQ index: physical domain (PDS), mental domain (MDS), time management demands (TMS), and output demands (ODS). Improvement in the WLQ index, and its 4 domains, is represented by a negative change from baseline. Improvement in work productivity represents a positive improvement in percentage of productivity loss. RESULTS: 504 patients were randomized (mean age 50.4 years; male: 49.4%). Of these, 261 were employed and completed at least 1 component of the WLQ were analyzed. At Week 16, APR20 and APR40, vs. placebo, were associated with a statistically significant 12-14% improvement in percentage of productivity loss (18.9% and 24.7% vs. -3.7%). CONCLUSIONS: APR20 and APR40 increased work productivity among patients with active PsA.

PM5 Relative Efficacy and Safety of Ustekinumab Compared to Anti-TNF-Alpha Therapies in Patients with Active Psoriatic Arthritis

OBJECTIVES: Assess the relative efficacy and safety of ustekinumab compared to biologics (bTNF) therapies in patients with active psoriatic arthritis (PsA). Methods: Randomized, placebo-controlled, at least 24-week-long, pivotal studies were searched in PubMed and EMBASE databases. Patients, participating in these trials, had active psoriatic arthritis. They were treated with DMARD and/or NSAID therapies and had not received any biological treatment before. Meta-analysis was based on ACR20, ACR50, ACR70, PASI75, HAQ-DI, AE and SAE endpoints. The quality assessment of evidences was based on EUnetHTA guidelines. For the application of the evaluation Atek’s method was used, while the meta-analysis used frequentist approach. The mean and the 95% confidence interval of odd ratios (OR) were estimated using the Mantel-Haenszel test and with the fixed effect method. Statistical homogeneity of studies was tested using the Chi-squared test and the I² test. Any NMA not correcting for baseline risk might result in biased results. After adjusting for differences in baseline risk between the trials, two studies were included in sensitivity analyses. Anti-TNF-alpha therapies had significantly better results on primary and accentuated secondary endpoints (ACR20 week 24 - ustekinumab vs. placebo: OR=2.56 (95%CI=1.74, 3.74); anti-TNF-alfa vs. placebo: OR=0.53 (95%CI=0.29, 0.91); golimumab vs. placebo: OR=3.46 (95%CI=1.94, 6.17); anti-TNF-alpha vs. placebo: OR=14.21 (95%CI=8.01, 25.23)). On the other secondary endpoints the differences were not significant, however results have shown a reduced number of adverse events for anti-TNF-alpha treatment against ustekinumab. During the safety comparisons we did not find a substantial difference between these treatments. CONCLUSIONS: Based on our evaluation the anti-TNF-alpha treatment appears more effective than ustekinumab in the first line biologic treatment of psoriatic arthritis.

PM6 Drug Usage Analysis and Health Care Resources Consumption in Patients with Rheumatoid Arthritis

OBJECTIVES: To determine the mechanisms of resource utilization in rheumatoid arthritis (RA), biological drugs have been developed, when insufficient response is observed, the initial dosage could be increased (dose escalation). The aim of the study was to assess dose escalation, among different biologic therapies, with the impact of chronic RA management on health-care resource use. METHODS: An observational retrospective cohort analysis based on 3 Local Health Units administrative databases was conducted. Patients who filled at least one prescription for biologic agents with a diagnosis of RA between 01/01/2009-31/12/2011 (enrollment period) were included and followed up for 12 months and characterized on the basis of the previous 12 months. Dose escalation and cost of illness were calculated on naïve patients (patients with no prior prescriptions of the index biologic), dose escalation was defined as having ≥2 consecutive claims with an average weekly dose 130% greater than the initial average weekly dose. RESULTS: 594 patients were analyzed, female: male ratio: 3:1, age 54±14. Biological at index date were Etanercept (39%), Adalimumab (25%), Infliximab (14%), Abatacept (10%), Tocilizumab (9%), Golimumab (3%). Naïve patients to index biologic were 293 (49%); among them, dose escalation was observed in 21.4 patients on Infliximab, 11.5 Adalimumab, 5.6 Abatacept, 4.0 Tocilizumab, 3.8 Etanercept. Hospitalized patients with RA as main discharge diagnosis were 96% Infliximab, 6.7% Golimumab, 6.6% Adalimumab, 2.9% Tocilizumab, 2.8% Etanercept, 2.4% Abatacept. Overall, 95% of cost of illness was driven by biologics, 2% traditional DMARDs, 3% non-pharmacological costs; annual cost of illness was €13,622 for Golimumab, €12,803 Adalimumab, €11,924 Etanercept, €11,830 Tocilizumab, €11,201 Infliximab, €10,943 Abatacept. Dose escalation was associated with a higher expenditure for biological (€12,048 vs. €11,232, p=0.023) and no difference on other costs (€464 VS €566, p=0.349).

CONCLUSIONS: Among patients with RA, Abatacept was associated to a lower cost of illness and hospitalization ratio, due to a low dose escalation rate.

PM7 Comparative Effectiveness of Biological Agents with Non-Response to TNF-Inhibiting Drugs for Methotrexate Failure

OBJECTIVES: Recently biological agents with a mechanism of action targeting the pathogens of rheumatoid arthritis (RA) have emerged as an important treatment. Especially, as anti-TNF (anti-tumor necrosis factor antagonist) drugs are effective...
for patients who do not respond to traditional disease modifying anti-rheumatic drugs (DMARDs). This study aimed to compare the efficacy of biological agents with traditional DMARDs for methotrexate (MTX) treatment failure patients. METHODS: Four DMARDs (hydroxychloroquine, sulfasalazine, methotrexate, leflunomide) and five anti-TNF drugs (adalimumab, etanercept, golimumab, infliximab, certolizumab) were randomly selected in expert consensus. Systematic reviews were performed including MEDLINE, EMBASE and Cochrane Library. Among the identified 52 systematic reviews, 3 systematic reviews were finally included from July 2010. Data extraction and methodological quality assessment using Cochrane Risk of Bias was performed in pairs. Comparative efficacy was analyzed using Bayesian mixed treatment comparison (MTC). RESULTS: A total of 85 trials from 7,938 citations were included. Nineteen trials were grouped as MTX failure patients (mean age: 52.9 years, mean of rheumatoid factor positivity: 76.6%). Nine studies were included in the analysis of Health Assessment Questionnaire (HAQ). The best treatment was certolizumab combined with MTX (MTX: 0.4±0.5 vs. MTX: 2.7±6.1). For comparative effects on ACR 70, the best treatment was certolizumab combination with MTX (OR: 10.66; 95% CI: 3.6±24.41) in 11 versus 5 trials. The best treatment was golimumab combined with MTX (OR: 17.53; 95% CI: 15.6±29.8) in 11 versus 5 trials. The best treatment was golimumab combined with MTX (OR: 17.53; 95% CI: 15.6±29.8) in 11 versus 5 trials. The best treatment was certolizumab combined with MTX (OR: 28.5±6.2) in 11 versus 5 trials. The best treatment was certolizumab combined with MTX (OR: 28.5±6.2) in 11 versus 5 trials.

PMSS1
QUALITY OF LIFE ASSESSMENTS IN KOREAN PATIENTS WITH RHEUMATOID ARTHRITIS (RA): AN ANALYSIS FROM THE PHASE III TRIAL TO EVALUATE EQUIVALENCE OF THE ETANERCEPT BIOSIMILAR HD203 AND ENBREL® IN COMBINATION WITH METHOTREXITE (MTX) IN PATIENTS WITH RA; THE HERA STUDY
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OBJECTIVES: Quality of Life (Qol) is important for patients with RA and Enbrel® has demonstrated Qol benefits in this patient group. HD203 is an etanercept biosimilar which reported pharmacokinetic bioequivalence to the reference product Enbrel® in a Phase III trial (NCT01803931). This study recently demonstrated comparable safety in a phase III randomized trial in Korean patients with RA. Assessing Qol was a secondary objective of the HERA study, the results of which are reported here. METHODS: Patients (male or female aged ≥20 years) with active RA were randomized (1:1) to mg HD203 or Enbrel®, administered subcutaneously twice weekly with MTX for 48 weeks. Qol assessments (Short Form 36, SF-36; Functional Assessment of Chronic Illness Therapy–Fatigue, FACIT-F; EuroQol-5 dimension, EQ5D) were performed at weeks 12, 24 and 48 of therapy, and Week 24 and Week 48. Qol comparisons between Groups A and B at Week 24 and Week 48 were compared. RESULTS: Of the 17 patients randomized (147 to HD203, 147 to Enbrel®). There was no significant difference between groups on Qol assessments at baseline. Qol assessments were similar for HD203 and Enbrel® at week 24 and 48 overall. However, SF-36 Role Emotional and Bodily Pain subscales showed significant improvement in favour of HD203 at week 24 (p=0.07) and week 48 (p=0.004) respectively. No significant difference was observed between HD203 and Enbrel® for FACIT-F scores at week 24 or 48, except at week 48, where the Emotional Role subscale was improved with Enbrel® vs. HD203 (p=0.019). No significant differences between groups in EQ5D scores were observed at any time. CONCLUSIONS: Together with previous reports on equivalent pharmacokinetics and comparable safety, these data support the biosimilarity of HD203 vs. Enbrel®.

PMSS2
COMPARISON OF DISEASE STATUS AND OUTCOMES OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING ADAILUMAB OR ETANERCEPT MONOTHERAPY IN EUROPE
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OBJECTIVES: To compare the disease status and outcomes of patients with RA receiving adalimumab and etanercept monotherapy in Europe. METHODS: A multi-country, multi-center medical chart-review study of RA patients was conducted among rheumatologists in UK/ France/Germany/Ireland/Italy/Spain to collect demographic data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30 yrs) and patient volume (incl. >5 RA biologic patients/month) and recruited from a large panel to ensure geographical representativeness in each country. Eligible patient charts (>2 yrs) were randomly selected and updated to July 2013. Data extraction and methodological quality assessment using Cochrane Risk of Bias was performed in pairs. Comparative efficacy was analyzed using Bayesian mixed treatment comparison (MTC). RESULTS: Patients were patients (mean age: 52.9 years, mean of rheumatoid factor positivity: 76.6%). Nine studies were included in the analysis of Health Assessment Questionnaire (HAQ). The best treatment was certolizumab combined with MTX (MTX: 0.4±0.5 vs. MTX: 2.7±6.1). For comparative effects on ACR 70, the best treatment was certolizumab combination with MTX (OR: 10.66; 95% CI: 3.6±24.41) in 11 versus 5 trials. The best treatment was golimumab combined with MTX (OR: 17.53; 95% CI: 15.6±29.8) in 11 versus 5 trials. The best treatment was certolizumab combined with MTX (OR: 28.5±6.2) in 11 versus 5 trials. The best treatment was certolizumab combined with MTX (OR: 28.5±6.2) in 11 versus 5 trials.

PMSS3
USING HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX TO ESTIMATE EQ-SD UTILITY VALUES FOR PATIENTS WITH RHEUMATOID ARTHRITIS IN TAIWAN
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OBJECTIVES: This study aims to provide estimates of EQ-SD as a function of Health Assessment Questionnaire – Disability Index (HAQ-DI) scores in patients with rheumatoid arthritis (RA). METHODS: Frequency-based D-EQ (utility) values were used to identify ACR 70 responders on a total of 140 patients aged between 30 and 70 years old were recruited from the rheumatologist outpatient clinics of four hospitals located in northern, central, and southern Taiwan during June 2013-May 2014. The severity distribution of patients was mild RA (Activity Score Index (ASI) 2, Disease Activity Score 28 (DAS28) <3.2 (N=57), moderate RA (3.2< DAS28<5.1, N=44), and severe RA (DAS28>5.1) (N=39). Socio-demographic and clinical information were collected, and the HAQ-DI and the EQ-SD questionnaires were completed. Generalized linear regression models were used to predict EQ-SD utility values as functions of HAQ-DI scores, age, and gender. RESULTS: Patient mean age was 50.8 years old (standard deviation [SD], 11.3 years). 81.4% of the patients were women and mean disease duration was 9.65 years (SD, 6.84 years). HAQ-DI <0.5, 5% (0.5%); HAQ-DI<1.4, 16% (1.1%); HAQ-DI<1.6, 5% (9.7%); ... HAQ-DI >2, 12%, and HAQ-DI>2.1, 4%. HAQ-DI and EQ-SD mean scores were 12.01 (SD, 7.8) and 0.67 (SD, 0.34), respectively. The models were able to predict actual EQ-SD across the range of the HAQ-DI. Age and gender were found to be significant determinants in estimating the utility functions. CONCLUSIONS: Utility values have very often not been assessed in the data collection process in a clinical trial. This study showed that HAQ-DI scores can be used to derive EQ-SD utility values for patients with RA in Taiwan to facilitate conducting a cost-utility analysis.

PMSS4
REAL RATE IN A 1,910 FRESH FRUITS TREATED WITH LOW-INTENSITY PULSED ULTRASOUND (LIPUS)
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OBJECTIVES: Patient age is one of many potential risk factors for fracture occurrence. We hypothesized that age and sex is a factor for women in particular. Patients aged 60 years or older are an important target group for fracture prevention programs. METHODS: A LIPUS device was approved in 1994 to accelerate fresh fracture healing, though the FDA required a Food and Drug Administration (FDA) market clearance and a 510k clearance. Samples were collected from October 1993 until October 1998 and were reviewed and
validated by a registered nurse. We required 4 data elements to report a patient: date when treatment ended and outcome (healed vs. failed, by clinical and radiological criteria). Data were used to calculate: days to treatment (DTT), and days on treatment (DOT). All fresh fractures with DTT, DOT, and outcome are reported. RESULTS: 7,765 patients in the registry. For the year in question, fractures were lost to follow-up: 11% withdrew or were noncompliant, and 3% died or are missing outcome. Among compliant patients, HR was 96.2%. Logistic estimates of the odds ratio for healing are significant for patients aged 30-79 years. Nevertheless, patients who failed treatment were 4.5 years older than patients who healed (p < 0.0009). DTT was significantly shorter for patients who healed (p < 0.0001). Data show that obesity, smoking, diabetes, vascular insufficiency, osteoporosis, cancer, rheumatoid arthritis, and chronic use of NSAIDs reduce HR. CONCLUSIONS: HR mitigates the effect of age on fracture HR. Patients who used LPS had a 96% HR, whereas the expected HR averages 93%. Time to treatment was significantly shorter among patients who healed (p < 0.0001), consistent with increased market uptake scenarios, the total budgetary savings were $0.23 million. In the latter comparison setting, the cost savings were attributed to reduced drug and administration costs. More specifically, the greater replacement of an intravenously administered TNF-α inhibitor (adalimumab) reduced to the greatest reduction in IMU injection costs than in the former comparison setting (cost savings: $0.17 vs. $0.14 million). CONCLUSIONS: A potential increased use of CZP treatment was shown to be associated with cost savings over the next 5 years in Greece. 

PMS15 BUDGET IMPACT ANALYSIS OF CERTOLIZUMAB PEGOL IN THE MANAGEMENT OF PATIENTS WITH MODERATE-TO-SEVERE ACTIVE RHEUMATOID ARTHRITIS IN GREECE

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OBJECTIVES: To investigate the budgetary impact of increasing the patient share of cost. CERTOLIZUMAB PEGOL (CZP) versus the other recommended biologic disease modifying anti-rheumatic drug (DMARDs); etanercept, adalimumab, golimumab, infliximab, abatacept, tocilizumab) for the treatment of moderate-to-severe active rheumatoid arthritis (RA) in Greece. METHODS: A Markov model was developed to simulate the long-term clinical and cost-effectiveness consequences of an increased market uptake of CZP in the Greek health care market, were estimated and individually compared to the current market trend scenario, which incorporates original biologics erosion from biosimilar entry in the coming year. Costs pertaining to drug acquisition, administration (only for intravenous drugs), and monitoring were included in the analysis and corresponded to 2014 costing year. Officially published sources were used to derive unit costs. The outcome measures were the annual cost of treatment of patients presented as total cost and disaggregated by drug cost, administration cost and monitoring cost, as well as the incremental cost savings per year. RESULTS: Comparing CZP current versus conservative market uptake scenarios, the total budget was decreased by approx. 0.1% ($0.01 million). Once cost versus increased market uptake scenarios, the total budgetary savings were $0.23 million. In the latter comparison setting, the cost savings were attributed to reduced drug and administration costs. More specifically, the greater replacement of an intravenously administered TNF-α inhibitor (adalimumab) reduced to the greatest reduction in IMU injection costs than in the former comparison setting (cost savings: $0.17 vs. $0.14 million). CONCLUSIONS: A potential increased use of CZP treatment was shown to be associated with cost savings over the next 5 years in Greece.
OBJECTIVES: Lumbar spinal stenosis (LSS) occurs as a degeneration of the spine in aging populations. Treatment options comprise surgical and non-surgical interventions. The aim of this study was to compare annual costs between LSS patients treated with instrumental spinal surgery (ISS) and those non-surgically treated.

METHODS: A retrospective claims data analysis was conducted using anonymized claims data from the Health Risk Institute research database. The study period comprised the period between January 2009 to 31 December 2010. A total of 4,915 patients receiving an ISS were compared to an age and gender matched non-operated control group with comparable disease state. Patients were identified by ICD-10-GM code M48.0” in the inpatient setting. Costs for reoperations were calculated based on group comparison of patients with reoperation and those without reoperation (control group). Existing differences in cost levels in the year before the primary ISS were adjusted by the difference in differences approach.

RESULTS: Annual costs for reoperations were calculated based on group comparison of patients with reoperation and those without reoperation (control group). The study aims to estimate the incidence and costs of osteoporotic fractures in general population. The results showed that the average annual incidence of osteoporotic fractures was 40% (scenario 1). The increase in hip fractures ranged from 60% (scenario 3) to 79% (scenario 2). In 2010 approximately 200 million Euros was spend on treatment of osteoporotic fractures. The costs for osteoporotic fractures increased with 50% from 2010 till 2030 (scenario 1). The increase in costs for hip fractures was highest, ranging from 60% (scenario 1) to 148% (scenario 3&4 combined).

CONCLUSIONS: The expected high increase in incidence and costs of osteoporotic fractures calls for a wider use of prevention and treatment options.

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PmS19 COST PER RESPONDER OF APREMILAST VERSUS ETANERCEPT AND ADAHILUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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OBJECTIVES: The purpose of this study was to estimate the annual and cost per responder for psoriatic arthritis (PsA) patients treated with apremilast, etanercept, and adalimumab in adults with PsA in the United States. METHODS: Comparative efficacy data were obtained from a Bayesian network meta-analysis of biologic and non-biologic disease-modifying antirheumatic drugs as of October 2013. The primary outcome was ACR20 response at Week 24. Response rate differences in treatment arms were assessed using a Bayesian analysis. Costs were attributed to US wholesale acquisition cost as of June 2014 and approved labeled dosing were used to derive drug treatment costs. RESULTS: At Week 24, the adjusted ACR20 response rate was 40.3% for apremilast, 53.4% for etanercept, and 57.8% for adalimumab. The cost per ACR20 responder at Week 24 was $25,562 for apremilast, $30,346 for etanercept, and $25,978 for adalimumab. By Week 52, the cost per ACR20 responder was $53,704 for apremilast, $65,750 for etanercept, and $56,273 for adalimumab. The annual cost to achieve 100 responders was $5,370,387 for apremilast, $6,574,981 for etanercept, and $5,627,380 for adalimumab. The rate was 40.3% for apremilast, 53.4% for etanercept, and 57.8% for adalimumab.

CONCLUSIONS: Of all registered fractures 32% could be attributed to osteoporosis. In women this percentage was larger than in men (36 versus 21%). This resulted in an incidence for all osteoporotic fractures of 964 per 100,000 women and 245 per 100,000 in men for 2010. Over time (2010-2030) the overall increase in incidence of osteoporotic fractures was 40% (scenario 1). The increase in hip fractures ranged from 60% (scenario 3) to 79% (scenario 2). In 2010 approximately 200 million Euros was spend on treatment of osteoporotic fractures. The costs for osteoporotic fractures increased with 50% from 2010 till 2030 (scenario 1). The increase in costs for hip fractures was highest, ranging from 60% (scenario 3) to 148% (scenario 3&4 combined).

PmS20 DIRECT NON-MEDICAL COSTS OF RHEUMATOID ARTHRITIS BY DISEASE LEVEL IN PORTUGAL

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OBJECTIVES: Direct non-medical costs may be difficult to assess, so these are often disregarded in cost-of-illness studies. This analysis aims to estimate the annual direct non-medical costs of treating a patient with Rheumatoid Arthritis (RA) in Portugal, per level of disease activity. METHODS: Patients with RA followed by 5 different rheumatologists across the country, were asked to participate in a survey, and informed consent was given by all patients. Besides socio-economic data, the survey included questions regarding the following cost components: number of medical appointments and treatments attended by the patient and its associated medical cost, number of hospitalisations and their associated medical cost, number of days tied up resources. This study aimed to estimate the total costs of AS, including the indirect burden of AS patients in Hungary and to obtain an overview of the SHI perspective. As demonstrated elsewhere, these cost might be partly avoidable by using intra-operative 3-D imaging with navigation.

.PmS21 CLAIMS DATA ANALYSIS ON THE ANNUAL FREQUENCY AND INCREMENTAL COSTS OF REOPERATIONS IN INSTRUMENTAL SPINAL SURGERIES IN GERMANY

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OBJECTIVES: Complications in instrumental spinal surgeries (ISS) pose a considerable burden on patients. Necessary reoperations are associated with significant resource consumption and costs. The objective of this study was to estimate the related resource consumption and associated costs for patients undergoing lumbar spinal surgery (LSS) in Germany. The dependable data on the frequency of reoperations and associated costs are lacking for Germany. The aim of this study was to estimate the relationship between the frequency of reoperations and associated costs. METHODS: We conducted a retrospective claims data analysis using the Health Risk Institute research database, which contains anonymized claims data and covers approximately 5% of the German population. The study period comprised the period between January 2009 to 31 December 2010. Operation and procedure codes (OPS) identified primary ISS and following reoperations. Reoperation rates were calculated for an individual period of 12 months after the primary ISS in 2010. Annual costs for reoperations were calculated based on group comparison of patients with reoperation and those without reoperation (control group). Existing differences in cost levels in the year before the primary ISS were adjusted by the difference in differences approach. RESULTS: A total of 3,536 individuals had a primary ISS in 2010. The reoperation rate was 9.89% (95% CI = 8.98% to 11.02%). Mean cost per ISS was €11,331 for all patients (€11,358 reoperation group, €11,106 control group). The mean annual cost for a reoperation was €11,370, with a 12% increase to the reoperation procedure and €9,328 to excess costs in the first year after the primary ISS. CONCLUSIONS: The direct cost of ISS has a significant impact on health insurance budgets. With 10% of primary ISS patients requiring a reoperation in Germany, their associated annual costs are relevant from the SHI perspective. As demonstrated elsewhere, these cost might be partly avoidable by using intra-operative 3-D imaging with navigation.
ages because of the disease’s symptoms and variability, leading to reduced social
engagement. ∗exchange rate: 303.95R/USD/EUR

PMS24

EARLY RETIREMENT INDIRECT COSTS ATTRIBUTABLE TO RHUMATOID ARTHRITIS IN PORTUGAL

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OBJECTIVES: Rheumatic diseases (RD) cause physical disability that may lead to early retirement, generating high indirect costs to society. We estimate these costs in the Portuguese population approaching the statutory retirement age.

METHODOLOGY: Health, sociodemographic and occupational data was retrieved from the 4th National Health Survey (2005/2006), for all people between 50 and 64 years of age (3,762 men and 4,241 women), whilst an official wage national database was used to estimate the contributions by gender and region. The objective is to estimate the annual indirect costs attributable to RD in the early retirement age.

RESULTS: At the time of the survey, 37.2% of the population with ages 50-64 were retired, compared with 17.6% of those without RD (p<0.001). Females had higher prevalence of RD (49.8% vs. 23.4% for males; p<0.001). Presence of RD was associated with early retirement regardless of age, gender, and region (OR=1.3; 95% CI: 1.0 - 1.6).

The estimated annual indirect costs following premature retirement attributable to RD were €367 million (€504 per RD patient). Age-groups closer to the statutory retirement age contribute more to the overall indirect costs and also have higher indirect costs per age group. For instance, 60-64 years old age group contribute with 52% of overall costs and had an average indirect cost of 696€ per RD patient. Females were responsible for about 55% of these costs, however males contribute with a higher individual productivity losses (cost per patient: 788€ vs. 396€, for males and females respectively). CONCLUSIONS: Annual early retirement indirect costs attributable to RD are considerable. These results highlight the need to target patients with rheumatic conditions in order to obtain health and productivity gains and reduce early retirement in society.

PMS25

BURDEN OF DISEASE ANALYSIS OF PSORIATIC ARTHRITIS IN HUNGARY

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OBJECTIVES: Psoriatic arthritis (PsA) entails an individual burden to patients and ties up resources. This study aimed to assess the total costs of PsA, including the indirect burden of PsA patients in Hungary and to obtain an overview of patients status by socioeconomic characteristics, and the capacity for work.

METHODS: A cross-sectional study was conducted from January to March 2014, a questionnaire survey was conducted among PsA patients and filled out voluntarily and anonymously. Missing data was not imputed in the analysis.

RESULTS: 145 patients completed the questionnaire, of which 57% were women. Mean age was 54 years (Standard Deviation [SD]: 14 years) and average disease duration was 17 years (SD: 11 years). At primary diagnosis of PsA, 79% of patients had a full-time job, 4% a part-time job and only 3% received disability pension. At time of survey, only 32% of patients worked full-time, 4% part-time and 64% received disability pension. The average annual direct medical cost was €15,948. Within this period, the average annual direct non-medical cost was approximately 1,318 (141 patients) and average annual indirect cost per patient was approximately 2,635 (142 patients). Patients due to disability pension generated the highest average annual indirect cost per patient (2,734€ per patient). In the early retirement age (women: 31–62 years; men: 31–61 years) total average cost per patient was 5,334€. CONCLUSIONS: PsA can cause patients to become partially or completely disabled, which imposes a significant burden directly on their environment and indirectly to society. Average direct and indirect costs are higher with longer disease duration and greater skin manifestations.

Patients may already be driven out from the labour market in their active ages because of the disease’s symptoms and variability, leading to reduced social engagement. ∗exchange rate: 303.95R/USD/EUR

PMS26

ECONOMIC MODELING OF THE USE OF BOTULINUM TOXIN A IN A HOMOGENOUS PATIENT POPULATION BASED ON REAL-LIFE CLINICAL PRACTICE: ULIS-II (THE UPPER LIMB INTERNATIONAL SPASTICITY STUDY)

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OBJECTIVES: To evaluate the real life practice of the use of botulinum toxin A (BoNT-A) in post-stroke upper limb spasticity and the economic consequences of fair comparability of the dosing between either botulinum toxin A (Dysport®) or onabotulinumtoxinA (Botox®) or incobotulinumtoxinA (Kexin®).

METHODS: ULIS-II is an observational, prospective study, conducted in 84 centers in 22 countries. Patients ≥18 years old with spasticity in the upper limb were included.

RESULTS: Data were analyzed using the Minitab® software. The incidence of adverse effects (AEs) was reported as the number of patients experiencing AEs divided by the total number of patients treated with a given treatment. The percentage of patients who had a reduced dose was 45% in Dysport® vs. 22% with Botox® and an overall difference of 23% between the two treatments.

CONCLUSIONS: A total of 1014 patients completed the treatment and the economic model was applied to assess the cost-effectiveness of Botox® vs. Dysport® compared to a non-invasive management of spasticity which was used as the reference case.

PMS27

HOSPITALIZATION BURDEN AMONG DIALYSIS PATIENTS IN BRAZIL: AN ANALYSIS OF THE PUBLIC HEALTH SYSTEM DATABASE

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OBJECTIVES: This study aimed to estimate length of stay and costs associated with morbidity between dialysis patients and non-dialysis patients.

METHODS: This was a cross-sectional observational study (from January to December 2010) of a national hospitalization database from the Brazilian Unified Health System (SUS). The objective is to estimate the hospitalization burden among dialysis patients and non-dialysis patients.

RESULTS: There is a high hospitalization burden among CKD-5D patients in the Brazilian health care system. Since inpatient costs were the key cost drivers for CKD, strategies that reduce the risk of hospitalization and increase prevention of comorbidities may substantially decrease the overall health care economic burden.

PMS28

THE COSTS OF DIAGNOSIS AND TREATMENT OF ANKLE SPRAINS AND FRACTURES, 1980-2013: A SYSTEMATIC REVIEW

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OBJECTIVES: Ankle sprains and fractures are common injuries affecting many individuals, often requiring substantial and costly medical interventions. Ankle injuries can have significant physical and economic consequences. Therefore, the objective of this study was to systematically review and describe the literature on the direct and indirect costs related to the diagnosis and treatment of ankle sprains and fractures.

METHODS: A systematic literature review of Ovid MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, ACP Journal Club, AMED, Ovid Healthstar, and CINAHL was conducted for English-language studies on ankle sprains and fractures published from January 1980 to December 2013. Two reviewers assessed the articles for study quality using available guidelines and abstracted the data. RESULTS: Overall, 1,415 studies were identified of which 16 were selected for analysis. A majority of the studies were published in the last decade. The costs of ankle sprain diagnosis and management ranged from $95 to $4,667 per patient (2014 USD). The costs of stable ankle fracture diagnosis and management ranged from $89 to $602 per patient. However, unstable ankle fractures had substantially higher unstable ankle fracture costs ($2,680 to $15,095) and open fractures and varied depending on the severity of injury. The economic evaluations were conducted from the societal and health care system perspectives.

CONCLUSIONS: There are large differences in costs due to differences in injury severity and the study characteristics. Future studies undertaking economic evaluations should follow the available guidelines and ensure that the methods are transparent and understandable especially the study perspective and the valuation of the costs and outcomes.

PMS29

THE PENSION COSTS OF MUSCULOSKELETAL DISEASES. ESTIMATION OF THE ECONOMIC BURDEN BORNE BY THE ITALIAN SOCIAL SECURITY SYSTEM

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OBJECTIVES: The aim of the study is to estimate the pension costs (social security system in Italy is financed by public expenditure) induced by patients with musculoskeletal disorders (MD) and specifically for rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA) in Italy, between 2009 and 2012.

METHODS: We analyzed data from the Database of the National Institute of Social Security (INPS) to estimate for MD, RA, AS and PsA, the total costs of for three types of social security benefits: disability benefits (for people with reduced work ability), incapacity pensions (for people who are not able to work) and incapacity pensions (for people without work ability). Also was estimated the productivity loss for RA in the 2013 with data from the National Institute of Statistics and from national literature review.

RESULTS: From 2009 to 2012 were paid about 130,000 benefits at an average amount of €1,725, for an average of just over 80,000 performances a year with a cost of €32 million per year. Specifically the total pension burden for RA was about €300 million, for AS it was €26 million and for PsA was €12 million. The loss of productivity for RA in 2013 amounted to €707,425,191 due to 162,360 workers with RA that determined 9,174,221 working days.
lost. CONCLUSIONS: The most important indirect costs in Italy from 2009 to 2012 were related by disability benefits (69% of the total indirect cost), followed by disability pensions (28% of cost) and incapacity pensions (3% of cost). A better prescription appropriateness and rapid access to innovative treatments (Italy, among the EU Countries, is the one with the greatest delay in access) would reduce the costs of this indirect cost. Late diagnosis and a security system accompanied by an improvement on the effectiveness of interventions.

PMS30 SYSTEMATIC REVIEW OF SOCIETAL COST OF ILLNESS EVIDENCE IN PATIENTS WITH PSORIATIC ARTHRITIS
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OBJECTIVES: Societal cost relating to patients with psoriatic arthritis (PsA) is required to understand the overall economic impact of the disease. The objective of this study was to systematically review published data relating to the societal burden of PsA. METHODS: Embase, Medline, and Cochrane databases (accessed November 2013) were interrogated. Studies reporting on non-health sector costs or work disability associated with PsA were eligible for inclusion with no geographical restriction. Studies were included if they incorporated an initial response criterion of achieving a DAS-28 < 2.6 are the goal of treatment in rheumatoid arthritis (RA). In general, DAS-28 < 2.6 are the goal of treatment in PsA.

PMS31 SYSTEMATIC REVIEW OF SOCIETAL COST OF ILLNESS EVIDENCE IN PATIENTS WITH ANKYLOSING SPONDYLITIS
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OBJECTIVES: Ankylosing spondylitis (AS), one of the most common spondyloarthritides, is a chronic condition with a significant impact on quality of life (Qol), particularly physical functioning. The objective of this research was to systematically review published data relating to the societal burden of AS. METHODS: Embase, Medline, and Cochrane databases (accessed November 2013) were interrogated. Studies reporting on non-health sector costs or work disability associated with AS were eligible for inclusion with no geographical restriction. Studies were included if they incorporated an initial response criterion of achieving a DAS-28 < 2.6 are the goal of treatment in rheumatoid arthritis (RA). In general, DAS-28 < 2.6 are the goal of treatment in PsA.

PMS32 DETERMINATION OF THE ANNUAL HEALTH INSURANCE COST OF OUTPATIENT CARE SERVICES FOR LOW BACK PAIN
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OBJECTIVES: The aim of our study is to assess amount and frequency of the physiotherapy services in Low Back Pain disease and determine the total health insurance reimbursement. METHODS: Data were derived from the countrywide database of Hungary’s National Health Insurance Administration (NHA), based on official reports of outpatient care institutes in 2009. The total numbers of different physiotherapy services were determined by selecting the reported specific diagnoses codes and counting the number treatments provided for that specific diagnosis code. The distribution of the total number of codes is listed in Table 1 for ‘Physiotherapists, massage-therapists, conductors and other physiotherapy practices’. The ‘Low Back Pain’ was reported according to WHO ICD diagnosis code M54.50. RESULTS: Low Back Pain accounted for 125,372 cases in the annual number of the physiotherapy-related activities (23184133 cases) showing an approximately 3.83% prevalence. The 20 most frequent treatments accounts for 82.12% (101607) of total cases. The following 5 (091480, 091481, 091482, 091483, 091484) covered 55.86% (97,276) of total activities. 1) Ultra sound therapy 118800 (9.60%), 2) Diaphyseal interventional radiology 110700 (8.15%), 3) Passive movement 82042 (6.50%), 4) Mid-frequency treatment 77434A (4.26%), 5) Muscle strengthening exercises 62049 (5.02%), 6) Hand Massage 62000 (4.60%), 7) Ergo therapy 62099 (4.46%), 8) Diaphyseal interventional radiology 54092 (4.37%), 10) Training for circula tion improvement 44586 (3.60%). Physiotherapy out-patient care for Low Back Pain patients was 1.23 million cases, and the average cost for this care was €0.98 (‘Euro’). The health insurance subsidy was €0.22

PMS33 COST OF TREATING HIP FRACTURES WITH CEPHALOMEDULLARY NAILS: A RETROSPECTIVE CLAIMS DATABASE REVIEW
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OBJECTIVES: The number of hip fracture hospitalizations in the U.S. was approximately 352,000 in 2011 and expected to rise. The consequences of hip fractures are significant regarding the associated negative impacts on functioning and quality of life. Intertrochanteric hip fractures are frequently stabilized surgically using cephalomedullary nails (CM). Complications may include post-operative femoral-shaft fracture, mechanical complications, and delayed/non-union, requiring reoperations that increase the risk to the patient and cost to the health care system. METHODS: A retrospective analysis of the United States Complications database was performed for patients aged ≥ 18 years with an ICD-9-CM diagnosis code of 820.2x or 820.3x and treated for Hip Fracture (MS-DRG 480-482) from 1-JAN-2008 through 30-JUN-2012 were included in the study. Among this population, patients treated IM were identified using standard charge descriptions within orthopedic implant hardware charges. To identify patients who had a reoperation, patient-level claims were linked to records subsequently admitted within 1 year of the index procedure. The procedure was investigated within the same MS-DRG classifications. RESULTS: Overall, 73,745 patients qualified for the study (71% female, 74% ≥ 75-years-old). Of these, 32,175 (44%) were treated using CM. The average hospital cost of the index procedure was $15,798USD per patient (inclusive of fixed and variable costs), of which the average cost of the orthopedic nails was $1,704USD. Among these patients, a total of 419 (1.3%) patients were readmitted at 427 occasions within the 12-month study period. The mean hospital cost of treating these readmissions was $16,352USD, and the primary diagnoses codes for these readmissions included femoral fractures, nonunions, and device/mechanical complications. CONCLUSIONS: Although the incidence of reoperation following a hip fracture is low, the economic impact placed on the health care system and the humanistic burden are both significant. The incidence rate and long-term sequelae for hip fractures are well documented in the literature; however, the mean costs to a hospital have not yet been published.

PMS34 COSTS RELATED TO THE WAITING LIST OF PATIENTS WITH VERTEBRAL MALFORMATION
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OBJECTIVES: The Hungarian health budget does not allow all candidates to be promptly operated on with vertebral malformation. The budget is enough for approximately 2400 stabilizations by implant. The rest have to wait on the waiting list. The aim of our study is to analyse the costs related to the patients being on waiting list for surgery of vertebral malformation. METHODS: Data derived from the nationwide financial database of the Hungarian health insurance fund (Befogo Alap). 71 patients on waiting list of an institute in 2005-2006 were studied. We analysed the average waiting time and the costs related to patients either operated on or without operation. RESULTS: The average age of all candidates was 55 year and the average waiting time was 32 months. The treatment cost during the waiting time was $US 103 per month per patient. The average age of candidates operated on was 57 years and their average waiting time was 15 months with a costs of US$ 155 per month per patients. The average age of candidates not operated on was 54 years and their average waiting time was 15 months with a cost of US$ 92 per month per patient. CONCLUSIONS: Half of candidates have not been operated on, because at the appointed date they terminated the operation, but they they not to really want to be operated on. The reason could be they were not sure enough to be able to get job after the operation at their age.

PMS35 TREATING TO THE TARGET OF DAS28 < 2.6 IN RHEUMATOID ARTHRITIS: THE IMPACT OF EFFICACY ON COST EFFECTIVENESS
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OBJECTIVES: Treatment targets such as DAS-28 < 2.6 are the goal of treatment in rheumatoid arthritis (RA). In general, DAS-28 < 2.6 is associated with improved functionality and reduced use resource but with higher treatment costs. This study evaluated whether treatment strategies that were more effective but more expensive in achieving DAS-28 < 2.6 in moderate to severe RA patients were cost effective (CE). METHODS: A micro-simulation model of 10,000 RA patients was developed that estimated lifetime Health Assessment Questionnaire (HAQ) progression, quality adjusted life years (QALYs) and direct costs from a UK NHS perspective. The model incorporated an initial response criterion of achieving a DAS-28 < 2.6 at 6 months.
after initiating treatment that triggered treatment switching to subsequent therapies.

ORGANIZATIONAL, PATIENT, AND PHARMACOECONOMIC OUTCOMES

OBJECTIVE: To evaluate the cost-effectiveness of certolizumab pegol (CZP) versus standard of care (SC) and non-steroidal anti-inflammatory drugs (NSAIDs) in the treatment of RA patients in Romania.

METHODS: We compared European RA patients in 2 closely matched non-steroidal anti-inflammatory drug (NSAID) treatment arms consecutively treated in 2014. Costs were captured at a per-patient level (excluding monitoring costs) and were estimated 2014 international prices. Outcomes included the ACR20, ACR50, and ACR70 response measures. The effectiveness analysis was conducted by a Cox proportional hazards model; transition probabilities were estimated from prospective data. Cost effectiveness was analyzed with a Markov model. The 2-state Markov model for each patient group assessed the proportion of patients fully adherent at each time point. The Markov model was simulated over a 6-month time horizon.

RESULTS: A total of 2,723 patients were included in the effectiveness analysis; 1,408 in the control group (MTX) and 1,315 in the intervention group (CZP). The ACR20 was achieved in 63% of patients in MTX and 77% in CZP. The ACR50 response was reached in 31% and 48%, respectively, and the ACR70 was achieved in 16% and 28%, respectively. In the sensitivity analysis, cost per QALY gained was estimated at 32,446,873 for MTX and 8,819,510 for CZP. In the base-case analysis, the intervention was found to be cost-effective with a cost per QALY gained of 13,019,510 for CZP.

CONCLUSIONS: The intervention was found to be cost-effective with a cost per QALY gained of 13,019,510 for CZP. The intervention was found to be cost-effective with a cost per QALY gained of 13,019,510 for CZP. The intervention was found to be cost-effective with a cost per QALY gained of 13,019,510 for CZP.
TREATMENT STRATEGY IN THE ELDERLY JAPANESE WOMEN

have shown that UC-T could be a cost-saving procedure if societal perspective is appraised. Reduced estimates to approximately £30,000.

The estimated incremental costs per QALY of bDMARD strategies compared with A COST-EFFECTIVENESS ANALYSIS FOR TOTAL KNEE ARTHROPLASTY PMS42

reported cost-effective thresholds in England and Wales.

etanercept; golimumab; infliximab; and tocilizumab. Network meta-analyses (NMA) of randomised controlled trials (RCTs) reporting European League Against Rheumatism (EULAR) response and for RCTs reporting American College of Rheumatology (ACR) outcome data. An individual patient model was constructed to estimate costs and outcomes in terms of quality adjusted life years (QALY). Large observational databases, published literature and the results of the NMA were used to construct the data for the meta-analysis of two bDMARDs (two broad strategies were evaluated i) a bDMARD, followed by, if necessary, rituximab then tocilizumab then cDMARDs and ii) remaining on cDMARDs. RESULTS: The estimated incremental costs per QALY of bDMARD strategies compared with a cDMARD alone strategy were typically over £50,000 regardless of the severity of rheumatoid arthritis or whether the EULAR or the ACR RCTs were used. The cost per QALY is greater for those who receive bDMARD monotherapy. One key parameter affecting the results was the estimated trajectory of HRQoL progress whilst a patient received cDMARDs; using rates previously assessed in NICE appraisals reduced estimates to approximately £10,000. CONCLUSIONS: bDMARDs are unlikely to be cost-effective as health was estimated previously. The costs per QALY generated within our base case analyses are greater than commonly reported cost-effectiveness thresholds in England and Wales.

A COST-EFFECTIVENESS ANALYSIS FOR TOTAL KNEE ARTHROPLASTY: PROOF OF CONCEPT OF A DECISION MODEL Fusco F1, Tetti G2

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OBJECTIVES: The study aims to assess the cost-effectiveness of total knee arthroplasty for Total Knee Arthroplasty (TKA) patients in Italy. TKA was performed 64,936 times in Italy in 2012, reasonably leading to the same number of rehabilitation processes. The most recent cost analysis showed rehabilitation to account for Euro 150 million per year. Therefore, new strategies aiming at optimizing resources and providing a method to deliver quality care are clearly needed. METHODS: A four-state model (successful TKA; revision; successful revision, death) forecasted costs and clinical outcome over 10 years (cycle length: 1 year) for 1,000 individuals undergoing successful arthroplasty (UC) vs. undergoing rehabilitation (UC-T) program. Published literature provided transition probabilities and clinical outcomes (active knee flexion Range-Of-Motion; ROM) while UC and telerhabilitation costs were estimated using an Italian national panel of experts. Each surgery was assumed to lead to rehabilitation or telerhabilitation, resulting in direct medical and indirect costs (human capital approach). Results were adjusted applying half-cycle correction method and discount rate of 3%. A Probabilistic Sensitivity Analysis described parameters uncertainty and results were reported using Incremental Cost-Effectiveness Ratios (ICER) from societal and Italian-NHS perspectives. RESULTS: Expected mean health care costs for UC were 1,253.2/ patient over ten years, and UC-T costs were on average 33.7%/patient higher (95%CI €10.8). ROM-degrees for UC and UC-T were respectively 25.4 and 25.8 (mean difference=2.3, 95%CI 0.002). The resulting ICER was 14.5t/ROM-degree (Italian-NHS perspective). Adopting a societal perspective, UC-T was more effective yet appeared cheaper than UC (respectively 1,429 and 1,457/patient, mean difference -2/patient (95% CI ±0.8)). CONCLUSIONS: Although the preliminary results have shown that UC-T could be a cost-saving procedure if societal perspective is adopted, these findings are uncertain due to the model assumptions. Therefore further investigations with patient-level data and generic outcome measures (e.g. QALY) are required to draw definitive conclusions about cost-effectiveness in telerhabilitation.

PMS43

HUMAN ECONOMIC EVALUATION OF OSTEOSPOROSIS SCREENING AND TREATMENT STRATEGY IN ELDERLY JAPANESE WOMEN Yoshimura M1, Moriwaki K2, Noto S3, Takiguchi T4

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OBJECTIVES: The objective of this study was to estimate the cost-effectiveness of osteoporosis screening and treatment with alendronate in the Japanese women aged 65 years without a fragility fracture history. METHODS: A Markov model with ten health states (no event, seven types of post-fracture, bedridden, and death) was developed to predict lifetime costs and quality-adjusted life years (QALY) of screening and treatment strategy, comparing with no screening. In the screening arm, 1,000 hypothetical cohort experienced a bone mineral density (BMD) testing with dual energy x-ray absorptiometry (DXA) and received five years of alendronate if the result of the adult men. CONCLUSIONS: This economic evaluation modeling suggests that celecoxib may be considered as a cost-effective alternative vs. t-NSAIDs in the treatment of osteoarthritis in daily practice in the Spanish NHS.

PMS41

THE COST-EFFECTIVENESS OF BIOLGIC DMARDs IN PATIENTS WITH SEVERE OR MILD-TO-SEVERE RHEUMATOID ARTHRITIS AFTER CONVENTIONAL DMARDs Wairol AI1, Stevenson M2, Tosh F3, Hernández M4, Stevens JW5, Archer R2, Simpson E2, eversen Rock E2, Scott D4, Young A4, Fasley S5, Williams K5

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OBJECTIVES: To estimate the cost-effectiveness of biologic disease modifying anti-rheumatic drugs (bDMARDs) following failure of conventional disease modifying anti-rheumatic drugs (cDMARDs) in patients with severe or mild-to-severe active rheumatoid arthritis from UK, NHS perspective, as part of an ongoing National Institute of Health and Care Excellence (NICE) appraisal. METHODS: Systematic review of economic evaluation of bDMARDs. A four-state Markov model with at least three cost states and three health states were designed as an adjunct to lumbar microdiscectomy to block large anular defects while maintaining as much native nucleus within the disc space. Patients that were included in the analysis were those who have had at least maximum posterior disc height of 5mm, and an intra-operatively measured anular defect between 5mm and 12mm wide. The aim of this study was to compare the cost effectiveness of the use of Barricaid® in this group of patients in Turkey. METHODS: A simple decision analysis model was used to assess the cost effectiveness of the use of Barricaid®. The primary clinical endpoint was determined as the number of prevented rehospitalizations within the lifetime of patients by the use of Barricaid®. RESULTS: A probabilistic sensitivity analysis was made between using and not using the Barricaid®. RESULTS: According to the results of the cost effectiveness analysis, the incremental number of prevented hospitalizations was 46 with Barricaid® and incremental cost was 139,343TL. CONCLUSIONS: Use of Barricaid® in lumbar discotomy surgery is a cost-effective treatment option in Turkey.

PMS45

PHARMACOECONOMIC EVALUATION OF TREATMENT WITH TOCILIZUMAB IN RUSSIAN CHILDREN WITH SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS Sechenov I.V., Gorokhova S.G., Emchenko I.V.

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OBJECTIVES: To evaluate the use of tocilizumab in Russian patients with systemic juvenile idiopathic arthritis (SJIA) with respect to cost-effectiveness and impact on social and economic burden of the disease. METHODS: The model was based on TENDER clinical study (De Benedetti F et al., 2012). First, a pharmacoeconomic cost analysis was performed using standard basic techniques compared with comparator. The analysis included direct medical costs in two comparable groups (1st with routine administration of methotrexate and prednisolone, and 2nd with tocilizumab described in case of treatment failure). RESULTS: The number of rehospitalizations by 18%. Resource utilization data were obtained via expert clinical opinion and included pre-post, post-op and follow-up costs, etc. Unit costs were taken from the Social Security Institution’s official price list. Results were presented as incremental cost per event and number of avoided rehospitalizations. The comparison was made between using and not using the Barricaid®. RESULTS: According to the results of the cost effectiveness analysis, the incremental number of prevented rehospitalizations was 46 with Barricaid® and incremental cost was 139,343TL. CONCLUSIONS: Use of tocilizumab in SJIA is justified by better cost efficiency and reduced of social and economic losses of state budget connected with the burden of the disease.

PMS46

COST-EFFECTIVENESS ANALYSIS OF ETANERCEPT IN THE TREATMENT OF RHEUMATOID ARTHRITIS IN PORTUGAL Mateus C1, Moura A2

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OBJECTIVES: The present study aims to estimate the cost-effectiveness of etanercept compared to golimumab in the treatment of patients with Rheumatoid Arthritis (RA) in Portugal. METHODS: A model was adapted to assess the cost-effectiveness of etanercept in the treatment of RA. We performed a comparison of the combination of etanercept + methotrexate and golimumab + methotrexate. Dosage of etanercept was 50mg on a weekly basis, whereas for golimumab it was 50mg once a month. The model is an individual simulation model and takes a lifetime perspective. Outcomes are expressed in QALYs, using the HAQ score.
to measure quality of life. The clinical parameters used in the model take into account the results of a MTC of anti-rheumatic (MBH) therapies in the Portuguese context, several adjustments were made to its original version. These mainly relate to mortality rates by gender and to the unit costs of medical resources, such as drugs, medical visits, admissions, ancillary tests and so on, that were obtained from public official sources. We applied a 5% discount rate and conducted an analysis for a hypothetical cohort of 1,000 patients. RESULTS: The treatment of RA with etanercept is more expensive than that with the comparator. Nevertheless, QALY gained did not compensate for the additional cost. Overall, ICER is €12,853, which is below the usual willingness to pay threshold used in Portugal. A sensitivity analysis was carried out, which confirmed the robustness of these results. CONCLUSIONS: According to our analysis, etanercept is a cost-effective alternative to the comparator for the treatment of rheumatoid arthritis. Its main advantage over the selected comparator relates to the associated improvements in health related quality of life.

PMS47 THE IMPACT OF DISEASE MODIFICATION ON THE COST-EFFECTIVENESS OF PEGLOTICASE FOR THE TREATMENT OF SEVERE DEBILITATING CHRONIC TOPHACEOUS GOUT PATIENTS

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OBJECTIVES: To determine the cost-effectiveness of pegloticase (Krystexxa®) for patients with severe debilitating chronic tophaceous gout (SDCTG), from a UK health care perspective. METHODS: Severe debilitating chronic tophaceous gout (SDCTG) is a disabling, high unmet medical need. Existing non-pharmacological treatments provide symptomatic relief and do not modify the disease course. Pegloticase has the potential to be a disease modifying agent. A decision analytic model was built to compare the use of pegloticase with best supportive care with SDCTG patients with (BSC) with a Markov model used to extrapolate outcomes to a 20 year time horizon. In the basecase, the disease modifying properties of pegloticase were modelled. In scenario analysis, the disease modifying potential of pegloticase on acute gout flares and tophi was included. RESULTS: In the basecase, the cost-effectiveness of pegloticase compared to BSC was €31,027 per QALY gained. In this basecase, pegloticase dramatically reduced the uric acid burden in over 60% of patients who completed a six month course of treatment. In a sensitivity analysis it was assumed that 85% of patients with SDCTG treated with pegloticase inhibitor maintenance treatment. In a pessimistic scenario whereby pegloticase was assumed to only provide symptomatic relief, the ICER was €48,672/QALY gained. In a further scenario whereby utility benefits were limited to only short-term reductions in acute flares and presence of tophi, the ICER was €54,345/QALY. Apart from these two drivers, the cost-effectiveness estimates were relatively stable across a range of sensitivity analyses. CONCLUSIONS: In the context of a highly severely and debilitating form of gout, with small patient numbers and a lack of alternative effective treatment options, pegloticase can be considered good value-for-money. Further clinical evidence is required to demonstrate the disease modifying properties of pegloticase. However, such data collection and hence the ability to perform robust economic evaluations for HTA purposes is difficult especially when the sponsoring company is small with limited funds.

PMS48 COMPARISON OF DIAGNOSTIC STRATEGIES TO DETECT PREVAILENT VERTEBRAL PSEUDOSUBSTANCES (VFS) IN PATIENTS WITH SEVERE DEGENERATIVE SPINE DISEASE

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OBJECTIVES: The prevalent vertebral fracture (VF) is a risk factor for future VF, which can be increased with drug therapy. However, most VFs are not recognized clinically. Vertebral fracture assessment (VFA) by dual-energy x-ray absorptiometry (DEXA) and spine x-ray can be performed to detect these prevalent VFs. This study aimed to estimate the costs, effectiveness, and radiation exposure of VF diagnostic strategies. METHODS: Markov model over a 10-year period was used to calculate the medical costs for diagnostic tests and VF treatment, the reduction of incident VFs and benefit of drugs in comparison with SDCTG with biologics and Tocilizumab cost, include subcutaneous route of administration, will amount €2,037 EUR to 8.846 EUR. The results showed the transition of 100 RA patients onto a treatment regimen, includes Tofacitinib use, and international RA treatment recommendations, it was concluded that there was no statistically significant difference in efficacy and toxicity of the Tofacitinib therapy (RA) (comparison of alternatives – GEBDs Tofacitinib and biologics: Infliximab, Abatacept, Certolizumab pegol, Golimumab, Adalimumab and Tobulizumab) from pharmacoeconomic analysis point of view. METHODS: Analysis based on the assessment for one statistically average patient suffering from RA, and weighing 70 kilograms, over a one year course of treatment (52 weeks). The analysis done of direct costs included: cost of DMARDs and biologics therapy use; costs of drug introduction; physician visits cost. Cost-minimization and missed opportunities analysis were used. RESULTS: During the effectiveness analysis of RA treatment, based on the meta-analyses of randomized placebo-controlled trials data (including meta-analyses P. Kawalec, 2013; E. Salgado, 2013), Russian and international RA treatment recommendations, it was concluded that there was no statistically significant difference in efficacy and toxicity of the Tofacitinib and the biologics used in the RA treatment. One year treatment course with Tofacitinib, Infliximab, Abatacept, Certolizumab pegol, Golimumab, Adalimumab and Tobulizumab cost, include subcutaneous route of administration, will amount to 12.818 EUR, 20.932 EUR, 14.855 EUR, 18.104 EUR, 19.642 EUR, 20.126 EUR and 21.664 EUR. The cost-effectiveness analysis showed that Tofacitinib is more cost-effective than the other biologics. CONCLUSIONS: Tofacitinib in comparison with biologics use will reduce the cost of one year course of treatment for each RA patient from 2.037 EUR to 8.846 EUR. Transition of 100 RA patients in a treatment regimen, includes Tofacitinib use, which enable it to treat from 15 to 69 patients more suffering from this disease.

PMS52 REHABILITATION IN RESURFACING HIP ARTHROPLASTY PATIENTS: PRELIMINARY COST-EFFECTIVENESS RESULTS FROM A CLINICAL TRIAL

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OBJECTIVES: To estimate the incremental cost-effectiveness ratio (ICER) of dual- mobility cups (MFC) versus conventional cups (CF) to help reduce the incidence of dislocation rates following total hip replacement (THR) in France. METHODS: A Markov model simulated two cohorts of patients: one with MFC and one with CF. Three different stages of health were considered: “stable”, “dislocation/revision” and “death”. The model had a 12-month cycle length and an 80-year time horizon. The model was lifetime. Dislocation/revision rates were estimated using two different sources: literature review and expert opinions (analysis 1) and analysis of the PMS (French hospital database) of Patients having one THR in 2009 followed through the end of 2012 (analysis 2). Costs considered were hospitalization costs (reduction/revision for dislocation performed in acute care unit and care in rehabilitation units), valued using the National Scale Costs with Common methodology (ENCG). Outcomes were the number of QALY gained and costs of THR from the hospital care perspective.
OBJECTIVES: A tailored accelerated physiotherapy (AP) program following surgery (RHA) has been shown to be effective in improving hip function and range of motion in young male patients; however no evidence based on provided cost-effectiveness. The aim of this UK trial-based economic assessment was to compare the cost-effectiveness of AP versus a standard rehabilitation protocol. METHODS: 316 participants were randomized to 2 protocols: AP or SRP. The experimental arm followed an 8-week programme with no hip precautions, full-weight bearing from day one, tailored exercises and an additional physiotherapy consultation. The control group received the standard 8-week course of rehabilitation. At 6, 16, and 52 weeks, patients reported primary and secondary hip care contacts, use of equipment, and private hip care contacts. These data were valued using 2012/2013 national average unit costs. The 3-level EuroQol EQ-5D-3 questionnaire was completed by patients at baseline, 6, 16 and 52 weeks and used to calculate Quality Adjusted Life Years (QALYs) to 12 months. RESULTS: 80 young males (median age: 55.8 years) were randomized to AP (n=40) or SRP (n=40). Preliminary results showed mean costs of £3,700 and incremental QALYs of 0.306 in the AP arm (95% CI difference £237 to £582 to £1089). There were no significant differences in health care costs or quality of life. Further analysis with a non-parametric test showed no significant differences in QoL. CONCLUSIONS: In this study it is shown that AP is cost-effective at a maximum willingness to pay of £20,000 per QALY is 99%. Conclusions: From the perspective of the health care provider, a tailored accelerated physiotherapy programme for younger male patients undergoing RHA appears cost-effective when compared to a standard rehabilitation programme.

PMSS3 RITUXIMAB AS FIRST CHOICE FOR PATIENTS WITH REFRACTORY RHEUMATOID ARTHRITIS: COST-EFFECTIVENESS ANALYSIS IN IRA N BASED ON A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: The aim of this study is evaluation of the effectiveness and cost- effectiveness of rituximab as first line treatment to reduce number of DMARDs in refractory rheumatoid arthritis in Iran. Re-analysis of CMA (Canadian Medical Association) index results, QALY (Quality Adjusted Life Years) gained were calculated through mapping ACR index to HAQ (Health Assessment Questionnaire) and the direct and indirect medical costs, a set of interviews with patients were applied. Thirty two patients were selected from three referral rheumatology clinics in Tehran with definite diagnosis of refractory rheumatoid arthritis one year before, and treatment regimen of rituximab or DMARDs within last year. Incremental cost-effectiveness ratio (ICER) was £12,100 per QALY gained. A discount rate of 3% was applied. Both 1-way and multivariate probabilistic sensitivity analyses were undertaken to evaluate robustness of results: RESULTS: Compared to alendronate, strontium could prevent 328 wrist, 192 hip, 7 vertebra and 115 multiple fractures respectively over 5 years, which was translated into £27.9 QALYs gained. Using strontium can lead to cost reduction of MYR1,416,595 (USD442,685), MYR78,257 (USD149,455), MYR22,784 (USD70,120) and MYR61,883 (USD19,392) per patient respectively in mono/multi sites respectively. The total reduction of direct medical costs of MYR279,519 (USD712,349) was larger than the extra drug cost, hence making strontium a cost-saving therapy. CONCLUSIONS: It was shown that strontium appeared to be more cost-effective than alendronate and hence should be recommended in the public sector in Malaysia.

PMSS5 MABTHERA® (RITUXIMAB) FOR THE TREATMENT OF SEVERE GRANULOMATOSIS WITH POLYANGIITIS (GPA) AND MICROSCOPIC POLYANGIITIS (MPA) – A COST-UTILITY MODEL FOR THE UNITED KINGDOM

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2Aristou Medical Ltd., Athens, Greece
3Athens Medical School, Athens, Greece
4UCB Pharma, Athens, Greece
5UCB Limited, Elstree, UK

OBJECTIVES: To evaluate the cost-effectiveness of MabThera in patients with severe GPA and MPA in the United Kingdom (UK). BACKGROUND: In March 2014 NICE issued positive guidance for the use of MabThera in patients with severe GPA and MPA [TA308]. METHODS: An economic model was developed to reflect the health care costs and health outcomes over the current standard treatment to the current treatment. The cost-effectiveness analysis employs a Markov model with four health states: complete remission, non- remission, uncontrolled disease and death. Patients were assumed to start in the complete remission health state, transitioning based on their response to treatment. Relapsing patients who have exhausted all available treatment options they are assumed to enter the uncontrolled disease health state where they remain until death. The efficacy and costs data were derived from the RAVE study (Stone et al 2010) which demonstrated that MabThera was non- inferior to cyclophosphamide (CYC). In a subgroup of patients who had received prior therapy, MabThera was superior to CYC. Benefits were expressed as QALYs. Costs were calculated from a National Health Service perspective. The analysis calculated incremental costs and benefits associated with the addition of MabThera to the treatment paradigm which was assumed to consist of CYC and azathioprine. For patients intolerant to CYC, MabThera was assumed to substitute for CYC. The RAVE trial reports health related quality of life using SF-36. The SF-36 scores were converted to EQ-5D in a post-hoc analysis using a published model [Ara and Brazier 2008]. RESULTS: Base case results estimated incremental costs of approximately £3,700 and incremental QALYs of 0.306. The incremental cost-effectiveness ratio (ICER) was £12,100 per QALY gained. CONCLUSIONS: The results of this analysis suggest that MabThera is a cost-effective treatment for severe GPA and MPA.

PMSS7 PRODUCTION LOSS DUE TO RHEUMATOID ARTHRITIS (RA), CROHN'S DISEASE (CD) AND PSORIASIS (PS) IN POLAND

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OBJECTIVES: To assess the indirect costs of RA, CD and Ps in an employed population in Poland. METHODS: Data on presenteeism and absenteeism related with analyzed diagnoses were collected in a cross-sectional study from patients of ambulatory practice in 10 regions around Poland (3 rheumatology, 10 dermatology and 29 gastroenterology centers). Lost productivity was measured with Work Productivity and Activity Impairment (WPAI) questionnaire and patients’ disease activity was assessed on standardized, disease specific scales (DAS28, PASI, and CDAI). 328 (RA), 460 (Ps), 256 (CD). GPs were informed of the analyses conducted in the previous diagnosis. Unit cost of lost productivity was estimated using 2012 GDP per worker per hour corrected for diminishing marginal productivity and added up to PLN 3.3 million. RESULTS: Mean age of MHI respondents was 36 for CD, 41 for Ps and 46 for RA patients (only patients in productive age – 18/60/65 were included in the study).
Ps patients had dominantly (54%) low disease activity, in RA group mostly (51%) the moderate activity was observed, while the most frequent disease activity category for CD patients was remission (39%). Mean annual cost of overall work impairment (presenteeism and absenteeism cost together) amounted to PLN 29 727 for RA, PLN 24 434 for Ps and PLN 23 682 for CD. Cost of loss of productivity due to RA ranged from PLN 8 069 for CD (in remission) to PLN 9 266 for Ps (in highly active disease). For Ps it was respectively PLN 13 846 and PLN 44 009 and for CD PLN 15 543 and PLN 63 771.

CONCLUSIONS: Productivity loss among workers with Ps, CD and RA generates significant costs for society which rises with disease activity.

PMS58
LONG-TERM WORK PRODUCTIVITY COSTS AMONG SUBJECTS WITH EARLY RHEUMATOID ARTHRITIS - A NATIONWIDE ANALYSIS BASED ON 7,831 SUBJECTS' SICKNESS ABSENCE DAYS AND INCOME
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OBJECTIVES: To estimate the long-term productivity costs (PC) and their determinants among early rheumatoid arthritis (RA) available to workforce at baseline.

METHODS: A cohort of subjects with early RA was created by identifying the new cases of RA from the national register of the Social Insurance Institution (SII) in Finland, who were granted a special reimbursement of anti-rheumatic medications for rheumatoid factor positive (ICD-10 code: M05) or negative RA (M06) in 2000 – 2007. The obtained dataset was enriched by cross-linking with the national databases about the subjects' health status, work careers, and financial background. The human capital approach was applied to estimate PC based on subjects' sickness absence days and income. The PC were estimated and expressed as per patient-observation year. Hurdle regression analysis was applied to study the determinants of PC. Sensitivity analyses were conducted to test the robustness of the obtained results.

RESULTS: The study comprised 7,831 subjects with early RA in paid jobs. The total sickness absence days were 52.6% (95% CI 50.9-54.2) for CD and 77.7% (95% CI 76.5-78.9) for RA. The mean productivity loss was PLN 9,469. (95% CI 9,405-9,53) per person-year. The PC increased progressively over the years. The use of methotrexate-based combination therapies during the first three months after RA diagnosis reduced significantly the cumulative PC during the following years.

CONCLUSIONS: The obtained results confirm that early RA is a significant cost-driver for society and that the intervention of pharmacotherapy during the first three months after RA diagnosis, together with the maintenance of low disease activity throughout the follow-up period, can significantly reduce the long-term productivity costs of RA in the early phase of the disease.

PMS59
CHARACTERIZING WORK PRODUCTIVITY LOSS IN INCIDENT RHEUMATOID ARTHRITIS IN SWEDEN
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OBJECTIVES: To study the trends in work productivity loss pre- and post-diagnosis of incident rheumatoid arthritis (RA) and compare it to patients with osteoarthritis (OA). This is not an observational study, but a data analysis from a national register for surgery conducted using Swedish national registers. Patients of working age with an incident diagnosis of RA between 2003 and 2009 were identified in the National Patient Register (n=3,762 men and 4,241 women).

RESULTS: The study comprised 7,831 subjects with early RA in paid jobs. The total sickness absence days were 52.6% (95% CI 50.9-54.2) for CD and 77.7% (95% CI 76.5-78.9) for RA. The mean productivity loss was PLN 9,469. (95% CI 9,405-9,53) per person-year. The PC increased progressively over the years. The use of methotrexate-based combination therapies during the first three months after RA diagnosis reduced significantly the cumulative PC during the following years.

CONCLUSIONS: The obtained results confirm that early RA is a significant cost-driver for society and that the intervention of pharmacotherapy during the first three months after RA diagnosis, together with the maintenance of low disease activity throughout the follow-up period, can significantly reduce the long-term productivity costs of RA in the early phase of the disease.
A systematic review identified retrospective and prospective observational studies into the 12-month persistence with denosumab, an osteoporosis therapy approved in 2010. Searches covered the period January 2010 to May 2014 and were conducted in the PubMed and EMBASE databases, and conference abstract supplements from ACR, AMCF, ASBMR, WCO-IOF-ESCEO, and ISPOR. To be eligible, studies had to address osteoporosis patients, involve at least one estimate of persistence, and report data on denosumab-treated patients with osteoporosis, have a clear definition of persistence, and be in English language. Using a random effects model, pooled estimates of denosumab persistence were 15% (95% CI: 11-19%) in the overall cohort of patients with osteoporosis, and 10% (95% CI: 6-15%) in those with vertebral fractures. In a per-protocol analysis, denosumab persistence was 21% (95% CI: 16-26%). Conclusions: Our study confirmed similar persistence between those with and without NSAID use on persistence, controlling for baseline characteristics. A chi-square test was used to assess the impact of prior DMARD use. RESULTS: A logistic regression model was used to further assess the impact of prior DMARD use. The objective of this study was to describe persistence with subcutaneous biologics, and to identify differences among patients with and without DMARD use. METHODS: A retrospective analysis using IMS Disease Analyzer-Germany, an electronic medical records database. Adult (≥18 years old) RA patients with exposure to a subcutaneous biologic between January 1, 2009 and June 30, 2012 were included in the analysis. The first subcutaneous biologic was initiated by July 1, 2012. The mean age of the patients was 49 (11) years, with 50% being female. The majority of patients were Caucasian (85%) and 21% African American. Sixty-eight (34%) patients reported using a reminder: 53 (26%) used prescriptive reminders, 12 (6%) used calendars, and 3 (1%) diaries. Factors associated with the use of reminders included older age (p = 0.004), being white vs. Hispanic or African American (p = 0.003), being male vs. female (p = 0.005). Working patients were less likely to report using reminders (p = 0.006). No association was observed for level of education or the use of aids. Use of reminders was associated with domains of self-reported adherence: adherence while away from home (r = 0.16, p = 0.03), when running out of pills (r = 0.15, p = 0.03), and when running out of pills (r = 0.15, p = 0.03). CONCLUSIONS: Older patients, males, and whites were more likely to use these aids, more often pill containers. Our study shows that reminders can assist patients with RA in taking their medications, particularly in situations when they are most prone to forget including being away from home or busy. Use of reminders should be encouraged by providers as a low-cost aid to enhance adherence.

PM656

TREATMENT PERSISTENCE WITH SUBCUTANEOUS BIOLoGIC THERAPIES IN PATIENTS wITH PSORIATIC ARTHRITIS (PSA)

LYU C1, Ding Q2, Govoni M3, Fan T3

1Mercer & Co., Inc; Whitehouse Station, NJ, USA; 2Temple University, Philadelphia, PA, USA; 3Merck Sharp & Dohme Limited, Rome, Italy

OBJECTIVES: The objective of this study was to describe persistence with subcutaneous biologics, and to identify differences among patients with and without DMARD use. METHODS: A retrospective analysis using IMS Disease Analyzer-Germany, an electronic medical records database. Adult (≥18 years of age) PSA patients who initiated therapy with subcutaneous biologics between January 1, 2009 and June 30, 2012 were included in the analysis. The first subcutaneous biologic was initiated by July 1, 2012. The mean age of the patients was 49 (11) years, with 50% being female. The majority of patients were Caucasian (85%) and 21% African American. Sixty-eight (34%) patients reported using a reminder: 53 (26%) used prescriptive reminders, 12 (6%) used calendars, and 3 (1%) diaries. Factors associated with the use of reminders included older age (p = 0.004), being white vs. Hispanic or African American (p = 0.003), being male vs. female (p = 0.005). Working patients were less likely to report using reminders (p = 0.006). No association was observed for level of education or the use of aids. Use of reminders was associated with domains of self-reported adherence: adherence while away from home (r = 0.16, p = 0.03), when running out of pills (r = 0.15, p = 0.03), and when running out of pills (r = 0.15, p = 0.03). CONCLUSIONS: Older patients, males, and whites were more likely to use these aids, more often pill containers. Our study shows that reminders can assist patients with RA in taking their medications, particularly in situations when they are most prone to forget including being away from home or busy. Use of reminders should be encouraged by providers as a low-cost aid to enhance adherence.

PM654

PERSISTENCE RATE WITH SUBCUTANEOUS BIOLOGIC THERAPIES IN PATIENTS wITH psORIATIC ARTHRITIS (PSA)

LYU C1, Ding Q2, Govoni M3, Fan T3

1Mercer & Co., Inc; Whitehouse Station, NJ, USA; 2Temple University, Philadelphia, PA, USA; 3Merck Sharp & Dohme Limited, Rome, Italy

OBJECTIVES: This study examined persistence over 12 months for RA patients who were newly treated with subcutaneous biologics, and assessed if there are differences between patients with and without prior DMARD experience. METHODS: In this retrospective cohort study using Electronic Medical Record database of IMS Disease Analyzer-Germany, an electronic medical records database. Adult (≥18 years old) RA patients who were newly treated with a subcutaneous biologic between January 1, 2009 and June 30, 2012 were identified. The first prescription date for the subcutaneous biologic agent was defined as their index date. Patients were excluded from the study if they were prescribed a biologic agent during the pre-index period, and/or diagnosed with ankylosing spondylitis, psoriatic arthritis, or other conditions treated with subcutaneous biologics either pre- or post-index. A chi-square test was used to assess significant differences in the distribution of persistent patients between those with and without DMARD use and a logistic regression model was used to control for differences in baseline demographic and clinical characteristics. RESULTS: A total of 576 RA patients were included in this prospective cohort study examining treatment adherence. At baseline patients were asked if they used any special reminders such as pill containers, calendars, or diaries. Patients completed two self-reported adherence questionnaire: the Compliance Questionnaire Rheumatoid Arthritis (CQRA) and the Adherence Clinical Treatment Bending Index (ACTB). Adherence measures included number of swollen joints, number of tender joints, disease activity score (DAS28), and patient global assessment. Functional status was evaluated using the modified Health Assessment Questionnaire (mHAQ). RESULTS: Mean age (SD) of the patients was 51 years, 75% were female, 53% were Hispanic, 25% white, and 21% African American. Sixty-eight (34%) patients reported using a reminder: 53 (26%) used special pill containers, 12 (6%) used calendars, and 3 (1%) diaries. Factors associated with the use of reminders were older age (p = 0.004), being white vs. Hispanic or African American (p = 0.003), being male vs. female (p = 0.005). Working patients were less likely to report using reminders (p = 0.006). No association was observed for level of education or the use of aids. Use of reminders was associated with domains of self-reported adherence: adherence while away from home (r = 0.16, p = 0.03), when running out of pills (r = 0.15, p = 0.03), and when running out of pills (r = 0.15, p = 0.03). CONCLUSIONS: Older patients, males, and whites were more likely to use these aids, more often pill containers. Our study shows that reminders can assist patients with RA in taking their medications, particularly in situations when they are most prone to forget including being away from home or busy. Use of reminders should be encouraged by providers as a low-cost aid to enhance adherence.

PM655

PERSISTENCE RATE WITH SUBCUTANEOUS BIOLOGIC THERAPIES IN PATIENTS wITH ANKYLOSING SPONDYLITIS (AS)

Govoni M1, Lyu R2, Ding Q2, Fan T3

1Mercer & Co., Inc; Whitehouse Station, NJ, USA; 2Temple University, Philadelphia, PA, USA

OBJECTIVES: This study examined persistence with subcutaneous biologics, and to identify differences among patients with and without DMARD use. METHODS: A retrospective study used IMS Disease Analyzer-Germany, an electronic medical records database. Data for adult (≥18 years of age) AS patients with a prescription for subcutaneous biologic between January 1, 2009 and June 30, 2012 were used for this analysis. The index date was the date of the first subcutaneous biologic prescription. Prescription for any biologic during the pre-index period or diagnosis for rheumatoid arthritis, psoriatic arthritis or other conditions treated with subcutaneous biologics either in pre- or post-index qualified patients for exclusion from the study. Differences between pre-index NSAID naïve and experienced patients were measured using a chi-square test. A logistic regression model was used to further assess the impact of factors associated with the use of reminders. RESULTS: A total of 231 patients were included in this analysis. The mean age of the patients was 47 years, with 70% being female. The majority of patients were Caucasian (85%) and 13% African American. Sixty-five (28%) patients reported using a reminder: 56 (26%) used a prescription reminder, 12 (6%) used calendars, and 3 (1%) diaries. Factors associated with the use of reminders were older age (p = 0.004), being white vs. Hispanic or African American (p = 0.003), being male vs. female (p = 0.005). Working patients were less likely to report using reminders (p = 0.006). No association was observed for level of education or the use of aids. Use of reminders was associated with domains of self-reported adherence: adherence while away from home (r = 0.16, p = 0.03), when running out of pills (r = 0.15, p = 0.03), and when running out of pills (r = 0.15, p = 0.03). CONCLUSIONS: Older patients, males, and whites were more likely to use these aids, more often pill containers. Our study shows that reminders can assist patients with RA in taking their medications, particularly in situations when they are most prone to forget including being away from home or busy. Use of reminders should be encouraged by providers as a low-cost aid to enhance adherence.
95% CI: 0.53-2.07) and psoriasis (OR: 1.07; 95% CI: 0.56-2.03). CONCLUSIONS: More than half of the RA patients were persistent with the index subcutaneous biologic over a 12-month period with similar persistence rates observed among those with and without psoriasis and DMARD use.

PMS69

IMPACT OF MEDICATION ADHERENCE BY USING INDIAN VERSION COMPLIANCE QUESTIONNAIRE RHEUMATOLOGY (CQR) AND MEDICATION ADHERENCE RECIPE PHARMACY TOOLS ON QUALITY OF LIFE OF PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To assess medication adherence to DMARD in patients with Rheumatoid Arthritis using CQR and MARS tools, identification of factors affecting adherence and its effect on quality of life.

METHODS: A randomly selected sample of 110 adult patients with RA on DMARDs admitted to hospital were asked about their medication adherence, through self-report questionnaire [CQR and MARS] and quality of life was assessed by HAQ (Health Assessment Questionnaire). Additionally, various factors affecting adherence were identified.

RESULTS: According to the tools used, 86.4% (CQR), 74.29% (MARS - mean cut point) and 95.45% (MARS - prior study cut point) of patients showed adherence towards DMARD. Better adherence was seen in patients with primary education (CQR: 94% or secondary education (MARS: 83%). Patients who suffered from RA for more than 2yrs showed better adherence (CQR: 93%) compared to those with recent disease (<2yrs) (CQR: 89%). Non-adherence was seen in patients having co-morbidities compared to patients with only RA (CQR: 91% vs 94%, MARS: 62% vs 82%). Mean HAQ of adherent patients was better (2.83±1.05) than non-adherent patients (3.23 ± 0.74). Adherent patients showed highly active disease state (Mean DAS – 6.70 ± 0.84).

PAS expression in patients with PsA showed highly active disease state (Mean DAS – 6.70 ± 0.84). Conclusions: Patients reporting PASI, HAQ and the resulting utility (including multiplicative terms). Goodness of fit was assessed in Stata 11. SF-36 data were converted to EQ-5D using the mapping by US, 4Janssen-Cilag Ltd, High Wycombe, UK.

Hatswell A.J.

Utility improved over the 24-week blinded period by 0.04/0.06 in the Anti-TNF arms. In regression analysis utility was predicted as 0.897 – 0.004xPASI - 0.298xHAQ.

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PASI, HAQ and utility with previously published estimates, based on the PSUMMIT (HAQ, 0-3 scale) for skin and joints symptoms, respectively. Previous work in the management of PsA has used two of the commonly used measures for PsA are the Psoriasis Area and Severity Index (PASI, 0-100 scale) and the Health Assessment Questionnaire (HAQ, 0-3 scale) for skin and joints symptoms, respectively.

PASI expression in patients with PsA showed highly active disease state (Mean DAS – 6.70 ± 0.84). Conclusions: Patients reporting PASI, HAQ and the resulting utility (including multiplicative terms). Goodness of fit was assessed in Stata 11. SF-36 data were converted to EQ-5D using the mapping by USA, 4Janssen-Cilag Ltd, High Wycombe, UK.

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analgesics were NSAIDs (88.1%), alternative therapies, including glucosamine, 6.3 ± 6.3 years. IPR was reported by 52.0% of the patients. The most prescribed QUALITATIVE EQUIVALENCE BETWEEN A PAPER AND ELECTRONIC TABLET PMS75 have high impact on patients’ lives. <

 despite the use of analogics, over half of the Portuguese patients in SORT reported moderate to severe pain, allowing the diagnosis of these symptoms. These findings suggest that if an improvement of pain management in knee OA can be achieved, it may have high impact on patients’ lives.

 PMS75 QUALITATIVE EQUIVALENCE BETWEEN A PAPER AND ELECTRONIC TABLET VERSION AT THE WOMAC®NRS3.1 AND PATIENT GLOBAL ASSESSMENT®

 Despite the

 of SORT baseline.

 randomized to CZP at Wk0, 91% completed Wk24, 87% Wk48, and 80% Wk96. Rapid improvements observed to Wk24 were maintained to Wk96 for pain (Wk24 and Wk96, CFB: -28.5 and -31.3; MCID: 69.2% and 66.3%), fatigue (Wk24 and Wk96, CFB: -2.0 and -2.4; MCID: 64.1% and 60.4%), HAQ-DI (Wk24 and Wk96: CFB: -0.48 and -0.52; MCID: 48.7% and 48.0%), SF-36 PCS (Wk24 and Wk96, CFB: 8.01 and 9.01; MCID: 77.4% and 78.5%), SF-36 MCS (Wk24 and Wk96, CFB: 4.50 and 4.36%), PrADQL (Wk24 and Wk96, CFB: -3.87 and -4.50), and DLQI (Wk24 and Wk96, CFB: -5.8 and -6.0; MCID: 40.7% and 41.0%). Similar improvements were observed with both dosing regimens and in patients with or without prior anti-TNF exposure. Correlations were observed between improvements in PROs and DAS28 (data not shown).

 Conclusions: Improvements observed to Wk24 in generic and disease-specific PROs were sustained to Wk96 of the RAPID-Psa trial for both CZP dosing regimens.

 PMS77 QUALITY OF LIFE IN PATIENTS WITH AXIAL Spondyloarthritis IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY

 Spondyloarthritis (SpA) is a group of diseases that share common clinical, radiographic and genetic features. Axial SpA is one major subgroup including patients with radiographic (rad-axSpA) and nonradiographic axSpA (nr-axSpA). There has been limited research on nr-axSpA patients in clinical practice and the impact of the disease on patient’s health-related quality of life (HRQoL). The aim of this study was to characterize patients with axSpA in clinical practice and to investigate similarities/differences between rad-axSpA and nr-axSpA with respect to their HRQoL. This study was conducted involving usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication for their condition. Interviews were conducted in two waves of 10 participants each, with revisions to the PGA made in between the rounds, which allowed for the qualitative and quantitative version of the instrument to be evaluated. The PGA recall period was revised from “at this time” in wave 1, to “over the past 24 hours” and bolded for emphasis. In wave 2, similar issues with glare and stylus response were found, while 80% used the correct recall period on the PGA, with 20% using 68 hours. CONCLUSIONS: The study showed excellent qualitative equivalence between the paper and electronic WOMAC® with only minor usability issues. The two wave study design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

 PMS78 QUALITY OF LIFE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY

 In this study, the two wave study design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

 PMS76 LONG-TERM MAINTENANCE OF IMPROVEMENTS IN MULTIPLE FACETS OF PSORIATIC ARTHRITIS WITH CERTOLIZUMAB PEGOL: 96-WEK-PATIENT-REPORTED OUTCOME RESULTS OF THE RAPID-PSA STUDY

 PMS74 INADEQUATE PAIN RELIEF AMONG PATIENTS WITH PRIMARY KNEE OSTEOARTHRITIS - ANALYSIS FROM THE PORTUGUESE SAMPLE OF THE SURVEY OF OSTEOARTHRITIS REAL WORLD THERAPIES (SORT)

 and Painful Disorders (PMD)”, Humarkin Y.1, Harmon C.1, 4objectives: Pain medication diaries have traditionally been collected via paper due to challenges of patients entering unlimited medications, units, dosages, and administration schedules. This study developed an electronic diary that permits site staff to enter medications that patients are taking, enables the patient to update medication taken and to enter new medications within the reporting period, and reduces the possibilities of data entry errors. The objective of this electronic diary was evaluated to ensure that patients in a clinical trial setting could successfully update their diaries in real-time to accurately track pain medication intake.

 PMS77 QUALITY OF LIFE IN PATIENTS WITH AXIAL Spondyloarthritis IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY

 Conclusions: The study showed it is possible to develop an electronic pain medication diary that allows patients to update their medications during a study. Extensive training was provided, the usability of the version two design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

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 PMS74 Inadequate Pain Relief Among Patients with Primary Knee Osteoarthritis - Analysis from the Portuguese Sample of the Survey of Osteoarthritis Real World Therapies (SORT)

 Patients with IPR scored higher than non-IPR patients in WOMAC – Stiffness (61 vs 39.7, p<0.001) and WOMAC – Physical function (59.0 vs 39.4, p<0.001), meaning worse condi-

 The aim of the study was to characterize patients with axSpA in clinical practice and to investigate similarities/differences between rad-axSpA and nr-axSpA with respect to their HRQoL. This study was conducted involving usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication for their condition. Interviews were conducted in two waves of 10 participants each, with revisions to the PGA made in between the rounds, which allowed for the qualitative and quantitative version of the instrument to be evaluated. The PGA recall period was revised from “at this time” in wave 1, to “over the past 24 hours” and bolded for emphasis. In wave 2, similar issues with glare and stylus response were found, while 80% used the correct recall period on the PGA, with 20% using 68 hours. CONCLUSIONS: The study showed excellent qualitative equivalence between the paper and electronic WOMAC® with only minor usability issues. The two wave study design provided the opportunity to detect and make changes to the PGA recall period and formatting that showed improvement in the second wave.

 PMS76 Long-term Maintenance of Improvements in Multiple Facets of Psoriatic Arthritis with Certolizumab PEGol: 96-Week Patient-reported Outcome Results of the Rapid-PSA Study

 Pain medication diaries have traditionally been collected via paper due to challenges of patients entering unlimited medications, units, dosages, and administration schedules. This study developed an electronic diary that permits site staff to enter medications that patients are taking, enables the patient to update medication taken and to enter new medications within the reporting period, and reduces the possibilities of data entry errors. The objective of this electronic diary was evaluated to ensure that patients in a clinical trial setting could successfully update their diaries in real-time to accurately track pain medication intake.

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 PMS77 Quality of Life in Patients with Axial Spondyloarthritis in Clinical Practice in Sweden: Baseline Results from a Longitudinal Study

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 PMS77 Quality of Life in Patients with Axial Spondyloarthritis in Clinical Practice in Sweden: Baseline Results from a Longitudinal Study

 Conclusions: The study showed it is possible to develop an electronic pain medication diary that allows patients to update their medications during a study. Extensive training was provided, the usability of the version two design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.
present study was to measure the functional status and quality of life in RD patients receiving the biologic agent golimumab in Greece (PsA). This potential may help estimating the annual Quality-of-Life (QoL) improvement for 148 patients diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). QoL was estimated with standardized questionnaires such as EQ-5D and HAQ questionnaire. In addition, twenty specific parameters including “general health”, “severity of pain”, “productivity level” et cetera were assessed on 10-point Likert scale. Data was collected by doctors across the country at 3 month intervals (4 waves of questionnaire). A total of 86 patients with RA were recruited; 81 patients with PsA were additionally asked to indicate the difference in their estimated EQ-5D VAS scale of the amount of money per month they would be willing to pay for treatments that would prevent a decline in HRQoL by 10 points. Price sensitivity curves were created by means of linear regression analysis that predicted the proportion of patients who would pay to pay a certain amount of money per month, depending on the amount of money per month.

RESULTS: For both PsA (R² = 0.82) and RA (R² = 0.86) monthly cost out of pocket (x-variable) was a good predictor of the proportion of patients that is willing to pay $100 per month out of pocket whereas this is 47% among PsA patients. CONCLUSIONS: PsA patients are prepared to pay higher monthly cost out of pocket than RA patients. Further research is required to understand what drives this difference.

PM839

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLARTHROPATHY

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OBJECTIVES: To report the long-term effect of certolizumab pegol (CZP) on work productivity and household productivity up to 96 weeks (wks) in patients with active axial spondyloarthropathy (axSpA), including ankylosing spondylitis (AS) and non-radiographic axial spondylarthropathy (nr-axSpA).

METHODS: The ongoing RAPID-axSpA trial (NCT01087762), is double-blind and placebo-controlled to Wk24 and dose-blind to Wk48 and open-label to Wk96. Patients have axSpA according to ASAS criteria, including AS and nr-axSpA patients. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose [LD]) or placebo (PBO) at Wk0, continued on their assigned dose in the OLE. CZP patients entering dose-blind phase were re-randomized to CZP LD followed by CZP 200mg Q2W or 400mg Q4W after Wk42 or, for non-responders, after Wk16. The statistically significant improvements in workplace productivity (specific Work Productivity Survey [WPS]) and household productivity (LOCQ imputation) in patients originally randomized to CZP are summarized descriptively over 96 wks. RESULTS: 325 patients were randomized, of whom 218 received CZP (200mg Q2W or 400mg Q4W) from Wk0. Of patients randomized to CZP at baseline (BL), 93% completed Wk24, 88% Wk48 and 80% Wk96. At BL, 72% of CZP patients were employed outside of the home. Employed CZP patients reported reductions in workplace absenteeism and presenteeism to Wk24, with continued improvements to Wk48 and Wk96. Patients who were employed outside of the home improved productivity up to 96 weeks (wks) in patients with active psoriatic arthritis (PsA).

PM884

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH PSORIASIS ARTHRITIS

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OBJECTIVES: To examine the long-term effect of certolizumab pegol (CZP) on workplace and household productivity up to 96 weeks (wks) in patients with active psoriatic arthritis (PsA).

METHODS: The ongoing RAPID-Psa trial (NCT01087768) is double-blind and placebo-controlled to Wk24, dose-blind to Wk48 and open-label to Wk96. Patients had active PsA, defined New York criteria) and non-radiographic axSpA (nr-axSpA). Patients entered the study like this. The primary endpoint was improvement in work and household productivity up to 96 weeks (wks) in patients with active axial spondyloarthropathy (axSpA), including ankylosing spondylitis (AS) and non-radiographic axial spondylarthropathy (nr-axSpA).

CONCLUSIONS: The initial improvements in CZP with in workplace and household productivity and increased participation in social/leisure activities were continued to Wk96 in axSpA, as in nr-axSpA patients.
with CZP in workplace and household productivity, and social participation were sustained up to 96 wks in PsA patients.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS5

MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES - PART II: DECISION DRIVER CHARTS ACROSS GLOBAL MARKETS

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OBJECTIVES: With rising pressures on health care budgets, health technology assessment (HTA) agencies are increasingly scrutinizing medical devices (MDs) for economic justification. This study aimed to identify and compare the evidence-based level of coverage granted in many unfavorable recommendations from agencies and only a small proportion of unconditionally favorable reviews. As an extension of our work reported at 2013 ISPOR Annual Congress (Dublin, IR) this study aims to: 1) Identify key criteria cited by HTA agencies, 2) Note common criteria among reviews that were positive, negative, or positive with reservations, and 3) Analyze temporal or geographic trends among decision drivers. METHODS: A review of 68 HTAs and reimbursement decisions of implantable MD with a variety of indications was conducted, focusing on decisions published from 2008-2013 identified by Quintiles’ HTA Watch from North America, Europe, and Australia. Clinical, economic, and other factors noted as pivotal to HTA and reimbursement decisions were registered and compared. Importantly, care was exercised to note only the criteria that triggered a HTA to make a favorable or unfavorable decision, as opposed to criteria that were only correlative. RESULTS: Key product attributes affecting HTA decisions include 1) sufficiency and quality of evidence, 2) cost offsets and budget impact, 3) adverse event profiles, and 4) comparison to existing alternatives where available. Notably, 33% of HTA decisions were negative, with many decisions citing insufficient evidence. Additionally, a majority of favorable HTA decisions were reserved in their recommendations, citing a need for additional evidence to uphold the initially favorable recommendation. The relative importance of economic considerations varied across countries. CONCLUSIONS: HTA agencies’ scrutiny of sufficiency of evidence, among other methods, may significantly impact market access of medical devices. As such, manufacturers need careful planning to align evidence development, pricing, and access plans with HTA agency, payer and pricing authority requirements.

PMS6

ANTITNF BIOSIMILARS INDICATED FOR RHEUMATOID ARTHRITIS ARE INCREASINGLY AVAILABLE IN EUROPE: HOW DO Payers AND Key STAKEHOLDERS PERCEIVE THEM?

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OBJECTIVES: The process of bringing a biosimilar to market in Europe is quicker, easier and cheaper than developing a new biologic. As a class, rheumatoid arthritis (RA) has the greatest number of anti-TNF biosimilar molecules in development, with more expected to follow. This research was focused on the key issues reported by payers and stakeholders (KOLs) in four European countries (UK, Italy, Spain, Germany). METHODS: Supported by secondary research our study entailed conducting one hour telephone interviews with influential senior payers involved in budgetary decision making in the national and regional level in addition to KOLs. These structured interviews explored how stakeholders perceived the introduction of anti-TNFs biosimilars. RESULTS: Payers see anti-TNF biosimilars as an opportunity to reduce the biologic budget but KOLs want to treat more patients without having to develop a larger appetite. Greater confidence in the efficacy of biosimilars than their counterparts in Italy. Treatment naive patients are considered most suitable for anti-TNF biosimilars while automatic substitution was not favoured by any respondent. Nonetheless, price played a role and some KOLs stated they may attempt to switch existing patients who have a low risk of acute complications with anti-TNFs. CONCLUSIONS: Biosimilars may be perceived unequally across markets. Manufacturers are likely to require the use of differentiated value stories when presenting their biosimilar products to payers and KOLs, with the latter more inclined to perceive them as an opportunity to treat more patients with the same expenditure instead of reducing budgets. Manufacturers will likely struggle to encourage the switching of existing patients on biosimilars without offering a significant discount. In France and Germany, anti-TNF RA biosimilars are currently generating demand that closely matches their increasing prevalence.

PMS7

COMPARISON OF CLINICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING BIOLOGIC MONOTHERAPY AND BIOLOGIC-CONTAINING COMBINATION THERAPY IN EUROPE

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OBJECTIVES: To assess the clinical characteristics of patients with RA who received biologic monotherapy (“Mono”) or biologic-containing combination therapy (“Combio”) in Europe. METHODS: A multi-country, multi-center medical chart review study of patients with RA conducted in Q4 2012 and Q4 2013 recruited from a large panel to be geographicly representative from across Europe. Patients were included in the study if they received standard of care care and met all inclusion and none of exclusion criteria. The primary outcome was to collect de-identified data on patients who were recently treated with a biologic as part of usual care in France/Germany/Italy/Spain/UK. Physicians were screened for duration of practice (≥ 30yrs) and patient volume (≥ 20 RA biologic patients/year) and recruited from a large panel to be geographicly representative from across Europe. Eligible patient counts (≥ 5yrs) were randomly selected from among the patients visiting each center/practice during the screening period. Physicians abstracted data on diagnosis, treatment patterns/dynamics, and symptomatology/ disease status. Mono and Combo patients were compared used descriptive statis-
OBJECTIVES: To estimate future scenarios of utilization of knee arthroplasty (KAS) revision and to evaluate the impact on primary KA utilization. METHODS: A discrete event simulation model was built to represent the utilization of KA for 20 years (2011–2031) in the Spanish National Health System, especially the burden of KA revision according to different KA types. Data for the KA demand and KA utilization were obtained from the Spanish National Health System and from other European countries. The database was completed with a survey of Spanish orthopedic surgeons. RESULTS: A total of 95,000 KAS procedures and 12,000 KAS revisions were estimated to be performed in 2011. Future KA demand is expected to increase by 2031 to 162,000 KAS procedures, with 21,000 KAS revisions. The utilization of KA revisions in 2011 is 12,000 cases. A total of 5,900 cases are expected to be performed in 2031, representing a 40% increase in the use of KA revisions. CONCLUSIONS: The results of this study suggest that future KA demand and KA utilization will increase significantly in the next decades, with a higher rate of KA revisions. The implementation of cost-effective strategies to reduce KA complications and improve patient outcomes is crucial to manage the rising demand of KA revisions.

PM593
OSTEOPOROSIS PATIENT CHARACTERISTICS OF A PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE CARE MAP OF WOMEN WITH POSTMENOPAUSAL OSTEOPOROSIS (PMO) IN SWITZERLAND (CAMPOS)

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OBJECTIVES: Report baseline patient characteristics of the CAMPOS study, which is evaluating the PMO care map in Swiss clinical practice. METHODS: Between June 2012, 2013, 2014, 2015, 2016, and 2017, 1136 patients were evaluated. RESULTS: At baseline, patients were characterized by a number of chronic diseases. We have characterized cachexia and seen by primary or secondary diagnosis and then compared those with cachexia to all sample of cachexia individuals. Hospitalizations associated with cachexia had an increased LOS compared to their peers. Differences were seen in loss of function (LOF) with cachexia patients ranging from 8.3% to 31.6% increase at the short-term and from 38.3% to 176.9% at the long-term. CONCLUSIONS: Projections of the burden of knee arthroplasty provide a quantitative basis for future policy decisions relating to concentration of high complexity procedures, the non-academic nature (81%), and specializing in rheumatology (71%), recruited 275 women. Two-hundred-sixty-three met the inclusion criteria and were included in the study. Age of 64.2 years and experienced improved mean BMD T-scores at the LS, TH, and FN. At first denosumab injection (baseline) and 1-year follow-up. Descriptive statistics were conducted. RESULTS: 222 women met the inclusion criteria with a mean (SD) age of 64.2 years at baseline and 65.7 years at 1 year follow-up. Descriptive statistics were conducted. 65% of the patients reported a prior fragility fracture, with vertebral the most common site (71.2%) followed by hip (6.8%) and other sites (22.6%, excluding hip). At baseline, 1.7% were receiving vitamin D and 7% calcium supplementation. At 1-year follow-up, all women had BMD assessed at ≥ 2 T-scores were increased to 2.7 (±0.7) at the LS (n=187), -2.1 (±0.7) at the TH (n=65) and -2.4 (±0.68) at the FN (n=123). CONCLUSIONS: Postmenopausal women with OP receiving 2 denosumab injections in Bulgarian clinical practice had a mean age of 64.2 years and experienced improved mean BMD T-scores at the LS, TH, and FN after 1 year. Study funded by Amgen.
CONCLUSIONs: The purpose of this analysis was to estimate how higher persistence in RRMS patients treated with interferon beta-1a and its electronic injection device (Rebismart®) affects the rate of escalation to 2nd line therapies. METHODS: A 2-year, decision-analytic model was developed to track a hypothetical cohort of 1,000 RRMS patients initiating treatment with either interferon beta-1a and Rebismart® or another 1st line self-injectable disease modifying drug (DMD). The model calculated the expected probability of escalating to 2nd line therapy, which was defined as either Gilenya® or Tysabri®. Persistence curves were estimated from a real-world dataset collected through the UK NHS Scottish Registry. Sensitivity analysis described may provide a model for the development of an important tool to assess the substantial burden of osteoporosis and to monitor the quality of care over time.

PMs97
GASTROINTESTINAL RISK FACTORS AND TREATMENT PATTERNS OF RHEUMATOID ARTHRITIS (RA), RHUMATOID ARTHRITIS (RA) OR (NSAID) ANd PROTON PUMP INHIBITORS (PPIS) IN NEwLY dIAGNOSEd Patients between January 1st 2010 and May 31st 2012 were selected. Patients must have had a diagnosis for OA, RA, or AS within 6 months of treatment initiation, but no diagnosis in the year prior. Patients were followed for 6 months to assess treatment patterns. Results were compared to Canadian longitudinal pharmacy data. PATIENTS AND METHODS: Beckerman R. et al. [2010] made a model for the development of an important tool to assess the substantial burden of osteoporosis and to monitor the quality of care over time.

PMs96
CONCOMITANT USE Of NON-STEROIdAL ANTI-INfLAmmATORy dRUGS (NSAIDs) AND PROTON PUMP INHIBITORS (PPIS) IN NEwLY dIAGNOSEd Patients between January 1st 2010 and May 31st 2012 were selected. Patients must have had a diagnosis for OA, RA, or AS within 6 months of treatment initiation, but no diagnosis in the year prior. Patients were followed for 6 months to assess treatment patterns. Results were compared to Canadian longitudinal pharmacy data. RESULTS: There were 692 patients included, 56% females and a mean age of 44 years old. Their most prevalent co-morbidities prior to treatment initiation were affective disorders (14%) and diabetes (12%). 99% of NSAIDs were prescribed by general practitioners, while 90% of PPIS were prescribed by general practitioners. CONCLUSIONS: Patterns observed in the Canadian longitudinal pharmacy data. PATIENTS AND METHODS: Beckerman R. et al. [2010] made a model for the development of an important tool to assess the substantial burden of osteoporosis and to monitor the quality of care over time.

PnD2
A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOThERAPIES USEd FOR PATIENTS WITH ADVANCED PARKINSON’S DISEASE. Ken GI, Cooper K*, Cooper IA*, Smith HTI, ShakhI S*. Sheffield University, Sheffield, UK, *University of Sheffield, Sheffield, UK, **CGR, Brentford, UK OBJECTIVES: To identify the pharmacotherapies used for patients with advanced PD and explore their effectiveness. PATIENTS AND METHODS: The systematic search was conducted in MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, DARE and HTA. A random effects NMA was used to derive the safety of treatment options. RESULTS: Three United Parkinson’s Disease Rating Scale (UPDRS) scores, patient withdrawals, and six adverse events in WinBUGS. An additional analysis was conducted to assess treatment class. Node-splitting approach was used to assess the assumption of consistency when direct and indirect evidence was combined. RESULTS: Forty-three trials with 9,453 patients were identified. Immediate-release levodopa plus pramipexole produced the greatest reduction in off-time relative to immediate-release levodopa plus placebo (1.71 hours/day, 95% CI: 1.15-2.27, p < 0.001). Up to 20% of patients with advanced PD are expected to escalate on Rebismart®, vs. 2.3%; while at the upper bound of the OWSA, 13.3% of Rebismart® patients are expected to escalate vs. 42.7%. CONCLUSIONS: The NMA showed that all levodopa formulations were superior to placebo. However, add-on dopamine agonists were associated with a statistically significant reduction in off-time. Dopamine agonist class as adjunctive to levodopa therapy had the greatest reduction. IPX066 was broadly comparable with add-on dopamine agonists, and comparable with add-on MAOBIs and COMTis on UPDRS scores. However, the treatments were associated with an increase in the risk of having dopaminergic side effects, particularly dyskinesia.
burden. Improving the control of PD motor symptoms on patients may contribute to prevent anxiety and HRQoL deterioration in caregivers.

**PND4**

**A COMPREHENSIVE LITERATURE REVIEW OF THE BURDEN OF GAUCHER DISEASE**

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**OBJECTIVES:** Restless leg syndrome (RLS) is a condition with possibly high prevalence in hemodialysis (6–60% according to the literature), and a specific treatment available. Thus it’s important to identify it among other conditions present in this population that treat RLS in HD patients (such as peripheral vascular disease or neuropathies). An approach based on a self-completed screening test will be assessed in this study, along with an estimation of RLS prevalence in hemodialysis.

**METHODS:** Patients from two hemodialysis units answered a RLS screening test. Those with a positive screening completed the International Restless Legs Syndrome Study Group Rating Scale (IRLS) that assesses symptom severity. A neurologist performed a clinical interview to confirm the diagnosis, including a supervised administration of the IRLS. RESULTS: 164 patients were recruited. Mean age was 65.5 years (range 33–87; Pct25-75: 55.5–77.5), 67% were male and mean time in dialysis was 64.16 months. Self-completed screening test identified 69 possible cases of RLS (42.07%), 44 (26.8%) patients from the IRLS were classified as RLS according to the self-reported IRLS and 79% of them were classified as having moderate to severe RLS symptoms. The clinician confirmed just 22 of those cases (13.4% of the total sample), with a demographic profile similar to the other 67% of patients with RLS (age, gender, time in dialysis).

**CONCLUSIONS:** Diagnosis of RLS is essential to prevent anxiety and HRQoL deterioration in caregivers.

**PND5**

**RESTLESS LEG SYNDROME DETECTION IN HEMODIALYSIS**

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**OBJECTIVES:** Restless leg syndrome (RLS) is a condition with possibly high prevalence in hemodialysis (6–60% according to the literature), and a specific treatment available. Thus it’s important to identify it among other conditions present in this population that treat RLS in HD patients (such as peripheral vascular disease or neuropathies). An approach based on a self-completed screening test will be assessed in this study, along with an estimation of RLS prevalence in hemodialysis.

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**CONCLUSIONS:** Diagnosis of RLS is essential to prevent anxiety and HRQoL deterioration in caregivers.

**PND6**

**CEREBROSPINAL FLUID β-AMYLOID1–42 LEVELS IN THE DIFFERENTIAL DIAGNOSIS OF ALZHEIMER’S DISEASE: SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** The purpose of this study was to carry out systematic review of the literature and meta-analysis to evaluate the diagnostic utility of cerebrospinal fluid (CSF) levels of the 42 amino acid form of amyloid-β (Ab1–42) as a biomarker for differentiating Alzheimer’s disease (AD) from non-AD dementia. **METHODS:** Systematic search of PubMed and EMBASE databases was performed for all published papers using search terms related to Ab deficiency and AD or non-AD dementia, and (ii) assessment of Ab1–42 levels using appropriate comparative tests. **RESULTS:** A total of 15 studies (15 diagnostic evaluation studies) were identified in which levels of CSF Ab1–42 were assessed. Meta-analysis was performed on seven studies that used the same Ab1–42 diagnostic criteria and two non-diagnostic criteria and 4095 healthy subjects and 400 individuals (n = 1587), 10 studies that compared AD with non-AD dementia (n = 860), and four studies that compared a-MCI (amnestic mild cognitive impairment) subjects (n = 6). Overall, Ab1–42 levels were reduced in CSF from AD patients versus healthy controls or non-AD dementia. The effectiveness of this test was evaluated for diagnostic accuracy. Diagnostic accuracy for identifying Ab1–42 ELISA was high (positivity sensitivity 0.772 (95% CI 0.747–0.796); pooled specificity, 0.732 (95% CI 0.699–0.762). **CONCLUSIONS:** Reduced CSF Ab1–42 levels are of potential utility in the differential diagnosis of AD versus non-AD dementia and healthy controls.

**PND7**

**PREVALENCE OF CYSTIC FIBROSIS AMONG THE U.S. NATIONAL MEDICARE POPULATION**

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**OBJECTIVES:** Cystic fibrosis (CF) prevalence according to U. S. geographic region as well as patient age, gender and race was examined in the U. S. Medicare population for patients younger than age 45. **METHODS:** Patients ≤45 years from the Medicare fee-for-service (FFS) population of 40.03 million (2009) were identified. A comprehensive literature was conducted. MEDLINE, EMBASE, CENTRAL and “grey” literature sources published in English between January 1990 and February 2013 were searched for relevant publications. **RESULTS:** A total of 59 publications focusing on the epidemiologic, clinical, and socioeconomic burden of GD, treatment options and guidelines were summarized. The standardized incidence and prevalence of GD in the general population varies from 0.30 to 5.80 per 100,000 and 0.31 to 1.75 per 100,000, respectively, and GD1 is the predominant type in most regions. The risk of mortality is highest in GD patients younger than age 5 years and generally increased after age 55; the life expectancy is lower than the general population. Common manifestations of GD such as anemia, thrombocytopenia, splenomegaly, hepatomegaly and bone disease lead to a decreased quality of life. Reduced CSF Ab1–42 levels are of potential utility in the differential diagnosis of AD versus non-AD dementia and healthy controls.

**PND8**

**RISK OF RELAPSE AMONG PROPENSITY SCORE MATCHED MULTIPLE SCLEROSIS PATIENTS RECEIVING NATALIZUMAB OR PLATFORM THERAPY IN THE US**

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**OBJECTIVES:** To examine claims-based relapse rates and time to relapse among multiple sclerosis (MS) patients treated with platform therapy (interferon beta/glatiramer acetate) in the US. **METHODS:** The Truven Health MarketScan Research Databases were used to identify adults with a MS (ICD-9-CM code 340) diagnosis treated with natalizumab or platform therapy, the first claim between January 1, 2009 and April 1, 2012 was the index. Patients had to have one year continuous enrollment pre- and post-index and remain on index therapy for 12 months. Patients were excluded if they used a non-index therapy in the pre-index. Natalizumab and platform patients were propensity scored matched using nearest neighbor matching on demographic characteristics, selected comorbid conditions and medications, MS severity (using an adaptation of Kurtzke’s Functional System), pre-index relapse and pre-index expenditures. Natalizumab was defined as MS-related index patient (IP) admission, IV or oral cortisone use. Cox Proportional Hazard models were used to evaluate time to relapse, controlling for demographic characteristics and index clinical characteristics. A total of 897 natalizumab patients met the study criteria, 882 of which were 1:1 matched to 882 platform therapy patients (mean age 45 years, 70% female) with a standardized difference ≤0.1 on all matching measures. Compared to platform patients, natalizumab patients were significantly less likely to have MS relapse post-index (26.5% vs. 35.5%, p<0.001), with lower post-index rates of MS-related IP admissions (1.0% vs. 2.6%), IV/corticosteroid use (15.6% vs. 19.0%) and oral corticosteroid use (15.4% vs. 23.1%) (all p<0.01). Natalizumab patients also had a lower rate of relapse-free days (308 ± 283 days, p<0.001). Post-index MS relapse risk was lower for natalizumab patients (HR=0.69, p<0.001) after controlling for baseline characteristics. **CONCLUSIONS:** Natalizumab was associated with a significantly lower risk and rate of MS-relapse and had longer time to a MS-relapse compared to platform therapy.
ment of the catheter tip was associated with fewer shunt failures, as demonstrated in 9 centers. Staging studies that evaluate accuracy in placement of the catheter tip include the AirXpress (Medtronic Inc). In addition to being costly, studies showed shunt revision surgery was associated with significant morbidity and lower long-term QOL. In a study of 80 paediatric Hydrocephalus patients, investigators found that patients with a history of more than 2 shunt revisions had a significantly worse QOL, as measured by the Hydrocephalus Outcomes Questionnaire (HOQ).

CONCLUSIONS: The use of IGNS significantly increases the accuracy of ventricular catheter placement compared to the use of imaging techniques in hydrocephalus patients with a history of shunt insertion. Clinical studies have shown the use of IGNS in shunt placement surgery results in lower shunt failure rates, which improve QOL and lowers the economic impact to payers.

PDN10 ASSESSING THE COMPARATIVE OUTCOMES FROM TERTIFLUNOMIDE AND DIMETHYL FUMARATE STUDIES IN RELAPSING MS: USE OF “NUMBER NEEDED TO TREAT” ANALYSIS

Kayden PJ, Huang MH, Thompson AK, Miller AE, Chadwick DW, Perconte C, McDonald WI

OBJECTIVES: Tertiflunomide and dimethyl fumarate (DMF), oral therapies for relapsing-remitting multiple sclerosis (RRMS), have demonstrated efficacy in clinical trials. Despite challenges in comparing outcomes across studies, exploratory analyses of treatment effects can be compared informally using relative reductions in a specific end point. Moreover, these outcomes do not account for differences in disease severity among study populations or differences on very low event rates. The number needed to treat (NNT) to prevent an event is an important outcome to consider in any comparison across different treatment options. METHODS: NNTs were derived using data from studies with tertiflunomide 14 mg (TEMSO, NCT00134563; TOWER, NCT00751881) or DMF (DEFINE, NCT0042012; CONFIRM, NCT00451451) based on incidence rates across tertiflunomide and placebo treatment groups. RESULTS: Tertiflunomide studies included patients with progressive disease; patients in DEFINE had slightly lower Expanded Disability Status Scale scores. Tertiflunomide and DMF significantly reduced risk of relapse (all studies). NNTs to prevent one relapse in any of the similar studies (5.9 [TEMSO], 5.6 [TOWER], 5.3 [DEFINE], 5.6 [CONFIRM]). Risk of disability progression sustained for 12 weeks was significantly reduced in TEMSO, TOWER, and DEFINE but not CONFIRM. Corresponding NNTs to prevent disability progression were 13.8, 17.4, 10.8, and 10.2. Risk of relapse leading to hospitalization was significantly reduced in TEMSO and TOWER but not in DEFINE and CONFIRM. Corresponding NNTs were lower in TEMSO (12.5) and TOWER (20) than in DEFINE (60) and CONFIRM (60). CONCLUSIONS: Using the NNT approach, we derived estimates for clinical effectiveness of DMF and tertiflunomide. NNTs to prevent disability progression with tertiflunomide showed a consistent significant reduction in risk versus placebo in both TEMSO and TOWER, whereas for DMF, comparable NNTs were derived from DEFINE and not in CONFIRM. Reduction of risk for relapse leading to hospitalization was significant only for tertiflunomide.

PDN11 THE CLINICAL EVIDENCE BASE OF TREATMENT OPTIONS IN ALZHEIMER’S DISEASE: A SYSTEMATIC LITERATURE SEARCH

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OBJECTIVES: Alzheimer’s Disease (AD) destroys brain cells, causing problems with memory, thinking, and behavior severe enough to affect work, family and social life. It leads to loss of daily living activities and over time it is incurable and fatal. Donepezil, galantamine, rivastigmine and memantine are the current treatment options but the latest evidence was not systematically reviewed recently. METHODS: PubMed, Health Technology Assessment Database, NHS Economic Evaluation Database, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, DAHTA-Datenbank, PSYNDEX and PsyCINFO were searched systematically for randomized-controlled studies. For the abstracts that met the pre-defined inclusion criteria, full text articles were obtained. The abstracts that did not meet the search criteria were excluded. Based on these manuscripts it was evaluated whether each study meets the selection criteria. RESULTS: After elimination of duplicates the searched database included 86 articles. Of which 418 articles of which another 299 were excluded based on the title selection; after close review of the study characteristics. The educated people in developing Asia or the neighboring Arab countries. This might reflect the role of hormone in this study is somewhat higher than the usual 2:1 in the standard text and seen in Asia or the neighboring Arab countries. This might reflect the role of hormone in this study is somewhat higher than the usual 2:1 in the standard text and seen in this study. The educational level of patients in Khorasan provinces. Data was collected by employing a 32-item self-administered questionnaire in a face to face interview. RESULTS: A total of 248 patients were recruited (186 female, 75%, 62 male, 25%). The mean age was 31 ± 9.8 (male) and 50 ± 10.3 years (female). The proportion of patients with a history of MS patients was reported in 11%. However, there was no a significant difference between men and women. 56% of patients had a DMD use. Similar rates and trends in the proportion of patients with a DMD were observed when stratified by gender (42.8% [2006] and 51.3% [2012] [female]; 41.5% (2006) and 50.7% (2012) [male]), respectively. CONCLUSIONS: In a recent 5-year period, MS prevalence in a 15,000 insured population increased slightly, with a greater increase in the likelihood of DMD use.

PDN14 THE CHARACTERISTICS OF MULTIPLE SCLEROSIS IN IRAN

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OBJECTIVES: Multiple Sclerosis (MS) is a chronic disease of the Central Nervous System. The aim of this paper is to characterize the various clinical and demographic feature of the MS population. METHODS: In a 6-month cross-sectional study 488 patients were investigated in Khorasan provinces. Data was collected by employing a 32-item self-administered questionnaire in a face to face interview. RESULTS: A total of 248 patients were recruited (186 female, 75%, 62 male, 25%). The mean age was 31 ± 9.8 (male) and 50 ± 10.3 years (female). The proportion of patients with a history of MS patients was reported in 11%. However, there was no a significant difference between men and women. 56% of patients had a DMD use. Similar rates and trends in the proportion of patients with a DMD were observed when stratified by gender (42.8% [2006] and 51.3% [2012] [female]; 41.5% (2006) and 50.7% (2012) [male]), respectively. CONCLUSIONS: In a recent 5-year period, MS prevalence in a 15,000 insured population increased slightly, with a greater increase in the likelihood of DMD use.
CATHETERS (AISC) IN THE TREATMENT OF HYDROCEPHALUS

THE CLINICAL AND ECONOMIC VALUE OF ANTIBIOTIC-IMPREGNATED SHUNT PNd17

Neurological Disorders – Cost Studies

NORTH AMERICAN STUDIES: To date, there is no evidence for the effectiveness and types of multiple sclerosis (MS) in Latin America. METHODS: We searched Medline, Embase, Scielo and LILACS using key words “multiple sclerosis” and “esclerosis múltiple”, plus “Latin America” and all country names. Accepted were full articles only. Results: We report original research in any language at any time, with MS diagnosed using any acceptable criteria. Clinically isolated syndrome was excluded. RESULTS: 1482 articles were identified and 263 reviewed in full, 88 were rejected and 115 were analyzed (38 prevalence, 3 incidence, 2 both, 72 clinical epidemiology, 68 (59%) full text and 47 (41%) abstracts. Studies originated in 14 countries, mostly larger, more affluent nations (47% Brazil, 15% Argentina, 8% Mexico). Prevalence studies from 2009 to 2012 identified 121,402 MS cases from 1968-2012; rates ranged from 0.15/100,000 person-years in Panama to 1.76 in Argentina (mean=1.32, median=1.35). 3.87/3.65 new cases/year in Latin America. Authors noted increasing prevalence and incidence rates over time. Clinical epidemiology MS data were obtained from 94 studies; 66% used Poser criteria, 48% McDonald (various versions), and 34% other, from 19,893 patients (72% females). The average age at assessment was 38.2 and 32.2 at a disease onset with average EDSS of 3.1. The relapsing-remitting form was most prevalent (74% of cases), followed by secondary progressive (22%) and primary progressive (4%) forms. CONCLUSIONS: No studies examined 19,357 MS cases from 1968-2012; rates ranged from 0 in a group larger, more affluent nations (47% Brazil, 15% Argentina, 8% Mexico). Prevalence and incidence rates varied across different countries in Latin America in a low to medium range, but are increasing as reported in the reviewed studies. Information is scant with many gaps. More research is needed to provide a basis for decision making and budget allocations.

BDUCT IMPACT ANALYSIS OF FINGOLIMOD IN RELAPSE-REMITTING MULTIPLE SCLEROSIS

Objective: To investigate the clinical and economic impact of fingolimod in patients with relapsing-remitting multiple sclerosis (RRMS) in Italy. METHODS: A retrospective, observational, cohort study of patients with RRMS treated for ≥ 1 year with fingolimod in Italy. Data were collected from 1st January 2010 to 31st December 2013 and included information on patient demographics, Charlson Comorbidity Index (CCI), disease activity, adverse events, and resource utilization. The primary endpoint was treatment efficacy, measured by change from baseline in the Expanded Disability Status Scale (EDSS) at 12 months. RESULTS: 1,900 patients were included in the analytical cohort. Baseline characteristics were similar across treatment groups. At 12 months, the mean change in EDSS was -0.2 (95% CI -0.3 to -0.1) in the fingolimod group and -0.1 (95% CI -0.2 to -0.0) in the control group. The treatment difference was statistically significant (p<0.001). Adverse events were reported in 32% of patients in the fingolimod group and 28% in the control group. The most common adverse events were infections, gastrointestinal disorders, and fatigue. The cost savings associated with the use of fingolimod were estimated at €141.7 million over one, three, and five years, respectively. CONCLUSIONS: The use of fingolimod was associated with significant clinical benefits and cost savings in patients with RRMS in Italy.
This analysis aimed to assess if the early switch from IFNB to fingolimod impacts MS clinical course. This promotes better resource utilization from a Portuguese hospital perspective. METHODS: This analysis was based on TRANSFORMS phase III trial extension data. A cost-effectiveness model was developed to calculate the cost per relapse avoided with a 4.5 years of continuous treatment with fingolimod (early initiation) versus 1 year of treatment with IFNB followed by a 3.5 years of treatment with fingolimod (delayed treatment). A Portuguese hospital perspective was adopted addressing only direct costs: drug, monitoring and relapses' treatment. Drug costs were derived from Portuguese list prices, while a 50% cost of each complication was obtained from the Diagnosis Related Groups tariff. The costs of relapses were derived from the Portuguese literature. RESULTS: Assuming there are 819 patients treated with IFNB that are poor responders, the early treatment with fingolimod resulted in more relapses avoided when compared with delayed treatment with fingolimod (2,212 versus 1,843). The early treatment with fingolimod led to an increased cost of drug acquisition costs, but reduced costs associated with relapses' treatment. The total cost per relapse avoided was €80,820 per early treatment versus 79,257,091 for delayed treatment. This represents an average incremental investment of 1,933€ per patient per year. The early strategy resulted an incremental cost effectiveness ratio of 19,358€ per relapse avoided versus delayed per the delayed strategy. CONCLUSIONS: Under the Portuguese hospital perspective, early treatment with fingolimod is expected to result in better clinical outcomes associated with a more efficient health care resources allocation.

PND21
COST ANALYSIS OF TWO AFTERCARE STRATEGIES IN CHRONIC CONTINUOUS INTRACTABLE BACLOFEN THERAPY IN PATIENTS WITH INTRACTABLE SPASTICITY
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OBJECTIVES: Intrathecal baclofen (ITB) therapy is indicated for use in the management of intractable spasticity. Patients treated with ITB require a pump refill at least once every three months in the hospital (standard care (SC)). Since SC can be very burdensome for both patients and informal caregivers, an alternative approach (Care4homecare) has been developed which enables patients to receive intrathecal baclofen at home. Moreover, reliance of specially trained nurse practitioners ensures that there is no reduction in effectiveness. We compared the costs of both strategies.

METHODS: Resource use in both strategies was estimated using observational data of 38 adult patients with spasticity (due to, e.g., multiple sclerosis or spinal cord injury) that are currently living at home. We then combined this data with expert opinion and the Dutch costing manual to estimate the total one-year costs from a societal perspective. RESULTS: Patients included in this study had an average age of 56 years and 50% was men. The patients scored on average 44±12.5 points on the Care Dependency Scale. The Care4homecare strategy involves care that is almost identical to SC and therefore can result in comparable medical costs. However, patients receiving Care4homecare do not incur any travel costs compared with SC patients (489€). In addition, the productivity costs of informal caregivers (SC 195€; Care4homecare 40€) and of patients treated with Care4homecare are less than the costs of patients receiving SC. From a societal perspective, the total costs of Care4homecare will be lower than those of SC. CONCLUSIONS: Care4homecare is an alternative approach to treat patients with intractable baclofen that can be cost-neutral from a health care sector perspective. Moreover, it can be a welcome option for many patients and caregivers who want to avoid the burden of regular hospital visits.

PND22
COST ANALYSIS OF THE USE OF GLATIRAMER ACETATE COMPARED TO INTERFERON-Å IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS AND SPASTICITY
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OBJECTIVES: To analyze the costs associated with first-line use of glatiramer acetate (GA) compared to interferon-B (INF-Î±) in patients with relapsing-remitting multiple sclerosis (RRMS) and spasticity from the perspective of the National Health System of Spain. METHODS: A cost analysis of treatment and spasticity management with INF-Î± compared to GA for 6 months was analyzed. The clinical data were taken from the ESCALA study, which showed an improvement in spasticity in terms of spasm frequency, muscle tone, and pain 3 and 6 months after the start of GA therapy. Unit costs for the resources used were taken from the BOTPLUS 2.0 database and available literature. The cost analysis is expressed in euros as of 2014, and a price discount of 7.5% was applied as set forth in Spanish Royal Decree 8/2010. RESULTS: The costs associated with the management of RRMS, spasticity, and relapses using INF-Î± compared to GA for 6 months were €4,671.31 and €7,078.02, respectively, generating a cost savings of €2,406.72/patient, in favour of GA. CONCLUSIONS: The use of AG in the first-line treatment resulted in a cost saving of €2,406.72/patient with RRMS not only due to the effects of the drug, but also due to a strategy that offers savings cost after 6 months from the start of treatment. To initiate the treatment with AG and keep it in patients with optimal response would be a more efficient treatment option than INF-Î±.

PND23
SYSTEMATIC REVIEW OF THE ECONOMICS OF MULTIPLE SCLEROSIS IN LATIN AMERICA
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OBJECTIVES: To summarize published articles dealing with economic issues related to multiple sclerosis (MS) in Latin America. METHODS: We searched Medline, Embase, Scielo and LILACS using the key words “multiple sclerosis” and “escallospasticity” in combination with the key words “cost of illness” or “cost-effectiveness.” We included articles published in English or Spanish. A systematic search of the literature was performed using a predefined check list. RESULTS: Thirty-seven full-length articles and two abstracts reporting costs were reviewed. Two studies reported AED costs, drug-specific adverse event costs and non-drug health care costs subsequent to the AED costs. Two studies used a meta-analytic approach to estimate the cost of specific AEDs and the overall subsequent non-drug health care cost without stratification by event. Eighteen studies reported AED acquisition costs but did not report any other subsequent AED-related health care costs stratified by treatment. Thirteen studies reported the whole cost of illness with only a list of AEDs included. To date, no study has been specifically designed to compare the total costs between EAED and nEAED use, although some studies compared direct and indirect cost of EAED use. Conclusions: Insufficient data and heterogeneity in methodology prevent valid comparisons being made between the total cost of EAEDs and nEAEDs. More research is required to identify if meaningful differences in the total cost of treatment exist between EAEDs and nEAEDs.
COST-EFFECTIVENESS ANALYSIS of cohorts, based on the matched sample. Pharmacy benefits 1 year before and after index date. Study outcomes, including (PSM) to control for age, region, gender, index year and baseline Charlson baseline characteristics were balanced. A higher percentage of patients with PD botulinumtoxinA (798750 RUB/23287 $) and standard therapy (873312 RUB/25461 $). Total direct cost was highest in severe stages, being in year 4, 4,177,32 HYIV (95%CI: 21.95–73,751.10) and 1,66,66 HYIV (95%CI: 893,97–6,319.35) compared to year 1, 1,50,15 (95%CI: 624,66–2,977,27 HYIV (95%CI: 53–14,565,68). Direct medical costs ranged from 886,92 (95%CI: 475,13–1,298,11) HYIV and 2,376,30 HYIV (95%CI: 53–12,405,73) in year 1 to 1,099,96 HYIV (95%CI: 942,43–1,327,49) and 2,768,49 HYIV (95%CI: 34–21,524,76) at year 4. Direct non-medical cost variation was determined by PD temporal evolution, increasing between year 1 and 4 within each stage, 724,73 to €1,245,20 HYIV and €653,27 to €1,675,35 HYIV. Conclusions: The economic burden of PD increases with duration and severity of the disease, progressively impairing the direct, medical and non-medical costs. Besides to improve patients’ HRQoL, therapies aimed at controlling the symptoms severity will favor a more efficient management of the disease.

PND30

OBJECTIVES: To describe the medical and non-medical direct costs of PD in relation to the total direct cost and its variation with disease severity during 4 years of follow-up. METHODS: A descriptive, observational, longitudinal study in PD patients. RESULTS: Data were collected on 3 consecutive months, yearly, for 4 years. Direct medical (funded medical equipment, medications and medical assistance) and direct non-medical costs (alternative care, home assistance, non-funded medical equipment and medications) for 4 years depending on severity by Hoehn and Yahr (HY) was described. Costs were estimated by multiplying rates obtained from the database Obilike (http://www.obilike.com) and pharmacy costs from the BotPlus web (https://botplusweb.portalfarma.com) by the number of resources used. Costs were updated to Spanish €, 2012. RESULTS: 198 patients were included. Average: 63±11 years, 50% male, mean PD duration of 6±4 years. Mild (HY-I-II) and moderate (HY-III) patients showed increase of 76%, respectively, compared to year 1. Total direct cost was highest in severe stages, being in year 4, 4,177,32 HYIV (95%CI: 21.95–73,751.10) and 1,66,66 HYIV (95%CI: 893,97–6,319.35) compared to year 1, 1,50,15 (95%CI: 624,66–2,977,27 HYIV (95%CI: 53–14,565,68). Direct medical costs ranged from 886,92 (95%CI: 475,13–1,298,11) HYIV and 2,376,30 HYIV (95%CI: 53–12,405,73) in year 1 to 1,099,96 HYIV (95%CI: 942,43–1,327,49) and 2,768,49 HYIV (95%CI: 34–21,524,76) at year 4. Direct non-medical cost variation was determined by PD temporal evolution, increasing between year 1 and 4 within each stage, 724,73 to €1,245,20 HYIV and €653,27 to €1,675,35 HYIV. Conclusions: The economic burden of PD increases with duration and severity of the disease, progressively impairing the direct, medical and non-medical costs. Besides to improve patients’ HRQoL, therapies aimed at controlling the symptoms severity will favor a more efficient management of the disease.

PND31
Pharmacoeconomic aspects of multiple sclerosis treatments in Iran

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OBJECTIVES: Multiple Sclerosis (MS) is a chronic and progressive which represents a catastrophic payment to patient, society and health care system. Iran, differing to the other countries in MS incidence, is considered to have the highest prevalence of MS. Although much is known about the MS cost in the world, there is very a paucity of the MS cost study in Iran. The aim of study was to estimate the costs and QOL in MS individuals and determine whether these costs increase as disability progress. METHODS: We studied 160 MS patients who attended in the MS...
association of Khorasan privence (the widest province in Iran). Quality of life was measured using the MOSQLQ-54 instrument. Data was collected by employing a 32-item self-administered questionnaire in a face to face interview. Parametric, nonparametric tests and descriptive statistics analysis were applied (p-value<0.05). Patients were grouped into three disability stages according to their Expanded Disability Scale Score (EDSS) results. RESULTS: The Patients mean age were 31.78 (SD: 9.67). 54% % 73.8 were female and %26.2 were male, and their mean EDSS was 2.4 (SD: 1.26) whereas EDSS increases, the costs also increases, which is a positive correlation. The mean EDSS was 5.4 that as EDSS increases, whereas EDSS decreases, which is a negative correlation. The MS medications [Interferon] have a cost around $4625 per year for each patient that are subsidized about $24452 by governmental sector. Up to $17104 are paid by insurance and $5263 directly by patients. The costs per patient per year were calculated as $11560 - $27970.559. EDSS= 2-9. $296,000. 30015.645 (EDSS-3-4.5) and $34678.776 - $34799.22 (EDSS - 5-7.5). CONCLUSIONS: We conclude that the results are relevant in MS, especially when disability increases. The catastrophic cost has a high burden to patients, society and health care system.

PND2

WHOLE EXOME SEQUENCING AS A DIAGNOSTIC TOOL FOR COMPLEX NEUROLOGICAL DISORDERS

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OBJECTIVES: The primary objective of this study is to elucidate the effect of whole exome sequencing (WES) in diagnosing children with a developmental delay due to unexplained conditions presumed to be genetic: A secondary objective is to collect relevant data on children to gain insight into the total diagnostic time for the traditional diagnostic pathway and the additional costs to diagnose a patient using WES.

METHODS: We included twenty children at the Sylvia Toth Centre (STC) in Utrecht University Medical Centre, who have undergone extensive previous diagnostic workups and for whom no diagnosis was found after the last extensive workup. On all twenty children and parents WES will be performed, thereby obtaining a list of exonic and intronic changes. A final diagnosis for each patient and the costs to put WES into standard diagnostic practice at the STC and similar genetic centers over the world.

PND3

FINANCIAL AND CLINICAL IMPLICATIONS OF INTRAMUSCULAR VERSUS SUBCUTANEOUS INTERFERON BETA-1A IN PORTUGAL, BASED ON THE FINDINGS FROM THE COCHRANE COLLABORATION REVIEW OF FIRST-LINE TREATMENTS FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS

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OBJECTIVES: To estimate the clinical and financial impact of Interferon beta-1a intramuscular (IM) and subcutaneous (SC) formulations in Portugal, based on the findings from Cochrane review regarding first-line treatments for relapsing-remitting multiple sclerosis.

METHODS: An Excel® based cost-calculator was developed. Prevalence, epidemiology and mortality estimates for causative neurological conditions as well as costs were extracted from the literature. Unit costs (drugs, hospitalisation etc.) were taken from national databases and standard care treatment mix and resource use were derived from a US claims database. A range of market uptake rates were used with further sensitivity analyses undertaken.

RESULTS: The estimated cost of standard care in Scotland for PBA is circa £32.4 million annually (circa 22,500 patients). In year 1 following introduction, 67 patients are expected to receive Nuedexta, resulting in a cost increase of £1.0 million (circa per patient). By year 5, 386 patients are expected to receive Nuedexta, resulting in a projected total annual cost of £34.6 million. Therefore the estimated annual budget impact of Nuedexta ranges from £0.15 million (year 1) to £8.81 million (year 5). The incremental cost per patient is £2,246. The model was sensitive to changes in uptake rates, cost of background therapy and PBA symptom severity.

CONCLUSIONS: When patients with moderate to severe PBA symptoms receive treatment, the projected cumulative year 5 budget impact estimate is £7.56 million. The cost of treating Nuedexta in Scotland is modest. Even if more patients are identified, the relatively small incremental cost per-patient of Nuedexta is unlikely to have a major impact on the Scottish NHS.

PND36

ANALYSIS OF EXPENDITURE IN MULTIPLE SCLEROSIS DISEASE MODIFYING THERAPIES EVOLUTION BETWEEN 2004-2013 IN SPAIN

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OBJECTIVES: To analyze factors of recent evolution of Multiple Sclerosis (MS) Disease modifying Therapies (DMT) budgets in Spain between 2004 and 2013. METHODS: 2004-2013 single DMT monthly expenditure was provided by IMS Health. Monthly and annually evolution of number of patients, billing, drug cost per patient and cost per year of treatment were calculated. Two periods: 2004-2013 and 2017 (start marketing second lines DMT) - 2013 period were analyzed for each DMT line. (First line: subcutaneous and intramuscular interferon (IFN) -1a, subcutaneous IFN -1b and glatiramer acetate injection. Second line: natalizumab and fingolimod). RESULTS: During 2004-2013 DMT expenditure increased from €115.5M to €39.3M due to: a) A greater number of patients 147% (10.60 % annual growth per year) and a further growth of annual cost per patient: 12% (1.29 % annual growth per year). In December 2013 second lines classes correspond to a 29.61% of DMT expenditure. Annual cost per patient in second line represents 70% over cost per treated patient and 83% greater than first line DMT cost per year. Year 2017 is omitted from analysis (Only 68 second-line treatments and M1 44% of associated expense) and is analyzed 2008-2013 period, second-line DMT represent 43% of new treatments causing a 60% increase in DMT expenditure. In 2013 second line DMT participation reaches 64% of new regimes causing the 79% of increase DMT expenditure. CONCLUSIONS: The growing incorporation of new therapies and the notorious rise in the number of treated patients (29% annual growth per year) are components to consider in the pharmaceutical budget management.

PND37

HEALTH CARE RESOURCE USE AND COST OF MULTIPLE SCLEROSIS IN SLOVAKIA: RESULTS FROM THE NATIONAL CROSS-SECTIONAL STUDY

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OBJECTIVES: Comprehensive economic assessment of multiple sclerosis (MS) according to EDSS states can only be assessed by evaluating MS management in real clinical practice. The objective of this cross-sectional study was to measure the...
resource utilisation and the costs associated with health care management of MS in Greece, and to provide a basis for costs calculated with the use of a subcutaneous interferon beta-1a (SC IFN-1a) vs. intramuscular interferon beta-1a (IM IFN-1a) over 2 years in the management of relapsing forms of multiple sclerosis (MS) from a US health care payer perspective. METHODS: A 2-year decision analytic model was populated with data from the LIFELink and EVIDENCE studies. The model results are most sensitive to drug cost. CONCLUSIONS: A cost-effectiveness assessment may facilitate the decision-making process in selecting MS treatments. Using the highest-quality clinical data (Level 1, head-to-head study, EVIDENCE), the cost-effectiveness of 44 mcg SC IFN-1a was shown to be favourable compared with 30 mcg IM IFN-1a.

**PDN41**

**Cost-Effectiveness Evaluation of Data from the Evidence of Interferon Dose-Response: European North American Comparative Efficacy Study**

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**AIMS:** To use health economic modeling techniques to quantify and compare the cost-effectiveness of Lacosamide (LCM) in the management of epilepsy partial onset seizures in adults. METHODS: A decision analytic model was developed using 2014 wholesale and retail pricing data with consideration of patient copayment in the base case. RESULTS: The cost-effectiveness for 44 mcg SC IFN-1a and IM IFN-1a during the comparative phase was $123,854 and $148,749 per relapse avoided, respectively. The cost-effectiveness of patients who remained on 44 mcg SC IFN-1a throughout the study was $99,398 per relapse avoided, while the cost-effectiveness of IM IFN-1a patients who switched to 44 mcg SC IFN-1a for the open-label extension phase had an annualized relapse rate of 0.32. These data were used to model the cost-effectiveness of 44 mcg SC IFN-1a and IM IFN-1a (independently and together) over 2 years. A comprehensive literature search was conducted to test the model assumptions. The model was robust and was most sensitive to DMD cost. CONCLUSIONS: This decision analytic model evaluation shows that remaining on 44 mcg SC IFN-1a and switching from IFN-1a to 44 mcg SC IFN-1a were cost-effective treatment strategies.
and secondary analysis, respectively. Extensive sensitivity analyses indicated that results were robust. The most influential parameters were the utility estimates, probability of hospitalization per seizure and unit cost of hospitalization. The BIA showed that the annual cost of treating uncontrolled epileptic patients with LCM in Greece ranges between €274.9 and €271.5 million, in the primary and secondary analysis compared to the reference scenario with standard AED (€273 and €279.9 million). CONCLUSIONS: LCM appears to be both less costly and more effective compared with standard AED treatment in Greece and results in cost savings ranging between €2.4 and €8.5 million. Study funded by UCB Pharma.

PN43 COST-EFFECTIVENESS OF SUBCUTANEOUS VERSUS INTRAMUSCULAR INTERFERON BETA-1A IN PORTUGAL BASED ON THE FINDINGS OF COCHRANE COLLABORATION REVIEW OF FIRST-TIME TREATMENTS FOR RELAPSE-REMITTING MULTIPLE SCLEROSIS Silvia N., Sereno, 1M.; Moleti, 2D.

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OBJECTIVES: To estimate the cost-effectiveness of interferon beta-1a subcutaneous (SC) when compared with interferon beta-1a intramuscular (IM) in Portugal, based on the findings published by the Cochrane review of first-line treatments for relapse-remitting multiple sclerosis. METHODS: An Excel-based model estimated the number of relapses and costs incurred by a cohort of 3,000 patients treated with two types of interferon beta-1a. The model evaluated the consequences of each treatment based on the findings of a Cochrane meta-analysis (Filippini 2013). The analysis was performed from a Portuguese NHS perspective, including only direct costs. Costs of relapse were obtained from a local publication (Matias C, 2006) whereas costs of both drugs were obtained from local official databases (Catâlego). Although efficacy was kept constant as Cochrane did not report outcomes based on EDSS, costs of relapse were available for patients with different EDSS values, thus allowing estimation of cost-effectiveness for different types of population. RESULTS: According to the model, over a 2 year period and in a population with EDSS ≤ 3, treatment with IM interferon beta-1a will result in a total of 2,228 relapses, whereas treatment with SC interferon beta-1a will result in 1,709 relapses and a total cost of 70,480,835 €. For a population with EDSS between 3.5 and 4.5 cost values for IM and SC are 72,141,975€ and 72,451,157 €, respectively. Cost-effectiveness ratios were 1,748€ per relapse avoided when EDSS ≤ 3 and 1,817€ per relapse avoided when EDSS between 3.5 and 4.5. CONCLUSIONS: Considering that the cost of a relapse varies between 3,896€ and 5,000€ the model results were robust. The most influential parameters were the utility estimates, probability of hospitalization for seizure and unit cost of hospitalization. The BIA showed that the annual cost of treating uncontrolled epileptic patients with LCM in Greece ranges between €274.9 and €271.5 million, in the primary and secondary analysis compared to the reference scenario with standard AED (€273 and €279.9 million). CONCLUSIONS: LCM appears to be both less costly and more effective compared with standard AED treatment in Greece and results in cost savings ranging between €2.4 and €8.5 million. Study funded by UCB Pharma.

PN44 TREATING VERSUS NON-TREATING OBSTRUCTIVE SLEEP APEA IN ITALY AND FRANCE: A MARKOV MODEL-BASED COST-EFFECTIVENESS ANALYSIS Whitehouse 1T., Da Deppo 1D., Lazzaro 2C., Pedretti 3R., La Rovere 4MT., Pepin 1L., Delay 1N.

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OBJECTIVES: To investigate the cost-effectiveness of treating versus not treating obstructive sleep apnea (OSA) in Italy and France METHODS: A 5-year, 10-state Markov model simulating the health state transitions of patients with obstructive sleep apnea (OSA) diabetes, hypertension, myocardial infarction (MI), post-MI, stroke, post-stroke, atrial fibrillation [AF], heart failure [HF], and death; was developed to compare costs, outcomes and incremental cost-effectiveness ratios between current practice, standard medical practice, and a non-treatment option. The model included an initial health state followed by 10 subsequent health states. A 2-year transition probability matrix, estimated using the Finetech-Brindley device) compared to medical treatment (anticholinergics + catherization) in complete spinal cord injured patients with a neurological blader. METHODS: A probabilistic Markov model was elaborated with a 10-year time horizon, one-year cycles and a 2.5% discount rate. Three irreversible states were defined: 1) treatment without urinary complication, 2) surgery for urinary complication (shrinkutometory, urinary derivation); 3) death. Reversible states (urinary calculus; Finetech-Brindley device failures) were simulated in the two first irreversible states. The primary analysis was performed to estimate transition probabilities and Quality Adjusted Life Years (QALYs). In the perspective of the French Healthcare System, costs were estimated from a published comparative cost-effectiveness research on levodopa treatment for Parkinsons disease published in 2014. Costs of treatment were obtained from the French 2013 perspective payment system (PMSI) classification. RESULTS: In the primary analysis, the cost-utility ratio was 10,647/QALY gained. At a 30,000€ willingness-to-pay threshold, the model results were robust. The most influential parameters were the utility estimates, probability of hospitalization for seizure and unit cost of hospitalization. The BIA showed that the annual cost of treating uncontrolled epileptic patients with LCM in Greece ranges between €274.9 and €271.5 million, in the primary and secondary analysis compared to the reference scenario with standard AED (€273 and €279.9 million). CONCLUSIONS: Our model shows that SARS using Finetech-Brindley device offers the most important benefit and should be considered cost-effective at a 30,000€ ceiling ratio. Despite a high uncertainty, EVPI and partial EVPI may indicate that further research would not be profitable to inform decision making.

PN47 COMPARISON OF A MARKOV COHORT MODEL AND A DISCRETE-EVENT SIMULATION FOR ECONOMIC ANALYSES OF TREATMENTS FOR MULTIPLE SCLEROSIS Kampal A., Talazolzi A., Leipold R., Santa S.

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OBJECTIVES: Multicentric sclerosis (MS) is a disease with lifelong impact, making the cost-effectiveness (CE) of its treatments particularly sensitive to assumptions concerning the severity and evolution of the disease. METHODS: A similar population was simulated in the MM and the DES model, aggregated cost and utility estimates were compared over various time horizons. The average expanded disability status scale (EDSS) term was excluded from the DES model, the natural history simulations of the two models agreed more closely. CONCLUSIONS: Structural SA can help quantify the impact of key modeling decisions in this study, a comparative MM and a DES model showed that natural history predictions diverge over long time horizons, in part due to the consideration of disease history in the DES model. A better understanding of the differences between the two model designs helps ensure interpretation of the model results while taking into consideration the assumptions embedded in those designs.

PN48 THE LONG-TERM VALUE OF GLATIRAMER ACETATE FOR THE TREATMENT OF RELAPSING REMITTING MULTIPLE SCLEROSIS IN THE NETHERLANDS Whitehouse J.T., Peinemann, UK, 2Quintiles, Reading, UK

OBJECTIVES: To evaluate the cost-effectiveness of glatiramer acetate (Copanox®) as a disease-modifying treatment (DMT) for relapsing-remitting multiple sclerosis (RRMS). METHODS: A Markov model followed patients over 50 years through 21 health

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states: Expanded Disability Status Scale (EDSS) 0–9 for patients with RRMS and secondary progressive multiple sclerosis (SPMS) for patients with this disease.

OBJECTIVES: To calculate the expected value of partial perfect information (EVPPI) for the assessment of the cost-effectiveness of treating RRMS using teriflunomide and fingolimod in the treatment of RELAPSING-REMITTING MULTIPLE SCEROSIS.

Methods: A cost-effectiveness analysis was performed for 200 registered patients in Serbia could be €466,857.00 Euro.

reimbursement Listing).

minimisation) and data from Health Insurance Fond of Republic Serbia (2014) for treatment for cystic fibrosis.

Objective: To compare the cost-effectiveness of additional clinical trials. The evaluated outcomes were the precise knowledge of the disability progression efficacy of teriflunomide would allow health economists to better assess the impact of new treatments on patients care.

COnclusiOns: In the Netherlands, glatiramer acetate is a cost-effective treatment for N-FDS patients who are resistant or intolerant to oral therapy. However, many data included limitations and uncertainties within the DMT modelling. Additionally, the expected value of sample information analysis (EVSI) would be required in order to evaluate more precisely the cost-effectiveness of additional clinical trials.

COnclusiOns: Compared to patients in the comparator cohort, MS patients in the Medicare program incurred substantially higher health care resource utilization and costs.

COnclusiOns: Expanded Disability Status Scale (EDSS) 0–9 for patients with RRMS and secondary progressive multiple sclerosis (SPMS) for patients with this disease.
CHYLOMICRONEMIA SYNDROME – A SIMULATION MODEL APPROACH

Objectives: To estimate long term disease progression, costs and consequences of acute pancreatitis for FCS. An effective triglyceride lowering intervention could mitigate the consequences of FCS significantly.

Results: FCS patients are at high risk of life-threatening and costly acute pancreatitis. Reduction in triglyceride levels has a significant impact of morbidity and mortality associated with acute pancreatitis. FCS patients present massively elevated triglyceride levels (typically ≥2,000 mg/dL), resulting in increased risk of recurring acute pancreatitis. Standard triglyceride lowering medications are ineffective for FCS patients. A restrictive low fat diet to control their triglyceride. There is limited literature about long-term progression, the burden of illness or consequences of acute pancreatitis for FCS. An effective triglyceride lowering intervention could mitigate the consequences of FCS significantly.

PND5

LONG-TERM COSTS AND CONSEQUENCES OF PATIENTS WITH FAMILIAL CHYLOMICRONEMIA SYNDROME – A SIMULATION MODEL APPROACH

Objectives: To explore how MS DMT-persistence can be modelled, compare model’s performance and assess the independent drivers for DMT persistence. An effective triglyceride lowering intervention could mitigate the consequences of FCS significantly.

Methods: A parametric survival model was used to model DMT-persistence. Models were compared based on goodness-of-fit statistics (Akaike and Bayesian information criteria).

Results: Mean follow-up from first MS-symptoms and at first DMT-initiation were 13 and 12 years, respectively. 73% of patients were female. Based on the data exploration of all known covariates, three DMT-persistence approaches with different interpretations, selected covariates and data needs were modelled: 1) sex, birth year, time from symptom to DMT, age, DMT line (1st, 2nd, 3rd, 4th, 5-7th), DMT (interferon-β1a and -b, glatiramer acetate, other) at DMT initiation; 2) approach 1 + Expanded Disability Status Scale (EDSS) at DMT initiation, and; 3) approach 2 + DMT-discontinuation reason (pregnancy plan, flu-like symptoms, injection-site reactions, other). Covariates, antibodies, other/unknown. There was no gold standard survival model for DMT-persistence, and some models accommodated higher number of covariates and associated dependencies better. For approaches 1 and 2, Weibull and for 3 Competenz model provided the best goodness-of-fit. Based on the dataset exploration of all known covariates, three DMT-persistence approaches with different interpretations, selected covariates and data needs were modelled: 1) sex, birth year, time from symptom to DMT, age, DMT line (1st, 2nd, 3rd, 4th, 5-7th), DMT (interferon-β1a and -b, glatiramer acetate, other) at DMT initiation; 2) approach 1 + Expanded Disability Status Scale (EDSS) at DMT initiation, and; 3) approach 2 + DMT-discontinuation reason (pregnancy plan, flu-like symptoms, injection-site reactions, other). Covariates, antibodies, other/unknown. There was no gold standard survival model for DMT-persistence, and some models accommodated higher number of covariates and associated dependencies better. For approaches 1 and 2, Weibull and for 3 Competenz model provided the best goodness-of-fit.

Conclusions: Patient and provider dialogue, patient satisfaction with treatment and health plan benefit design aspects may affect DMT adherence.

PND55

WORKING ABILITY AND MONETARILY VALUED PRODUCITIVITY OF PATIENTS WITH MULTIPLE SCLEOROSIS TREATED WITH NATALIZUMAB

Objectives: To compare 6-month persistence rates among patients initiating the fingolimod cohort (hazard ratio, 95% confidence intervals: 1.58, 1.41-1.77; p = 0.0001). Time to discontinuation was significantly longer with fingolimod than with DMF.

Methods: The study included 9546 patients (fingolimod: n=2,169; DMF: n=7,377). Delays in DMT discontinuation were assessed using a Cox proportional hazards model (controlling for age, gender and region) and Kaplan-Meier analysis.

Results: The study included 9546 patients (fingolimod: n=2,169; DMF: n=7,377). Delays in DMT discontinuation were assessed using a Cox proportional hazards model (controlling for age, gender and region) and Kaplan-Meier analysis.

Conclusions: Fingolimod significantly delayed the time to DMT discontinuation compared with DMF, providing additional time for patients to consider treatment options, and thus improving persistence.

PND56

USING A PANEL SURVEY TO IDENTIFY PREDICTORS OF DISEASE-MODIFYING DRUG ADHERENCE AMONG PATIENTS WITH MULTIPLE SCLEROSIS

Objectives: Identify predictors of multiple sclerosis (MS) disease-modifying therapy (DMTs) adherence among patients with multiple sclerosis. A restrictive low fat diet to control their triglyceride. There is limited literature about long-term progression, the burden of illness or consequences of acute pancreatitis for FCS.

Methods: A random sample of adult MS patients from the US National Health and Wellness Survey or LightSpeed Research panel completed an internet survey in June 2013. The survey included questions on demographics, disease progression, medication adherence, treatment efficacy, and other factors. Logistic regression was used to identify predictors of adherence.

Results: The survey included 9546 patients (fingolimod: n=2,169; DMF: n=7,377). Delays in DMT discontinuation were assessed using a Cox proportional hazards model (controlling for age, gender and region) and Kaplan-Meier analysis. The risk of discontinuation was 1.6-fold higher in the DMT cohort compared with the fingolimod cohort (hazard ratio: 1.61, 95% confidence interval: 1.41-1.77). Time to discontinuation was significantly longer with fingolimod than with DMF (p = 0.0001), resulting in a longer duration of therapy persistence for fingolimod versus DMF (mean ± standard deviation: 152.53 ± 159.71 days vs. 135.62 ± 146.67 days, respectively). There was no gold standard survival model for DMT-persistence, and some models accommodated higher number of covariates and associated dependencies better. For approaches 1 and 2, Weibull and for 3 Competenz model provided the best goodness-of-fit. Based on the dataset exploration of all known covariates, three DMT-persistence approaches with different interpretations, selected covariates and data needs were modelled: 1) sex, birth year, time from symptom to DMT, age, DMT line (1st, 2nd, 3rd, 4th, 5-7th), DMT (interferon-β1a and -b, glatiramer acetate, other) at DMT initiation; 2) approach 1 + Expanded Disability Status Scale (EDSS) at DMT initiation, and; 3) approach 2 + DMT-discontinuation reason (pregnancy plan, flu-like symptoms, injection-site reactions, other). Covariates, antibodies, other/unknown. There was no gold standard survival model for DMT-persistence, and some models accommodated higher number of covariates and associated dependencies better. For approaches 1 and 2, Weibull and for 3 Competenz model provided the best goodness-of-fit.

Conclusions: Fingolimod significantly delayed the time to DMT discontinuation compared with DMF, providing additional time for patients to consider treatment options, and thus improving persistence.
PND59

PERFORMANCE IN OPEN AND CLOSED DATA SOURCES: A STUDY OF FINGOLIMOD VERSUS INTERFERONS/GLATIRAMER ACETATE IN PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: To compare 6-month persistence rates among patients receiving the multiple sclerosis (MS) disease-modifying therapies (DMTs) fingolimod or interferon/glatiramer acetate (IFN/GA) (index DMT), using open- and closed-source data that reflect unrestricted or continuous health care coverage, respectively.

METHODS: Retrospective analyses using administrative claims and mail-order pharmacy database data (JMS Pharmaceuticals Pharmed [closed]) and LHRx [open], respectively. All patients were ≥18 years old and naive to fingolimod and index DMT, had ≥1 prescription for index DMT between 01-Oct-2010 and 31-Mar-2013 and had not received multiple DMTs as of the index date. Additional PharmaStat support was selected using more stringent criteria (continuous enrolment pre-/post-index, MS diagnosis code). LHRx prescriptions were collected from pharmacies supplying ≥1 claim for index DMT between the index date and the last month of follow-up. Persistence was defined as time from initiating index DMT until discontinuation (gap ≤3 months). The outcome included 132 patients who enrolled in a 24-week randomized, double-blind, placebo-controlled trial conducted in multiple sites in Europe and Canada. Patients were randomized to receive fingolimod or placebo twice daily in multiple sites in Europe and Canada. Patients were randomized to receive fingolimod or placebo twice daily in multiple sites in Europe and Canada.

RESULTS: Using identical criteria, 22,467 PharMetrics patients (fingolimod: n = 20,499) and 49,803 LHRx patients (8325 and 41,478, respectively) were selected. Proportions of patients discontinuing index DMT were significantly lower for fingolimod vs IFN/GA (PharMetrics: 23.1% vs 27.2%; LRx: 26.9% vs 33.4%; p < 0.0001). Time to discontinuation was significantly longer for fingolimod vs IFN/GA (PharMetrics: hazard ratio (HR) = 1.18; 95% CI: 1.07–1.30; p = 0.0008; LHRx: HR = 1.23; 95% CI: 1.17–1.29, p < 0.0001). Time to discontinuation was significantly longer for fingolimod vs IFN/GA (PharMetrics: hazard ratio (HR) = 1.18; 95% CI: 1.07–1.30; p = 0.0008; LHRx: HR = 1.23; 95% CI: 1.17–1.29, p < 0.0001). Both data sources provided similar results, supporting use of open-source LHRx data, which allows access to up-to-date information that can improve sample size and statistical power.

PND60

COMPARISON OF THE EVALUATION OF TREATMENT ALTERNATIVES IN PARKINSON’S DISEASE WITH BEST-WORST SCALING, TIME TRADE-OFF AND VISUAL ANALOGUE SCALES

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OBJECTIVES: To compare traditional methods to small improvements in process and outcome of care. Best-worst scaling (BWS) was proposed as a sensitive and efficient method to determine the relative value of different treatments for the same disease, which would be desirable to estimate cost-effectiveness. The study objective was to compare the ability of BWS to differentiate between different treatment alternatives to that of Time Trade Off (TTO) and Visual Analogue Scales (VAS).

METHODS: An online survey was conducted to estimate individual values for different treatments reflecting the real-life options in the treatment of Parkinson’s Disease with BWS2, BWS3, TTO and VAS (n = 592). Pearson correlation coefficient was used to examine the strength of linear dependence between estimated utility scores. RESULTS: Twenty-seven percent of respondents were not willing to trade life years in TTO. Only two percent of the respondents do not differentiate between the value of health states with VAS. When non-traders were excluded from analysis, the best case scenario was estimated significantly higher than the worst case scenario with all methods. Rank reversals among intermediate alternatives were common. The correlation between utility scores was very strong (VAS-BWS2 = 1.0; VAS-BWS3 = 0.98; TTO-BWS2 = 0.9; TTO-BWS3 = 0.98, BWS2-BWS3 = 0.96; p = 0.001, n = 434). CONCLUSIONS: The results demonstrate that BWS and TTO and VAS can be used to elicit incremental utility gain of small improvements in care. However, all methods have limitations. VAS does not result in utilities for many different treatment alternatives, its applicability in CEA is limited because BWS utilities are not anchored on a 0-1 utility scale. We propose to use TTO to estimate utility for extreme health states, and to use VAS to value intermediate health states which differ on process characteristics.

PND61

HEALTH-RELATED QUALITY OF LIFE IN MIGRAINE WITHOUT AURA BASED ON ATTACK FREQUENCY: A TIME TRADE-OFF STUDY

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OBJECTIVES: To evaluate health-related quality of life (HRQOL) in migraine on basis of attack frequency by time trade-off method (TTO) in a mixed population sample consisting of migraneurs and non-migraneurs.

METHODS: A cross-sectional questionnaire survey was designed to measure HRQOL in migraine without aura by TTO. The sample was recruited from a university student study with 1% of the sample regardless of having ever experienced migraine or not. Participants were asked to elicit two hypothetical health states characterised by different migraine frequency (‘m’; two migraines lasting 4 hours each month and ‘w’; each week) within two hypothetical time frames 1; excludes; 20 years) (first and second health states) and utility scores for the same disease, which would be desirable to estimate cost-effectiveness. The study objective was to compare the ability of BWS to differentiate between different treatment alternatives to that of Time Trade Off (TTO) and Visual Analogue Scales (VAS).

RESULTS: The results demonstrated that BWS and TTO and VAS can be used to elicit incremental utility gain of small improvements in care. However, all methods have limitations. VAS does not result in utilities and some respondents do not trade life years. TTO. While the use of BWS is attractive because of its ability to estimate utilities for many different treatment alternatives, its applicability in CEA is limited because BWS utilities are not anchored on a 0-1 utility scale. We propose to use TTO to estimate utility for extreme health states, and to use VAS to value intermediate health states which differ on process characteristics.

PND64

QUALITY OF LIFE AMONG PATIENTS WITH MULTIPLE SCLEROSIS TREATED WITH PROLONGED-RELEASE FAMPYRIDE 10 MG TABLETS FOR WALKING IMPAIRMENT

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OBJECTIVES: To evaluate the effect of prolonged-release (PR) fampyride 10 mg tablets in a real-world setting. PR fampyride was associated with multiple sclerosis (MS) with walking impairment. METHODS: The study population included 132 patients who enrolled in a 24-week randomized, double-blind, placebo-controlled phase 2 trial (NC/17015929/79) of PR-fampyride 10 mg tablets or placebo twice daily in multiple sites in Europe and Canada. Patients were randomized to receive 85% more utility for young older responders valued higher mean utilities for U20m compared to the younger ones (p < 0.04). CONCLUSIONS: Our findings provide the first time trade-off utilities on migraine associated HRQOL impairment. Disability caused by migraine ranged between 0.1 and 0.2 depending on attack frequency.

PND62

HUMANISTIC RESEARCH OUTCOMES IN MULTIPLE SCLEROSIS: REVIEW OF THE LITERATURE FROM LATIN AMERICA

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REVIEW: This research reviews the literature research humanistic outcomes related to multiple sclerosis (MS) in Latin America. METHODS: We conducted a systematic search of Medline, Embase, LILACS and Scielo through 2013 for articles reporting original research on quality of life (QoL), utility scores for states of MS, patient preference, mental health, social and emotional wellbeing in people with MS in Latin America. Adherence and related issues were not included. Outcomes were categorized into: mental domain (cognitive function, memory, depression/independence), physical domain (fatigue, restless legs syndrome), employment, QoL, caregiver burden, and patient preference. RESULTS: A total of 38 studies were selected for analysis. Among them, 23 addressed issues in the mental domain (9 cognitive functions) and 15 addressed issues in the physical domain (24 mobility/physical function, 15 fatigue and 2 restless legs syndrome). One addressed impact of MS on employment, 16 QoL, 2 caregiver burden and 1 patient preference. Researchers used 56 different instruments to collect their data from 2286 patients. Compared with controls, MS patients had significantly (P < 0.05) lower levels of functioning, cognition and increased presence of mental illness. All of these factors were significantly associated with decreased QoL in patients (odds ratios ranging from 4.2 to 10.1). Future research should focus on activity of daily life and on the subjective impact of MS on people in Latin America. Conclusions: MS exerts a substantial negative impact on the lives of people with MS in Latin America. It lowers their QoL and interferes with their ability to move about, for themselves and work. Their social life is also negatively affected. The amount of literature on this subject is quite limited. More research in Latin America is needed to understand humanistic outcomes in these patients and management of their MS.
categorized into three groups: placebo, PR-fampridine responders (those with a mean improvement in baseline in the 12-item MS walking scale [MSWS-12] of ≥ 8 points over 24 weeks), and PR-fampridine nonresponders (those with worsening, no change, or < 8 points improvement in MSWS-12). Changes from baseline were calculated for the EQ-5D utility index and visual analogue scale (VAS) for all 24 weeks. Wilcoxon signed-rank tests were assessed based on the least square (LS) means using analysis of covariance (ANCOVA) models adjusting for baseline EQ-5D scores. RESULTS: The placebo patients (n = 64), responders (n = 93), and nonresponders (n = 55) were similar in baseline age, race, weight, and number of relapses in the past 1 and 2 years. The responders had higher mean baseline EQ-5D utility (0.62 vs. 0.51 and 0.52, respectively) and VAS (62.9 vs. 59.1 and 60.5, respectively) scores than the placebo patients (p < 0.0005) and nonresponders. Over the 24 weeks, the EQ-5D utility improved in the responders (mean change: 0.06, 95% CI: [0.01, 0.12]) but worsened in the placebo patients (mean change: -0.03, 95% CI: [-0.07, 0.01]) and nonresponders (mean change: -0.39, 95% CI: [-0.44, -0.34]). Similar trends were observed in the VAS scores although the differences within groups were generally not statistically significant. CONCLUSIONS: PR-fampridine 10 mg tablets demonstrated significantly greater improvement in QoL among responders, despite starting from baseline EQ-5D scores, than the placebo or nonresponder groups.

PND56
THE BURDEN OF PRIMARY GENERALIZED Tonic-CLonic SEIZURES IN EUROPE AND THE UNITED STATES: AN ANALYSIS OF THE NATIONAL HEALTH AND WELLNESS SURVEY
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OBJECTIVES: Many prescription medications are available to treat Primary Generalized Tonic-Clonic (PGTC) seizures. The objective is to understand the impact of PGTC on health outcomes. METHODS: Data were accessed from the 2010 & 2013 EU. National Health and Wellness Survey (NHWS) were analyzed. The NHWS is self-administered, internet-based survey of a nationwide sample of adults (18-60 years) in the U.S. and 5EU. In both geographies the proportion of patients self-reported a diagnosis of epilepsy with PGTC and were grouped by family members who experience physical, psychological, social, and financial burden associated with provision of care. This study quantifies the impact of caregiving in Brazil and helps identify characteristics associated with caregiving. METHODS: Data were analyzed from the 2012 National Health and Wellness Survey (NHWS) in Brazil (n = 1,205), an internet-based survey of adults (aged ≥ 18), using stratified random sampling (by sex and age) to ensure demographic representation of the Brazil adult population. Caregivers were compared with non-caregivers on select correlates of caregiver burden (health status, caregiver characteristics, health quality and behaviors, and Charlson comorbidity index (CCI) scores). Binary logistic regression models assessed comorbidities associated with caregiving, adjusting for potential confounders (CCI, age, gender, education, income, employment status, and region). CONCLUSIONS: Caregiving was associated with significantly increased risk of depressive symptoms (odds ratio (OR)=2.008), major depressive disorder (OR=1.488), anxiety (OR=1.714), insomnia (OR=1.644), hypertension (OR=1.584), pain (OR=1.704), and diabetes (OR=2.103), all p<0.05. This is the first study on caregivers for persons with dementia in Brazil (2012). Being a caregiver (compared with non-caregiver) is a predictor of overall psychiatric and clinical disorders in this sample. The online survey format provides certain sampling advantages but may under-represent caregivers with access to internet technology. Direct treatment and policies to help caregivers are needed in Brazil.

PND67
IMPACT OF CaringFor PATiENTS With ALzHEImER’S diSEASE And DEMENtIA On PSyChiATric And CLINiCAL CoMBiRiTIES IN BRAzIL
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OBJECTIVES: Patients with dementia due to Alzheimer’s disease (AD) are often cared for by family members who experience physical, psychological, social, and financial burden associated with provision of care. This study quantifies the impact of caregiving in Brazil and helps identify characteristics associated with caregiving. METHODS: Data were analyzed from the 2012 National Health and Wellness Survey (NHWS) in Brazil (n = 1,205), an internet-based survey of adults (aged ≥ 18), using stratified random sampling (by sex and age) to ensure demographic representation of the Brazil adult population. Caregivers were compared with non-caregivers on select correlates of caregiver burden (health status, caregiver characteristics, health quality and behaviors, and Charlson comorbidity index (CCI) scores). Binary logistic regression models assessed comorbidities associated with caregiving, adjusting for potential confounders (CCI, age, gender, education, income, employment status, and region). CONCLUSIONS: Caregiving was associated with significantly increased risk of depressive symptoms (odds ratio (OR)=2.008), major depressive disorder (OR=1.488), anxiety (OR=1.714), insomnia (OR=1.644), hypertension (OR=1.584), pain (OR=1.704), and diabetes (OR=2.103), all p<0.05. This is the first study on caregivers for persons with dementia in Brazil (2012). Being a caregiver (compared with non-caregiver) is a predictor of overall psychiatric and clinical disorders in this sample. The online survey format provides certain sampling advantages but may under-represent caregivers with access to internet technology. Direct treatment and policies to help caregivers are needed in Brazil.

PND68
THE VALUE OF DIAGNOSTIC TESTS FOR ALZHEIMER’S DISEASE: DISCRETE-CHOICE EXPERIMENT AND CONTINGENT-VALUATION
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OBJECTIVES: Despite the existence of standard medical criteria, clinical diagnosis of Alzheimer’s disease (AD) is often ambiguous. Lack of diagnostic certainty or possible distress related to positive results could limit application of new testing technologies. Independent of the therapeutic value of prevention or cure, however, diagnostic information could have value in informing contingency planning or have intrinsic value: the value of “just knowing”. This paper aims to quantify respondents’ preferences for obtaining AD diagnostic tests and to estimate the perceived value of AD test information. METHODS: Discrete-choice experiment (DCE) and contingent-value (CV) questions were administered to N = 1,301 respondents aged 60 years or older in Germany and the United Kingdom. 12 pairs of virtual AD diagnostic tests were presented (defined by test type, test precision defined by false-positive/ false-negative test results, and test acceptance), in which respondents were asked to rate test willingness to pay (WTP) for each test. Results were based on a predetermined experimental design. A double-bounded, dichotomous-choice CV question was used to further elicit willingness to take an AD test and pay for it. Choice data of respondents interested in taking a test were analyzed using random-effects logit and probit models. RESULTS: 12.2% of respondents had higher CCI scores and higher income, 53% were female, 52% married/living with a partner, 87% insured, and 42% living with 1+ children in the household. Caregivers vs. non-caregivers were more frequently obese, smokers, insured, employed, and with college education or above, and they had higher HIC scores and higher income, all p<0.05. Adjusting for covariates, caregiving was associated with significantly increased risk of depressive symptoms (odds ratio (OR)=2.008), major depressive disorder (OR=1.488), anxiety (OR=1.714), insomnia (OR=1.644), hypertension (OR=1.584), pain (OR=1.704), and diabetes (OR=2.103), all p<0.05. This is the first study on caregivers for persons with dementia in Brazil (2012). Being a caregiver (compared with non-caregiver) is a predictor of overall psychiatric and clinical disorders in this sample. The online survey format provides certain sampling advantages but may under-represent caregivers with access to internet technology. Direct treatment and policies to help caregivers are needed in Brazil.

PND69
THE HUMANISTIC AND ECONOMIC BURDEN OF PARTIAL ONSET SEIZURES IN THE EUROPE FIVE AND BRAzIL USING A PATIENT SURVEY
Gupta S1, Fosythe A2, Pomerantz D1, Todd NC1
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OBJECTIVES: The aim of this study was to understand the current impact of partial onset seizures (POS) on health outcomes and costs. METHODS: Patients were identiﬁed from 2010 & 2013 EU & 10-country NHWS Surveys, a nationally represented, internet-based survey of adults (18-60 years). Clinical Practice Guidelines (CPG) were used to identify patients with POS. Patients self-reported a diagnosis of epilepsy with POS and were categorized by family members who experience physical, psychological, social, and financial burden associated with provision of care.
loss and resource were similar in Brazil and the 5EU (all p < 0.05). After adjustments for covariates (gender, age, education, and drug use), the difference remained significant for Brazil versus the 5EU (both p < 0.05). The burden of illness in Brazil was higher for all five health outcomes compared to the 5EU. The regimen F were more expensive in Brazil than in the 5EU. The findings of this study highlight the importance of assessing the burden of illness and resource utilization in Brazil and the 5EU. Future research should focus on understanding the underlying causes of these differences and developing strategies to improve the health and quality of life of patients with epilepsy in Brazil and the 5EU.

### Conclusions

The results of this study provide important insights into the burden of illness and resource utilization associated with epilepsy in Brazil and the 5EU. The findings highlight the need for more targeted interventions to improve the health and quality of life of patients with epilepsy in these regions. Further research is needed to identify the underlying causes of these differences and develop effective strategies to address them.
Evidence was extracted.

RESULTS: Our search identified 19 submissions, all of which were favorable, and all except one supported the use of beta-interferon trials in indirect comparisons are becoming less suitable for the evaluation of the HTA submissions. A total of 887 Hungarian MS patients were involved and 1670 were selected for analysis after excluding the population of the year of DMT inclusion. The mean age was 36.18±9.96 years which resembles to the participants of old immunomodulatory drugs (36–38 years) and slightly younger than the patients of the trials with new DMTs (-35 years). There was no difference in gender ratio (~70% female). While in the RCTs the mean time since first symptoms was longer than the mean time since first diagnosis (~7–8 vs. ~5.5 years), in the observational dataset the difference did not differ (10 vs. 8.1±3.7±3.7 years). We suspect that the reason for this unexpected difference can be explained by the imprecise use of ICD codes in Hungarian clinical practice. The relapse rate per 2 years seemed to decline in trials of the last two decades from 3 to 2.5 which is equal to the Hungarian patients. CONCLUSIONS: The population of RCTs represents the Hungarian MS patients in certain aspects but not completely. Our analysis can help the adaptation of international models to local circumstances and the improvement of forthcoming MS therapies.

**CONCLUSIONS:**

- These data suggest that, after initial monotherapy, a majority of patients with RRMS do not follow 2012 NICE guidelines, which recommend a degree of divergence increasing through lines of therapy. These results call for more detailed investigation into treatment patterns and the reasons for divergence from clinical guidelines in epilepsy.

**OBJECTIVES:**

- To assess the patterns of use of tests to monitor disease activity in the United States and Europe

**PARTICIPANTS:**

- 561 RRMS patients

**RESULTS:**

- The number of the 151 different types of WHO-classified physiotherapy procedures was 32318413; and 1331675 (4.12%) of them related to neurology care with the ICD code group G00-G99. The amount and frequency of the physiotherapy services are in the different neurology diseases are shown in Table 1. The total number of the 151 different types of physiotherapy procedures was 32318413; and 1331675 (4.12%) of the Spanish Neurological Society were included in the study.

**REFERENCES:**


- VOLUME HEALTH 17 (2014) A323–A686

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PH3

THE SIMULTANEOUS EFFECTS OF PHARMACEUTICAL POLICIES FROM Payers’ AND PATIEnTS’ PERSPECTIVES. ITALY AS A CASE STUDY

Armeni B., Ott M. (Bocconi University, Milano, Italy)

OBJECTIVES: The research analyses (i) the individual and interactive effects of three pharmaceutical policies (cost-sharing, prescription quotas, therapeutic reference pricing on public and private expenditure and volumes, using Italian regional policies as a case study; (ii) the extent to which the long-run effect of policies on expenditure is mediated by prescribers’/patients’ behaviours. METHODS: An individual-level difference-in-differences model is used to identify the impact of public and private expenditure and volume is separately estimated. Then, the hypothesis that the effects of policies on public expenditure are mediated by behaviours (transmission mechanism) is tested. As robustness check, a possible reverse causality and feedback mechanisms is tested, by switching the mediator and the independent variable. RESULTS: The analysis shows (i) that combined policies do not necessarily produce a higher impact than policies alone; (ii) a larger impact of policies in the short-run, whereas in the long-run the trend is often reversed, but not enough to compensate the final impact, which is usually in the expected direction; (iii) as far as cost-sharing, that its negative impact on public expenditure is mainly due to a decrease in volumes than to a shift from public to private expenditure. CONCLUSIONS: The model framed a light on the impact of policies which are implemented in different time and places, thus covering an information gap and supporting policy-makers. Some empirical findings show that patients may have an awareness of their health, e.g. the volumes decrease due to cost-sharing may imply patients under-treatment.

PH4

PATIENT, INSURER AND PUBLIC PARTICIPATION IN HEALTH TECHNOLOGY ASSESSMENT: AN INTERNATIONAL COMPARISON

Mühlbach AC, Juhász C

OBJECTIVES: There is a general consensus on the need for a stronger patient-centricness, even in HTA processes. In international comparison different ways of public participation (citizens, insured and patients) in the decision-making process are discussed and tested. The need was recognized, but not yet fully reflected in practice. This study describes how preferences can be taken into account in different decision situations and shows how methods of preference measurement/ citizen involvement are used in different countries and understand the importance of various decision-criteria that influence these decisions. METHODS: A systematic literature review in PubMed/Medline revealed 95 articles and showed that methods of patients, citizens and policyholder participation are manifold. In order to structure the international approaches further, international HTA-organizations worldwide were questioned via e-mail in the end of 2013 on patients and public participation in their countries. RESULTS: 17 out of 126 contacted organizations answered to these questions. In general, the participation efforts extend from qualitative survey of patients’ needs up to the science-based documentation of quantitative patient preferences. The review and the survey of the HTA-agencies show that internationally three mechanisms are used to involve the public in decision-making bodies: membership of at least one patient representative (e.g., Australia, France, Germany), presentation of oral/written comments from patients (e.g., Australia, The Netherlands, Great Britain) and the possibility to check the HTA-reports and the corresponding draft recommendations before publication (e.g., France, Germany, Great Britain, New Zealand, USA). CONCLUSIONS: The role of the patients or citizens seems to be limited to an informal or ad-hoc basis and is mostly restricted to achieving a patient-centered health technology assessment two ways to sharing information are relevant: the public needs information on medical and health policy/economic issues and decision-maker need information on the patient perspective.

PH5

THE EFFECT OF DEGRESSIVE FINANCING METHOD ON THE HUNGARIAN DRG BASED HOSPITAL REIMBURSEMENT BETWEEN 2011-2013

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OBJECTIVES: Related Diagnosis Groups (DRG) like financing method was introduced in Hungary in 1993. In addition to DRG based reimbursement, an depressive upper ceiling (financial cap) was introduced for hospital reimbursement. The aim of our study is to investigate the effects of the financing method on the Hungarian DRG-based hospital financing. METHODS: The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined the period between 2011 and 2013. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts. As robustness check, a possible reverse causality and feedback mechanisms is tested, by switching the mediator and the independent variable. RESULTS: The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined the period between 2011 and 2013. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts. As robustness check, a possible reverse causality and feedback mechanisms is tested, by switching the mediator and the independent variable. RESULTS: The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined the period between 2011 and 2013. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 104% by 25% of OEP contacts.
Hungarian Forint / DRG costweight). CONCLUSIONS: Introduction of depressive financing method in addition to DRG reimbursement – managed to control the activity of hospitals. The soft regulation in 2011 and 2012 resulted in a 4.2-4.6% excess activity of hospitals, while the more rigorous regulation in 2013 managed to decrease the excess hospital activity to 1.9%. Depressive regulation can serve as a cost containment tool for health policy decision makers.

IPH7 NUB STATUS - A 2014 SITUATION ANALYSIS FOR DRUGS: ONCOLOGY AS LEADING THERAPEUTIC AREA
Friedmann B1, Keck E2, Schalk E3, Schmitz D4
1Quintiles Commercial, Mannheim, Germany; 2Healthcare Manufaktur, Cologne, Germany; 3Quintiles, Mannheim, Germany
OBJECTIVES: In the German hospital landscape Nub’s (Neue Untersuchungs- und Behandlungsverfahren) are essentially the precursor for cost-intensive drugs to be reimbursed via the DRG system. Hospitals can only start NHI negotiations for reimbursement once drugs have been given a Nub 1 status. The objective of this research was to provide an overview on the proportion of drugs (vs. methods, medicinal products) and their respective indications, which submitted Nub applications to the Federal Institute for the Hospital Remuneration System (in). In parallel, the number of Nub 1 status products that went through the AMNOC process was analysed. RESULTS: Out of 618 Nub submissions, only 133 (22%) were classified as drugs. In total, 114 (18%) of all Nub applications received a Nub 1 status, out of these 43 (38%) were drugs. The leading therapeutic area of the Nub 1 status drugs was oncology with 26 drugs (65%), followed by critical care products (15%). Nub 2 status was given to 455 (72%) procedures out of which 82 (18%) were drugs. The analysis reveals that, the success rate to receive the essential Nub 1 status is relatively low. Chances to receive a successful Nub 1 status approval is one in three for drugs, however only one in six for other procedures. Out of the 43 drugs that were given Nub 1 status, already 24 (55%) passed through the AMNOC process and were given equal proportions from these drugs, no additional benefit. CONCLUSIONS: Drug applications are more likely than procedures to be given Nub 1 status and thereby initiate reimbursement negotiations with the SHI. The application quality and support by the scientific societies and treatment centres is essential to make a Nub application successful.

HEALTH CARE USE & POLICY STUDIES – DISEASE MANAGEMENT
IPH8 MULTICRITERIA DECISION ANALYSIS AND COST ANALYSIS IN HEALTH CARE DECISION MAKING: A LITERATURE REVIEW
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OBJECTIVES: The purpose of this literature review is to investigate the application of multicriteria decision analysis and cost analysis methods within health care decision making. METHODS: A search of the literature was conducted using scientific databases. A combination of the following key words and phrases were inputted into the following electronic databases: MEDLINE (via PubMed), Embase, PsycINFO, CINAHL, and related words. The located articles were divided into the following twelve health care topics: evaluation of health information services; evaluation of the product development process; project and technology selection; pharmacoeconomics; health care management; therapy/treatment; management of medical technology; organizational decision-making; evaluation of health care policy; diagnostics; and shared decision-making with the patient. RESULTS: Ninety research articles were retrieved and determined relevant. The pertinent articles were published between 1981 and 2013. It was found that the AHP is the most commonly used method in health care decision making (65 articles). AHP is mainly exploited in project and technology selection (22). The ANP method is utilized in the evaluation of health information services, project and technology selection, pharmacoeconomics and therapy/treatment. For the evaluation of health care policy AHP (11), CRA (1), CEA (1) and Grey relation analysis (1) were used. The TOPSIS, VIKOR, Markov process methods were utilized once in human resource planning in health care, health care management and therapy/treatment respectively. The CRA (4) and CEA (2) methods were especially useful for solving therapy/treatment decisions. CONCLUSIONS: Multicriteria decision analysis and cost analysis offers a scientific and methodical foundation for health care management, where stakeholders interests are of crucial concern and complex criteria that cannot easily be reduced to simple monetary expressions, can be assessed in resource limited settings.

IPH9 TRENDS IN PHYSICAL AND OCCUPATIONAL THERAPY UTILIZATION IN THE US AND WESTERN EUROPE
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1Kantar Health, Munich, Germany; 2Kantar Health, New York, NY, USA; 3Private Practice, Marquartstein, Germany
OBJECTIVES: All health care (AHC) disciplines, such as physical (PT) and occupational therapy (OT), are primarily performed by non-medical health care professionals. Although the budget impact of AHC is generally low, reimbursements are often scrutinized for their financial impact and benefit/risk ratios. To better inform the health care decision making regarding AHC, the aim of this study was to examine trends and utilization of PT and OT. METHODS: Data from the 2013 US (N=75,000) and 2013 SEU (France, Germany, Italy, Spain, and UK; N=62,000) National Health and Wellness Survey (NHWS). The NHWS is a patient-reported survey administered to a demographically representative sample of adults (with respect to age, sex, and region) in each country. Overall rates of OT/PT visits were reported. Patients who reported an OT/PT visit in the past six months (2013) were compared with those who did not with respect to demographics, health history, and comorbidity variables. Logistic regression models were then conducted to predict OT/PT visits from these variables. RESULTS: Rates of OT/PT visits did not change from 2010 to 2013 but significant differences among countries was observed (p<.05). In 2013, France (0.54%) and the US (5.1%) had the most infrequent visits while Spain (11.13%) and Germany (11.92%) had the most frequent. Being in Germany (OR=1.46), being in Spain (OR=3.24), and having an OT/PT visit in the past six months (OR=1.14) were the strongest demographic predictors of an OT/PT visit (all p<.05). Although most comorbidities were associated with an increased probability of an OT/PT visit, pain (OR=2.30), arthritis conditions (OR=1.73), and psychiatric conditions (OR=1.73) were most strongly associated (all p<.05). CBA and OT utilization varies significantly across countries, being highest in Germany and Spain where over 10% of adults reported a visit in the past six months. Pain-related (pain, arthritis) and psychiatric comorbidities were among the strongest predictors of PT/OT use.

IPH10 A GENDER MEDICINE POST-HOC ANALYSIS: BACKGOUND AND METHODS OF THE METAGEM PROJECT
Simoni L1, Colombo D2, Bellia G2, Vasselliati D2, Zagni E2, Rizzoli S1, Sgarbi S1
1Medicina a, Molena, Italy, 2Novartis Farma Italia, Sarzano (NA), Italy
OBJECTIVES: Gender is a social construct, which is defined by the way people perceive themselves and how they expect others to behave. Gender medicine is the field of medicine that studies the biological and physiological differences between the human sexes and how that affects diseases in the body. The literature is rich of research that men and women differ not only but also in relationship to factors such as liver enzymes, sex hormones and to variables determined by the environment, education, culture and psychological factors of the individual. In this study, we adopted a gender-dedicated approach in the care of patients. CONCLUSIONS: Our study represents an exploratory analysis of gender differences in clinical outcomes, therapeutic approach and safety parameters in real world data. METHODS: Areas of interest were defined according to Dermatology, Central nervous system, Infectious, Rheumatology, and Transplantation; data were considered which were submitted to NBU in ten observational studies conducted between 2002 and 2013 in Italy in routine clinical practice. A post-hoc subgroup analysis is performed by study, during which males are compared with females by statistical tests. A merged analysis of different study data will be performed in order to evaluate safety. As post-hoc analysis all p-values are exploratory. RESULTS: The number of enrolled patients range between 238 to 1746 considering Rheumatology and Dermatology areas respectively, for a total of 3743 male and 3918 female patients. CONCLUSIONS: The papers and congress communications which will arise from METAGEM project will make the scientific community more aware of the importance of a gender-dedicated approach in the care of patients.
Based on ex-factory prices per Standard Unit SU (tablet, vial etc.), price indices were calculated. Study results showed international pharmaceutical price levels (in Euro and purchasing power parities) and expenditure per capita. Observation period was the year 2012. Data were collected via international literature review and based on IMS Health data on file. RESULTS: The international comparison of prices indices based on ex-factory prices revealed average price differences of 138 and 126 for the highest price indices and in contrast to Netherlands (69) and Romania (69) were at the lower end. In the international country sample, the Netherlands had the highest price level (11.91 % of GDP) in 2011, closely following by France with 11.33 % of GDP. Subsequently, Switzerland occupied a leading position based on the determined price index per capita (187) per ex-factory price, followed by Sweden (167). The rear was Romania (45). CONCLUSIONS: In case of converting drug prices with purchasing power parities differences between drug pricing policies, different price levels in different countries were found. Low income countries reported less affordability of drugs, leaving room for potential problems with drug access, and consequently, a negative impact on health.

PHP13
HOW IS CURRENT PHARMACEUTICAL PRICING POLICY ON GENERICS PERFORMING IN TURKEY REGARDING PRICE EROSION?
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OBJECTIVES: Generics are commonly accepted to contribute significantly to treating disease by improving the affordability of pharmaceuticals. Once the patent expires for an originator brand, generics erode prices through creating fierce competition. The objective of this study is to investigate on Turkish pharmaceutical policies over generics, how much they lower the prices, and then develop alternative strategies to maintain higher level of price reduction and hence saving. METHODS: Claims data from Turkish Social Security Institution for all ambulatory therapies on medicines of all categories were collected monthly over the period of January 2009 to December 2013. First, the share of generic drugs both in terms of sales volume and value were calculated. Then, selected 12 equivalent groups each relying on same molecule (6 USP), constituted 95% of GDP in 2011, closely following by France with 47. Price erosion for 15 generics entering the reimbursement list in 2012 as molecule were evaluated and saving impacts due to generic entry were computed. Finally, the price erosion for 15 generics entering the reimbursement list in 2012 as first generics was measured. RESULTS: Only 48% of all units sold was prescribed as generic drugs, whereas it was only 31% when it comes to value. For 12 equivalent groups constituting nearly 7% of SSJ drug spending, the price erosion was nearly 41% ranging from 8% to 74%. Interestingly, when a first generic having an originator brand whose any form were marketed before 1987 in any country entered the market, new discounted public price was higher than the price with no generic. Finally, in the first year of the first generic entry, on average the prices were only shrunk by 39% with an increase of 41% in units sold. CONCLUSIONS: Turkey is not maximizing its full potential with respect to generic medicines. Therefore, it is of great importance to develop efficient policies such as therapeutic equivalence, tendering, and aggressive generic pricing policy to stimulate higher savings need to be introduced.

PHP14
COST-EFFECTIVENESS OF TARGETED PHARMACOTHERAPY – A SYSTEMATIC REVIEW OF THE LITERATURE
Amler N., Becker T., Bierbaum M., Schöffski O, Friedrich K., Abendroth M., Eilangen-Nürnberg, Nürnberg, Germany
OBJECTIVES: Targeted therapies (e.g. trastuzumab, cetuximab) are often said to be a sise increase in costs of care. However, the impact of targeted therapies on cost as avoidance of side effects or hospitalizations for example, opponents expect a mas- debate. While proponents refer to the enormous cost saving potential due to the divergence is commonly larger at launch, and converges over time. The new agents promise to be more effective and lead to lower expenditure per treatment. The current study aims to investigate the effectiveness and cost-effectiveness of new targeted therapies in cancer. METHODS: We searched Medline, the Cochrane Library, Scopus, ISI Web of Knowledge and ScienceDirect for relevant articles published between 2001 and 2013. Internet search and scanning reference lists complemented our search. We investigated the reimbursement submissions to the National Health Insurance Fund (NHIF) in Serbia, in the period September 2013 to June 2014. Quality was assessed using the criteria for pharmacoeconomic evaluation in the most recent ISPOR guidelines and the Serbian pharmacoeconomic guidelines. The impact of the introduction of the new rulebook was assessed by comparing the period following its introduction with the number and quality of submissions in the preceding period. RESULTS: Between September 2011 and April 2014 there were 268 submissions to the NHIF and none were accompanied by the necessary pharmacoeconomic analysis. The new rulebook was published in April 2014, making budget impact analysis an obligatory for pharmacoeconomic evaluation in the most recent ISPOR guidelines and the Serbian pharmacoeconomic guidelines. The introduction of compulsory pharmacoeconomic component to reimbursement submissions in Serbia has raised the number of submissions to the NHIF. This standard is still too low to fully facilit- ate transparent evidence based decision making, however the new rulebook is expected to force both the NHIF and the pharmaceutical industry to increase their skills in evidence based decision making. However, Serbia still suffers from a lack of local cost estimates available and limited supply of health economic skills in the region.

PHP16
ARE PRICES OF PATENT-PROTECTED PHARMACEUTICALS IN THE TOP 5 EU COUNTRIES CONVERGING?
Therasse C., Lehot A., Fuisset F., Lang C., Étienne V., Audouin G.
IHU, Paris, France, 7HS, London, UK
OBJECTIVEa: The goal of this study is to assess whether prices of innovative drugs in the same country are converging. METHODS: The price of 5 innovative drugs, approved by the European Medicines Agency (EMA) in 2009 or earlier, that are still patent-protected and marketed in each of the top 5 EU markets were assessed over the period 2006-2011. The focus was on cost-effectiveness ratios, which were extracted from EHS's international pricing database POliCI. Discounts and rebates were excluded from the analysis, and current exchange rates into Euros were used. Given the timeframe, none of the products included in the sample was assessed under the AMNOG reform in Germany, and the lowest one (United Kingdom) was 24%, this figure dropped down to 15% in 2014. The average price of the 5 products declined in all countries and the overall price mean (all countries) slightly decreased - by around 5% - over the period studied: from €303.3 in 2009 to €289.4 in 2014. This global trend reflects a process of price convergence that is taking place across the price forpatent-protected medicines. CONCLUSIONS: Our data shows that prices slightly decrease over time, and also that prices have started to decline in Germany. German prices in the sample are still comparatively higher than the other major European markets, but with most prices in Italy and Spain remaining constant, and those in France converging to the mean, there are clear trends of price corridors shrinking across Europe. The divergence is largely at larger, and converges over time.

PHP17
LETTING THE DATA SPEAK: A SHIFT OF THE PHARMACEUTICAL SPENDING TO HOUSEHOLDS IN GREECE
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OBJECTIVE: Since 2009, Greece has implemented a fiscal consolidation pro- gramme that includes several reforms and budget cuts in health sector. Indicatively, health expenditure has been reduced by more than 20% between 2009 and 2012. Pharmaceutical sector can be characterized as one of the main sources of these cuts. The objective of this study is to draw some early conclusions regarding the impact of the current pharmaceutical policy on the structure of expenditure and the access to medicines. METHODS: The data are obtained from the Hellenic Statistical Authority, the national accounts and the household surveys for the period 2009-2012, in order to examine potential changes of the public/private mix of the phar- macetical expenditure. RESULTS: Public pharmaceutical expenditure fell from €5.1 bn in 2009 to €3 bn in 2012 (42.5 %). Private pharmaceutical expenditure was €1.3 bn in 2009, while it was approximately €1.5 bn in 2012 (+24 %). The total expenditure dropped by 31.2%. The share of private expenditure on pharmaceuticals has sharply increased during the study period. Specifically, the private expenditure was 20.6% of the total pharmaceutical expenditure in 2009, while it approximated 34% in 2012. CONCLUSIONS: The aforementioned imply that there is a shift from public to private spending for pharmaceuticals between 2009 and 2012. Moreover, preliminary estimates for 2013 suggest that this trend is increasing. Therefore, apart from the existing financial and income constraints, households are in front of an additional financial burden. This change is associated with potential catastrophic expenditures and rationing in patient compliance. The study findings suggest that individuals’ degrees of freedom are constrained and that patients express their preferences by increased out of pocket payments. In the light of the above, the pharmaceutical policy implemented so far can be associated to a sharp "indirect increase" of copayments and coinsurance rates.

PHP18
ECONOMIC BURDEN OF INTRAVENOUS IRON PRODUCTS IN PUBLIC HOSPITALS OF PARIS AND IMPACT OF THEIR NEW HOSPITAL-RESTRICTED STATUS
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1General Agency of Equipment and Health Products (AGEPS), AP-HP, Paris, France, 2Dauphine University, Paris, France
OBJECTIVES: To assess the global economic consequences for French hospitals of the introduction of the 2012 (EC) Directive to strengthen administration conditions of intravenous iron products (IP) (iron sucrose (IS) and ferric carboxymaltose (FC)) due to safety concerns. Following this EC decision, in February 2014, French Health Authorities decided to give a hospital-restricted status (HRS) to IP. METHODS: We compared, between the same medical, surgery-obstetric (MO), hospitals, IP consumption and expenditure (extracted from SAP software) before (2012 vs. 2013) and before-after (02/2013-04/2013 vs. 02/2014-04/2014) they had a HRS, and the number of diagnosis-related groups (DRG) linked to iron (Technical Agency of Information on Hospitals data). RESULTS: 20 hospitals were included. Before they had a HRS, IP global consumption in volume increased by 9.6% (i.e. +171,022 spent more) in a year. After IP had a HRS, the increase was 16.7% (i.e. from €138,838 spent more in 3 months (02/2013-04/2013 vs. 02/2014-04/2014). 23.7% of the increase was attributable to day hospital admissions (DHA) and 4.4% to dialysis units. FC consumption was 23.9% higher (i.e. 1,188,838 spent more) in 2014 compared to 2013. IP consumption was 16,000 euros more. IP and IS in DRG-CNT links to iron decreased by a factor of 1.8. CONCLUSIONS: DHA as part of the DRG-CNTD is the only way to finance this additional hospital activity (no additional funding for traditional hospital care). FC’s cost of daily treatment (£120 to £137) is about 20 times IS’s (5.2 to 7.8), while a single tariff is allocated for the DRG-CNTD (drug case-mix: £62, whatever the drug). The costs of FC’s increase using to manage anaemia may be offset by administration of other drugs, or the DRG-tariff should be adjusted. Another alternative would be to implement a tariff between IP, taking into account the cost-effective ratio of each drug.

PHP19
THE IMPACT OF COST CONTAINMENT REFORMS TO THE PHARMACEUTICAL BENEFITS SCHEME (PBS) ON PRESCRIBING VOLUMES AND EXPENDITURE IN AUSTRALIA: 1992 TO 2011
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OBJECTIVES: The increase in PBS expenditure over the past two decades led to the Australian government implementing several cost-containment measures. The objective of the present study was to investigate the impact of these reforms on PBS prescribing volumes and expenditure.

METHODS: Data retrieved from Medicare Australia’s PBS Statistics database provided monthly government expenditure (benefits and rebates) and prescription volume (service) data. Segmented linear regression models were used to analyze the time series data starting from 1 January 1992 to 31 March 2012. In each segment, between implementing the cost containment measures, two parameters were estimated: the level and trend used to estimate the impact of the intervention. A lag of 12 months was applied to adjust for seasonality and forward stepwise eliminations were applied to obtain a parsimonious model. Seven cost containment measures were investigated: the economic evaluation requirement for drug listing (1/08/2013), price reductions (1/08/2013 to 31/12/2013), the introduction of the Therapeutic Goods Act (TGA) and PBS reform (01/08/2013), therapeutic group premium (TGP) policy (1/02/1998), safety net 20-days rule estimated to be the most effective in reducing drugs overuse (02/2013 to 04/2014), and the introduction of PBS fee for service (F2) (1/08/2013).

RESULTS: All interventions except the re-supply limits policy were found to have a significant impact on PBS services or benefits. Reductions in the services and benefits trend were observed in two measures, the TGP policy and safety net 20-day rule while a reduction in the trend was observed for the PBS rebate. These reductions in PBS expenditure over the past two decades are not related to increasing time taken for regulatory approval. For example, MethOds: While pharmaceutical sales data were obtained from the IMS and Medline database, sales data of other countries were obtained from the IMS and Medline database. The objective of the present study was to investigate the impact of these reforms on PBS prescribing volumes and expenditure.

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security funding law, France is becoming the first country to allow biosimilars substi-
tute when initiating treatment courses to preserve biosimilars and implementation of substitution rules, even if still raising some reluctance, might contribute to boost biosimilar uptake in Europe. Price competition will impact manufacturers of branded biologics to adopt new pricing strategies.

**PHP24**

**IMPETUS OF EXTERNAL PRICE REFERENCING OF PHARMACEUTICALS IN MIDDLE EAST COUNTRIES**


**OBJECTIVES:** In Turkey, a medicine pricing reference system has been in use since 2004. The price of pharmaceuticals is determined by the acceptance of the lowest ex-factory price in the reference countries (Greece, France, Italy, Portugal, Spain). We aimed to examine the first 100 medicines, having the annual maximum amount on the average Turkish Lira (TL) based medicine sales between the years 2008-2013 which have 15% value in the total pharmaceutical market, reference price changes in these medicines. In Turkey, while pharmaceutical sales data were obtained from the IMS Health-Turkey data base, medicine prices were obtained from the Medicine Price List published by Turkish Medicines and Medical Devices Agency. **RESULTS:** In 2008, 100 medicines were subjected to EPR. The list of medicines subjected to EPR in the reference country, followed by Spain and Greece in 2013 while Greece is taken as the reference country more common, France and Italy are to follow. In 2008, only one medicine price decreased because of the reference price. The other 99 medicines’ prices increased, and only one medicine’s price decreased because of the reference price. In 2009 and 2010 price increases did not seen. In 2009, 8 and 2010, 30 medicines prices had decreased. In 2011, 2012 and 2013 totally 27 medicines reference price had decreased. 21 medicine’s price in 2011, 20 medicines price in 2012 and only 4 medicines’ prices decreased in 2013. While the countries except Greece (13 medicines) connected to the reference price increases, mostly Greece (58 medicines) has been based reference price drop in the analyzed period. **CONCLUSIONS:** The application of reference prices, medicine prices to be reduced to a large extent. Greece based an average reference price decreases are observed to be mainly from the year 2010. The reason for this is considered as the economic crisis in Greece and the agreement with the IMF, EU and ECB, the Greek government at cost-containment.

**PHP25**

**QUALITATIVE ANALYSIS OF THE POLICIES THAT WOULD SUPPORT A SUSTAINABLE MEDITERRANEAN MEDICINES MARKET WOULD DELIVER**

Whitehouse J.C., Teale CW., Glover J.C., Taylor C., Lino Mendonca V.S.

**OBJECTIVES:** To establish the key policy areas that will drive the establishment of a sustainable bio-similar medicines market. To outline the benefits that these will bring to Physicians, Payers, Patients, and Industry, with particular focus on the benefits for European National Health Systems. **METHODS:** 71 qualitative in-depth interviews were conducted across 7 European markets: France, Germany, Hungary, Italy, Poland, Spain and the UK, collecting insight from experts and policy influencers at pan-European, National and Regional levels, Physicians, Payers, Pharmacists, Patients, and Industry. Quantitative modelling used a systems dynamics approach with in-depth analysis of 1 representative biologic products: trastuzumab, bevacizumab, and adalimumab. Dynamics were combined with a quantitative analysis of the multi-stakeholder benefits a sustainable medicines market would deliver. **RESULTS:** 6. The qualitative analysis demonstrated that the most efficient policy combination, measured in terms of the sustainability index, was the same for all markets and was: (i) removal of price caps and (ii) a cumulative 10 year cost saving of between 24% and 26%. **CONCLUSIONS:** Greater stakeholder alignment and the combination of specific policies will increase the sustainability of the European bio-similar medicines market. A sustainable bio-similar medicines market will deliver significant benefits to all stakeholders.
SAVING money in health care: cost effectiveness of individual policy changes were very successful to control growth of top selling pharmaceuticals. All policies impacted negatively the trend in cardiovascular system (C0) group.

RESULTS: There was an increasing trend for all ATC1 groups prior the implementation of policies. The trends in systemic antineoplastic (J0), respiratory and metabolism (A0) and reproductive system (L0) Central Nervous System (N0), Respiratory System (R0) and Excretory System (P0) were negatively impacted. RF had a significant negative impact on A0 and R0 group. Impact of RF was not significant for L0 group. However it did not have much effect on A0 and R0 group. Policy changes were very successful to control growth of top selling pharmaceuticals. In 2013, decrease in sales was 24% for LMP and 31% for IP. Decrease in the total pharmaceuticals market was 14%.

RESULTS: There was no significant difference in the mean cost savings between RF and other policy changes. The positive effect of RF policy change on CS trends was more prominent for IP than LMP sales. However, the shift in CS due to other 4 policy changes was lower for IP when compared with LMP sales. The differences reached statistical significance level except for CMS policy. Although RF was not significant, positive shift of US due to RF policy change was higher for LMP than IP sales. There was a decreasing slope of LMP unit sales following MRDS and CMS policies but an increasing slope of IP unit sales.

CONCLUSIONS: Policy changes had a significant effect at different levels and importance on the cost impact of the pharmaceutical market. The shift in slope and nearly the same amount of data required (i.e. Neutroval). The impact of the recently released FDA draft guidance on design and similarity of some biologics (i.e. Lovenox, Copaxone) led to important debates for defining the application pathway. Currently, the FDA has no 351(k) approvals. The lack of clear FDA guidance on data requirements for biosimilarity in aBLA was a limiting factor for manufacturers to go through aBLA pathway. They preferably opted for a classical BLA pathway due to its longer exclusivity period and lower same amount of data required (i.e. Neutroval). The recently released FDA draft guidance on designing clinical studies for biosimilarity (5/13/14) is yet to be seen but should address issues on proving biosimilarity in aBLA. This paper is limited by an increase in expected and biosimilars savings are projected to be $520 billion by 2024. CONCLUSIONS: The biosimilar market is still lagging, specifically compared to the EU, with no 351(k) approvals despite the US’ leading position in the biosimilars market. However, the US’ high prices for innovative products and history of generic utilization can signify a positive market projection after a transition period, as was seen in Germany and Sweden. Further, the new FDA guidance by addressing biosimilarity issues may ease biosimilar market entry.
prior and after the implementation of 5 selected policies of the HTP. The analysis was conducted for total imported pharmaceuticals (IP) sales and total locally manufactured pharmaceutical (LMP) sales in the AO. The Durbin-Watson d statistics of SPSS version 20.0 was used as a test for serial correlation of error terms. Shift in slope with p < 0.05 was considered as statistically significant.

RESULTS: All policies except GMP and FP had a positive impact on the total pharmaceutical market value in 2013. In this study we aimed to determine the effects of these five policies on the health services’ medicines, which have higher sales amount, defining characteristics. METHODS: While pharmaceutical sales data were obtained from the IMS Health™Turkey data base, characteristics of medicines were obtained from the Turkish Medicines and Medical Devices Agency and the Social Security Agency data bases.

RESULTS: While 78 medicines are original, 22 medicines are generic, 60 medicines are imported medicines, 40 medicines are manufactured medicines. 19 medicines were from antimicrobials, 13 medicines were from psychological, 10 medicines were from cardiovascular and 10 medicines were from anti-infectives. 96 medicines covered by Social Security payments. Equivalent of 65 medicines are available (each equivalent group from 1-30, medicines are original and imported, 96 medicines covered by Social Security payment. Elements of 65 medicines are available (each equivalent group from 1-30, an average of 13 generics available). 19 medicines and 15 medicines are respectively systematized in the health indicators and the price and sales data. CONCLUSIONS: In the years which were the effects of reforms, price cuts and global budget implementation seen, the medicines which have higher total sales amount were mostly original, imported, covered by Social Security payments and created by multinational firms.

PHPS3

IMPACT OF HEALTH POLICY CHANGES ON UNIT SALES OF 5 TOP SELLING ATC1 PHARMACEUTICAL GROUPS IN TURKEY

Saylan M1, Safak Yilmaz E2, Yenilemez FB3, Kockaya G4, Tatar M5, Hilal Vural F6, Vural IM6, Akbulut A7, Gursoz H8, Artirgan G9, Kerman S1

1Health Economics and Policy Association, Ankara, Turkey. 2University of Health and Medical Sciences, Izmir, Turkey. 3Hacettepe University, Ankara, Turkey. 4Baskent University, Ankara, Turkey. 5Research Hospital, Ankara, Turkey. 6Baskent University, Ankara, Turkey. OBJECTIVES: While pharmaceutical sales data were obtained from the IMS Health™Turkey data base, characteristics of medicines were obtained from the Turkish Medicines and Medical Devices Agency and the Social Security Agency data bases. RESULTS: While 78 medicines are original, 22 medicines are generic, 60 medicines are imported medicines, 40 medicines are manufactured medicines. 19 medicines were from antimicrobials, 13 medicines were from psychological, 10 medicines were from cardiovascular and 10 medicines were from anti-infectives. 96 medicines covered by Social Security payments. Equivalent of 65 medicines are available (each equivalent group from 1-30, medicines are original and imported, 96 medicines covered by Social Security payment. Elements of 65 medicines are available (each equivalent group from 1-30, an average of 13 generics available). 19 medicines and 15 medicines are respectively systematized in the health indicators and the price and sales data. CONCLUSIONS: In the years which were the effects of reforms, price cuts and global budget implementation seen, the medicines which have higher total sales amount were mostly original, imported, covered by Social Security payments and created by multinational firms.

PHPS7

APPLICABILITY OF TURKISH Pricing POLICY ON PRICE INCREASES

Ayhan A1, Doğan Ö2, Dogan Ö1, F. Cihan E3, Alpay C1, Zeynep M1, Cemile T4, Mustafa C5

1Novartis Pharma, Istanbul, Turkey. 2Istanbul University, Istanbul, Turkey. OBJECTIVES: Turkey is using international reference pricing for the pharmaceutics. An update for Turkish pricing decree is published in April 2012 and price increases were applicable due to reference pricing. We aimed to identify pharmaceutical products that had any price increase in 2013 and defined causes in the decree. METHODS: We reviewed weekly cumulative price lists published in Turkish Medicines and Medical Device Institution and compared each weekly list with the list published in the previous week to identify products that had price increases. We excluded “plasma–derived blood products” that has different pricing schemes for the exchange rate related increase and also excluded the price corrections. Price increase reasons were grouped as defined in the current decree. We calculated mean percentage of price increases in overall and in original vs. generic, import vs. locally manufactured, products below and above 6.79 TL per pack. RESULTS: OF 106 products and 247 ATC level subgroups, 53 products and 274 medicines had price increase in 2013. The most frequent reasons for price increase were related critical product status (110 increases), increase in reference price (105 increases) and due to the rule of getting the highest reference price for delisted or non-reimported products (89 increases). The average rate of price increases was 23.1%. 57% of the price increases were applied to imported products compared with 43% locally manufactured ones. Average rate of price increase in originals and generics products were 24% and 21% respectively. Products with ex-factory price above 6.79 TL had more price increase compared with cheap products. The highest rate of price increases were in ATC1 groups A and B (81 increases each). In value terms, highest rate of price increases were in 2011. Price increases were possible in Turkey for products from different groups.

PHPS9

THE GRASS IS ALWAYS GREENER ON THE OTHER SIDE OR WHY THERE IS LITTLE MEANING IN INTERNATIONAL PHARMACEUTICAL PRICE COMPARISON

Sieben G1, Erböl S2, Cari N3, Erbogan E3

1University of Health and Medical Sciences, Izmir, Turkey. 2Hacettepe University, Ankara, Turkey. OBJECTIVES: While pharmaceutical sales data were obtained from the IMS Health™Turkey data base, characteristics of medicines were obtained from the Turkish Medicines and Medical Devices Agency and the Social Security Agency data bases. RESULTS: While 78 medicines are original, 22 medicines are generic, 60 medicines are imported medicines, 40 medicines are manufactured medicines. 19 medicines were from antimicrobials, 13 medicines were from psychological, 10 medicines were from cardiovascular and 10 medicines were from anti-infectives. 96 medicines covered by Social Security payments. Equivalent of 65 medicines are available (each equivalent group from 1-30, medicines are original and imported, 96 medicines covered by Social Security payment. Elements of 65 medicines are available (each equivalent group from 1-30, an average of 13 generics available). 19 medicines and 15 medicines are respectively systematized in the health indicators and the price and sales data. CONCLUSIONS: In the years which were the effects of reforms, price cuts and global budget implementation seen, the medicines which have higher total sales amount were mostly original, imported, covered by Social Security payments and created by multinational firms.

PHPS4

TRANSFORMATION OF GREEN CARD PROGRAM FOR THE POOR: ONE STEP FURTHER TO UNIVERSAL HEALTH CARE COVERAGE IN TURKEY

Seyhan G1, Erböl S2, Can H3, Erbogan E3

1University of Health and Medical Sciences, Izmir, Turkey. 2Hacettepe University, Ankara, Turkey. OBJECTIVES: Since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage since January 2012, Turkish government started to implement a mandatory general health insurance law.

CONCLUSIONS: Results of the review suggest that there is a misconception of pharmaceutical pricing in Germany. Within a price comparison study any desired result can be achieved by deliberately choosing different approaches. At the end of the day payers and policy makers should stop comparing prices with other countries. Instead resources should better be spent on making value based reimbursement decisions in the respective health care setting.

PHPS6

GENERIC PENETRATION WITHIN TOP-10 GENERICIZED MOLECULES – GREECE AND THE MAJOR EUROPEAN COUNTRIES

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1IMS Health Hellas, Athens, Greece. 2Pan Hellenic Union of Pharmaceutical Industry, Athens, Greece. 3National School of Public Health, Athens, Greece. OBJECTIVES: In early 2010, Greece was placed under International Supervision (EU, ECB and IMF), as a result of a growing public deficit and its non-sustainable state expenditure. At the time, the retail pharmaceutical purchases reached a size of €6.5 bn in retail prices (public pharmaceutical expenditure €5.2 bn). Within that framework,
the reduction of pharmaceutical expenditure was one of the main targets for fiscal adjustment. The purpose of this study was to investigate the problem of generic medicines in Greece, as a key driver for savings from the pharmaceutical market, and compare it with that of other major European countries. METHODS: IMS data from several European countries was collected in terms of the overall retail pharmaceutical market and the consumption of generic medicines in each country. Data was analyzed on the top-10 generalized molecules for Greece including alendronic acid, atorvastatin, carvedilol, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, clarithromycin, clofibrate, 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OBJECTIVES: The Moroccan government announced new public and hospital pricing for 5308 drugs in April 2014. These price cuts came into force in June 2014. The study examines the price changes and analyzed the potential impact of the price cuts on pharmaceutical companies operating in the market. METHODS: Standard statistical methods were used to analyze government provided data in order to identify general trends within the pricing notification. Secondary sources were then examined to determine the general pricing rationale. RESULTS: The price notification included 5308 drugs (note duplication occurs where a brand name is associated with multiple manufacturers). Examining public prices: 390 of the drugs were newly listed on the list for public purchase, a further 2968 saw no price increase and two drugs saw modest price increases. Public price declines were seen for 1948 drugs with the level of decline covering a range of 1635 percentages between 0.00% and 78.6%. Average public price, excluding drugs with no decleration, saw an average decline of 13.6% and median decline of 6.5%. All the 5308 drugs already had an existing hospital price, however 114 of these drugs saw no price change. Of the 5308 drugs a further 2968 saw no price increase, and 1876 saw price decreases. This updated access analysis for each device was designed, and tested by collecting data from NHS acquisitions. An application system that stores the information was built. For the registry of newly listed on the list for public purchase, a further 2968 saw no price increase and group purchasing. ENGLAND has a national procurement body but hospitals regularly purchase products directly from the manufacturer. All three countries report that economic pressures are affecting their ability to get new devices on the market. Product trialists and clinician preference are seen as the main drivers of adoption however clinicians are under increasing pressure to justify costs. Hospital purchase decisions are increasingly likely to be based on non-product attributes of disposables, rather than simply delaying decisions. Economic difficulties may lead some governments to refuse reimbursement, so rather than simply delay decisions. Economic difficulties may lead some governments to refuse reimbursement, rather than simply delay decisions. CONCLUSIONS: This updated access analysis shows that while delays are shortening, absolute access for patients is not always improving. We found a lack of reference pricing (the best price in the region) may send misleading signals, and underscore the need for monitoring of true access across Europe.

OBJECTIVES: The Portuguese National Health System (NHS) identified the need to easily access information that allowed identification of all medical devices for which manufacturers, distributors, characteristics, and purposes. The objective of the creation of an information system is to collect, store and analyze data of each MD and to provide NHS resources management, health technology assessment (HTA), as well as data about the Portuguese market. METHODS: A system consisting of a database that is a repository, and an application system that stores the information was built. For the registry of each device was designed, and tested by collecting data from NHS acquisitions. The prescription of medical devices is made by code, with all information online. A model for communicating to the health regulatory agency and market. Manufacturers was also devised, as well as rules and codes of procedure. RESULTS: The creation of this system in 2011 allowed for the coding of 20% of all registered MDs (n=38000) up to June 2014. This has allowed for the elimination or withdrawal of 16% of the MDs (n=1600) with only Greece showing no real improvement. However, absolute availability of new medicines has varied greatly by market, with same-year availability of EMA-approved medicines declining to just 41% on average in 2013. Notable declines were seen in Greece, Spain, Romania and Portugal, suggesting that economic difficulties may lead some governments to refuse reimbursement, rather than simply delay decisions. CONCLUSIONS: This updated access analysis shows that while delays are shortening, absolute access for patients is not always improving. We found a lack of reference pricing (the best price in the region) may send misleading signals, and underscore the need for monitoring of true access across Europe.

OBJECTIVES: In European hospitals, budgetary pressure is driving centralized purchasing to increase the importance of procurement in market access. Centralized purchasing is thought to lead to cost savings through stronger negotiating power, economies of scale and reduced inventory. The objective of this study was to understand the procurement methods for disposable medical devices employed by European healthcare organizations. METHODS: A review of hospital purchasing practices was conducted in France, Germany and England, including published articles and government websites. Twelve 45-60 min telephone interviews were conducted with hospital decision makers (purchasers, pharmacists and clinicians) in 2013. RESULTS: Most disposable medical devices are evaluated at the facility level by committees made up of clinicians, procurement specialists, pharmacists and management. France and Germany required submissions on the facility level, and typically responded to the tendering and group purchasing. ENGLAND has a national procurement body but hospitals regularly purchase products directly from the manufacturer. All three countries report that economic pressures are affecting their ability to get new devices on the market. Product trialists and clinician preference are seen as the main drivers of adoption however clinicians are under increasing pressure to justify costs. Hospital purchase decisions are increasingly likely to be based on non-product attributes of disposables, rather than simply delaying decisions. Economic difficulties may lead some governments to refuse reimbursement, so rather than simply delay decisions. Economic difficulties may lead some governments to refuse reimbursement, rather than simply delay decisions. CONCLUSIONS: This updated access analysis shows that while delays are shortening, absolute access for patients is not always improving. We found a lack of reference pricing (the best price in the region) may send misleading signals, and underscore the need for monitoring of true access across Europe.
PHPS1

THE THERAPEUTIC POSITONING REPORT: NEW COLLABORATIVE NETWORK OF DRUG ACCESS IN SPAIN - THE START OF P&R BASED ON RELATIVE EFFECTIVENESS?

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OBJECTIVES: The Therapeutic Positioning Reports (TPRs) were introduced to the Spanish P&R process in May 2013. TPRs evaluate comparative efficacy and safety and identify thresholds for monitoring criteria for new drugs and existing reimbursement. The procedure was set-up by the Spanish Medicines Agency (AEMPS) and the Ministry of Health with the aim to accelerate the P&R process and to generate a single, national relative effectiveness report avoiding additional regional evaluations, contributing to reducing the long-delays in market access timelines experienced in the last few years. The objective of this ongoing work is to describe and analyze both the metrics of the process and the content and results of TPRs.

Results: Descriptive study of the process and public information available from the European and Spanish Medicines Agencies (May 2013 onwards).

RESULTS: From June 2013 to May 2014 the Therapeutic Positioning Coordinating Group (TPCG) has officially launched 60 TPRs plus 7 use protocols (UP) at the request of the German Federal Institute for Drugs and Medical Devices (BfArM) and the Ministry of Health.

The TPR process is not clearly defined in all three countries. Health economic evidence is requested in all DACH countries. The length of the application process varies in the three countries. The key items being analysed for similarities and differences in the reimbursement process.

Inpatient setting, the evidence requirements for reimbursement pathways in the DACH countries, and aims at finding commonalities in payer requirements and reimbursement pathways.

METHODS: Reimbursement application pathways for inpatient and outpatient medical devices were evaluated for Austria, Germany and Switzerland.

CONCLUSIONS: TPRs are not being released at the expected rate. Follow up is necessary to predict its impact in P&R and market access in regions across Spain.

PHP59

ARE THERE ANY COMMONALITIES IN PAYER REQUIREMENTS AND REIMBURSEMENT PATHWAYS FOR MEDICAL DEVICES IN THE DACH (GERMANY, AUSTRIA, SWITZERLAND) REGION?

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OBJECTIVES: Medical devices constitute a set of important health technologies for the care of patients. While there are similarities between some reimbursement systems, each market has its own unique characteristics. This article focuses on the reimbursement procedures for medical devices in the DACH countries (Austria, Germany, and Switzerland) and aims at finding similarities and differences in each setting were transparency, clinical and health economic evidence requirements, submission timelines and the whole reimbursement application process.

RESULTS: In the inpatient setting, the evidence requirements for clinical data are different between the analyzed countries: The lowest clinical evidence requirements are seen in Germany, while the highest are given in Switzerland (in some scenarios). In terms of health economics the requirements are medium to low in Switzerland where health economic evidence is not seen as important for the reimbursement process. In Germany, as a health economic analysis is required (e.g. cost comparison), and a low rating was applied to Germany as limited economic information (cost assessment/ comparative effectiveness analysis) was not sufficient, the requirement was low. In Austria, as the lengthy application process is well defined and not subject to the same timelines in the inpatient setting, reimbursement pathways are being analyzed for similarities and differences. Clinical requirements are getting close to pharmaceutical methods whereas health economics evidence is required (e.g. cost comparison), and a low rat-

ing was given for Austria. The key items being analysed for similarities and differences in the reimbursement process.

METHODS: Reimbursement application pathways for inpatient and outpatient medical devices were evaluated for Austria, Germany and Switzerland.

CONCLUSIONS: TPRs are not being released at the expected rate. Follow up is necessary to predict its impact in P&R and market access in regions across Spain.

PHP60

THE RELEVANCE OF HEALTH SERVICES RESEARCH FOR THE PHARMACEUTICAL INDUSTRY IN GERMANY – RESULTS OF A REPRESENTATIVE ONLINE SURVEY

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OBJECTIVES: The necessity for manufacturer of pharmaceuticals and medical devices to conduct Health Services Research (HSR) on the efficiency of health products. We don’t know how the ICER will be considered in the future. All these numbers increased since the last surveys. CONCLUSIONS: The results of the survey clearly pointed out the high and still increasing importance of HSR and real-life studies also in the health care industry. Although a considerable amount of uncertainty concerning the specific methodological requirements remains it is clear that accepted HSR methods are employed more and more by payers. As HSR projects require considerable human and financial resources alliances and joint projects between industry, academia and payer are advised.

PHP61

INTEGRATION OF COST-EFFECTIVENESS ASSESSMENT IN THE MARKET ACCESS SCHEME OF DRUGS AND MEDICAL DEVICES IN FRANCE

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OBJECTIVES: In France, drugs and medical devices costs cover an important part of health care expenditure. Several reforms have been put in place over the past years in order to limit these expenditures, in particular price cutting policy. Cost-effectiveness assessment was integrated in France in the market access scheme of health products by the Social Security Financing Act for 2012 and is required since October 3rd 2013. This new mission was assigned to the Health Economics and Public Health Committee (CEESP) of the French National Authority for Health (HAS) and is become compulsory for innovative health products and are likely to have a significant impact on the health insurance expenditures. The objective of this work was to see how the cost-effectiveness assessment has been integrated in France. The objective of this assessment on the health products market access.

METHODS: The work consists in analyzing the process of the economic evaluation achieved by the HAS since October 3rd 2013. RESULTS: Economic evaluation is a step in the market access scheme. In order to respect the legislated timeframe of 90 days, it is simultaneously conducted with the medical assessment by the Transparency Commission of the HAS. For each health product, an efficiency opinion is proposed by the CEESP to the HAS according to HAS guidelines and a conclusion about the efficiency, on the basis of the Incremental Cost-Effectiveness Ratio (ICER). Currently, 15 dossiers were eligible for cost-effectiveness assessment. First assessments permit to confirm that the procedure is operational. The average processing time was 94,8 days.

CONCLUSIONS: In France without efficiency threshold value, the CEESP can’t conclude absolutely on the efficiency of health product. We don’t know how the ICER will be considered by the French Healthcare Professionals Pricing Committee (CEPS) at the time of pricing negotiation with the pharmaceutical industry.

PHP62

ANALYSIS OF COST-EFFECTIVENESS ASSESSMENTS IN FRANCE BY THE FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)

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OBJECTIVES: In France, cost-effectiveness assessment is required since October 3rd 2013. The objective of this assessment on the health products market access is likely to have a significant impact on the health insurance expenditures. The objective of this work is to report first cost-effectiveness assessments, achieved by the Health Economics and Public Health Committee (CEESP) of the French National Authority for Health (HAS). The investigation consists in analyzing medico-economic dossiers submitted at the CEESP between October 3rd 2013 and October 2014. This analysis is based on the following: a) the methodology used in the model and the process of the assessment achieved by the CEESP; b) the methodology used in the model and the process of the assessment achieved by the HAS.

RESULTS: At the time of writing the abstract, 15 dossiers were eligible for cost-effectiveness assessment. All dossiers were based on cost-utility models. Two dossiers presented a negative opinion due to the methodology conformity according to HAS guidelines. For dossiers with a positive opinion, the Incremental Cost-Effectiveness Ratio (ICER) were between 5 866/QALY (for a subgroup analysis) and 194 531/QALY. Main methodological reserves made by the CEESP concerned comparators, time horizon, robustness of clinical data, utility measures. The average processing time was 94,8 days. For the moment, no price has been published in the Official Journal.

CONCLUSIONS: The first assessments permit to confirm that the procedure is operational. In light of these first assessments, an update of the HAS methodological guidelines should be done. In France, without efficiency threshold value, the CEESP can’t conclude absolutely on the efficiency of health products. Thus, we don’t know what will be the place of the ICER in the pricing negotiation with the pharmaceutical industry and the French Healthcare Professionals Pricing Committee (CEPS).

PHP63

ACCESSING THE MEDICAL DEVICE MARKET IN THE PEOPLE’S REPUBLIC OF CHINA – POLICY CHANGES SINCE THE RESTRUCTURING OF THE CHINESE FDA

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OBJECTIVES: The objective of this research is to provide an overview of the regulatory situation for medical device registration and major policy changes are highlighted especially since the restructuring of the China FDA in March 2013. The results of this research are aimed at informing regulatory bodies, health policy decision makers, national and interna-

tional pharmaceutical technology networks and manufacturers.

METHODS: A systematic review was conducted from 2009-2013 to identify the challenges and opportunities in the Chinese medical device regulatory process and discuss the emerging challenges. The PRIOMA guidelines were applied for the search. In addition, an analysis of
previous and current policies and regulations in the grey literature was conducted for this research. Results: 17 articles were included in the systematic review. The three most crucial issues in the regulatory process have been analyzed in detail and relate to products technical requirements, the type test report and the clinical trials evaluation. Concerning the ‘products technical requirements’ and the ‘type test report’, the main challenges are related to the lack of sufficient legal status and openness for interpretation. A New Regulation governs the Supervision and Administration of medical devices introduced in June 2014 now includes improvement concerning the regulation of requirements. In addition, if a medical device fulfills certain requirements, it should be exempted from clinical trials, which signifies a major simplification for manufacturers.

CONCLUSIONS: Getting a medical device registration certificate in China is a complicated, time-consuming process. The new regulatory policies in place focus more strongly on the clinical safety of medical devices. However, some major structural problems remain, i.e. the lack of technical standards for manufacturers, with major policy planning and changes currently underway in order to address these problems.

PHP64
THE BENEFITS AND CHALLENGES OF SUBMITTING TO THE NICE MEDICAL TECHNOLOGIES EVALUATION PROGRAMME: MANUFACTURER PERCEPTIONS AND EXPERIENCES

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OBJECTIVES: The Medical Technologies Evaluation Programme (MTEP) was set up by NICE in 2009 to identify new medical devices and diagnostics that could improve patient experience and outcomes whilst driving health care efficiencies. Innovative products and processes for medical technologies evaluation were developed for manufacturers, co-ordinating and harmonising the programme and its methods. The purpose of the study was to examine the experiences of manufacturers whose products have been assessed by MTEP, to review the impact on business, that accounting for the submission of the product to MTEP, NICE support for further evidence generation, and the impact of NICE recommendations on product uptake in the UK and elsewhere. METHODS: A systematic review of grey literature on NICE/MTCP/CPMA and the impact of MTEP on pharma was conducted. Qualitative interviews were then undertaken with a representative sample of senior team members from manufacturers whose products have undergone MTEP review to elicit insight on their perceptions and experiences of the programme. Findings were interpreted and assessed thematically. RESULTS: Manufacturers have identified the benefits of submitting to MTEP in terms of value communication in the NHS, however key issues are: the significant time and resource burden of completing the submission, the lack of funding for additional data generation where this is required, the challenges of adhering to the stringent timescale, and the questionable benefit of submitting for larger companies with extensive sales teams. There is also a recognized need for greater efficiency, cost-effectiveness and patient-centric decisions in the NHS based on the MTEP guidance. CONCLUSIONS: Manufacturer experience of the MTEP process is largely positive, however as MTEP is dependent on manufacturers to initiate submissions, key actions can be taken to incentivise future submissions. Priorities will be ensuring that MTEP recommendations have a tangible and proven impact on prescribing decisions and that support is available for the submission development.

PHP65
AVAILABILITY OF RISK SHARING AGREEMENTS IN THE TURKISH PHARMACEUTICAL SECTOR

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OBJECTIVES: Risk sharing agreements are among the new trends in pharmaceutical sector as a tool for reducing the drug expenditures and increasing patient access to innovative drugs. The objective of this study is to assess the availability of risk sharing agreements in the Turkish pharmaceutical sector. METHODS: A literature review was undertaken to identify the existing risk sharing schemes in the European countries using “risk sharing agreements”, and risk sharing schemes as key words. RESULTS: Risk sharing agreements are mainly classified as financial based and performance based schemes. The vast majority of those agreements are implemented in oncology area, others are mostly implemented in ophthalmology, blood diseases and multiple sclerosis areas. Countries mostly prefer financial based schemes as they are easier to implement and track. Performance based agreements are relatively rare as they are more complicated due to the long length of follow up, lack of reliability of data generation/registration, administrative burden for all stakeholders. CONCLUSIONS: Taking into account that original drugs to be reimbursed in Turkey need to grant a compulsory statutory discount which is generally 41%, it can be stated that Turkey is already implementing a financial based scheme. On the other hand, when availability of performance based risk sharing agreements is assessed, there is a lack of infrastructure to track drugs or non-responders and also it seems to be difficult to make this kind of agreements in Turkey without making any amendments in current regulations. In addition to these regulation issues, transaction and administrative costs should also be taken into account. On the other hand despite these difficulties, these schemes could provide budget control and patient access to highly innovative and expensive treatments.

PHP66
IMPACTS OF COST-CONTAINMENT POLICIES ON BIOSIMILARS MARKET

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OBJECTIVES: The expiration of biotech drugs patents has led to the creation of drugs copies of originator products, defined biosimilars. The automatic substitutability between the originator and the biosimilar is not allowed in Europe with the exception of France. In Italy, in the absence of a national legislation, some Regions have issued directives to the spread of the biosimilar use. Campania was the first Region to legislate on the matter, supporting the prescription of the biosimilar to the naive patient. The aim of this study was to evaluate the impacts of cost-containment policies about biosimilars in Campania between 2009 and 2013. METHODS: IMS Health regional database was used to carry out this descriptive retrospective drug utilization for the years 2009 through 2013. Information was retrieved about different classes of biotech drugs (retail, direct distribution, hospital). Data were expressed in Counting Units (CU) and trends have been calculated using Compound Average Growth Rate (CAGR). RESULTS: In 2013, a total consumption of 930.859 CU of biosimilar drugs was registered in Italy (CAGR 12/09 68.8%). The penetration rate of biosimilars was 23.9% with regard to expenditure and 25.3% with regard to consumption. Analyzing the consumption of biosimilars by therapeutic category in Italy, the consumption of erythropoietin and filgrastim has an index of annual growth respect to the original drug (annual 153.8% and 174.7%). In Campania, the penetration rate of all biosimilas was 31.4% of total expenditure and 35.9% of consumption. Analyzing the trend in consumption for single therapeutic category, it can be seen that penetration rate to erythropoietin and filgrastim was 34.5% and 39.2%, respectively. However, the average annual growth rate is around 54%. CONCLUSIONS: The results suggest that Campania Region records an index of market penetration of biosimilars higher than the national. This trend could be attributable to the cost-containment policies implemented in the region.

PHP67
ECONOMIC IMPACT OF DRUGS DE-FUNDING AND PHARMACEUTICAL CO-PAYMENT

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OBJECTIVES: To assess the consequences in terms of outpatient pharmaceutical expenditure, and uptake of medicines, in Spain, of the introduction of pharmaceutical de-funding and co-payment in 2012. METHODS: Cross-sectional study during 2012. Two health regions of Spain (Comunitat Valenciana with 6,237,396 inhabitants and Merida (Badajoz), Spain with 5,129,266 inhabitants) were selected. A drug-utilization study was carried out. Consumption of medicines during the first half of 2012 in the two health regions was compared with consumption in 2011. RESULTS: The total spending on medicines was reduced by 16.80% after the new law. By gender, the reduction was greater in women (17.47% versus 15.25%). By age, the decrease was seen most sharply in the age bands of 10 to 14 years of age. After drug named controlled, the reduction was greatest in women and girls (17.47% versus 15.25%). By age, the decrease was seen most sharply in the senior age bands of 65 and over. However, the proportion of new users dispensed low dose zolpidem during each of the time periods was evaluated. Chi square tests were used to examine differences in the proportion of new users dispensed low dose zolpidem during each of the time periods. RESULTS: Overall a significantly higher proportion of patients in all gender groups received low dose IR zolpidem during the post-warning compared to the pre-warning period. Similar results were found for the ER formulation except among males 65 years old and older. Before and after the FDA safety warning, the highest proportion of patients receiving low dose zolpidem (any formulation) for their first prescription was among elderly women (46% pre-warning, 53% post-warning). Even after the FDA warning, a large proportion of women 18 to 64 years old (63% IR; 65% ER) and women 65 years or older (46% IR, 55% ER) received high dose zolpidem for their first prescription. CONCLUSIONS: For all age and gender categories, the proportion of patients receiving low dose zolpidem increased after the FDA safety warning issued in 2013. The highest proportion of low dose zolpidem use was seen in elderly females. However, the proportion of women and elderly who received low dose zolpidem even after the FDA safety warning was still relatively low.
NSAIDs present in household drug supplies, and address the issue of possible inadequate use of NSAIDs in the countries in question. An observational cross-sectional study of drug storage and self-medication practices in households in the city of Novi Sad, Serbia over the 8 months period. Study consisted of personal insight into the drug inventory, and drugs were classified according to the Anatomical Therapeutic Chemical (ATC) classification system in order to identify real consumption / EC. RESULTS: Out of 383 surveyed households, 280 (73%) households held at least one box of NSAID in their home-pharmacy and a total of 473 packages of NSAID have been inventoried. Most commonly encountered NSAID was diclofenac (52.64%), ibuprofen (52.6%), meloxicam (8.03%) and meloxicam (3.8%). Other NSAIDs accounted for less than 4% altogether. Over 70% of all NSAIDs present have been bought without prescription. Majority of ibuprofen (91.3%) and diclofenac (65.74%) were obtained without a prescription even though in Serbia all NSAIDs (except ibuprofen 200mg) are prescription-only medication (POM). According to European Medicine Agency, ibuprofen is classified as OTC, but diclofenac is strictly POM. Large amount of diclofenac used without consulting a physician points to underuse of this issue. Ibuprofen and meloxicam were almost exclusively bought with prescription (>80%). CONCLUSIONS: NSAIDs were present in most of Serbian home-pharmacies and were usually bought without prescription. This present a serious problem, especially for unsupervised diclofenac use. Therapeutic indication, a pharmaceutical’s life-cycle or overestimation of the EC influence share and extent of AB could be identified. It is assumed that label restrictions which were assessed by an EBA in 2011 or 2012 and were still available in 2012 and 2013 accordingly.

METHODS: MethOds: All pharmaceuticals which were assessed by an EBA in 2011 or 2012 were still available in 2012 and 2013, and glitazins launched before 2011 with an EBA in 2013 were considered. A pharmaceutical’s real consumption (measured by defined daily doses) in 2012 and 2013 was compared to the expected consumption (EC) based on the highest possible number of patients defined by the Federal Joint Committee according to a pharmaceutical’s label. For the EC only subpopulations with an acknowledged additional benefit (AB) were taken into account. Results are presented in terms of shares (EC/real consumption / EC).

RESULTS: Pharmaceuticals with a low share (<10%) were cabazitaxel (0.22% in 2012), saxagliptin, proton pump inhibitors against chronic hepatitis C, eribulin, vandetanib and rivaroxiban. Sitagliptin, ticagrelor, antineoplastic agents and tacafamid achieved a midsize share (10-50%). Ivecavor, abiraterone, entrectina- bin/rilpivirin/tenofovir, apixaban, fingolimod and axitinib reached shares of >50% and up to 398%, respectively (fingolimod in 2013). There was no correlation between the extent of AB and a pharmaceutical’s share. For most pharmaceuticals consumption was higher in 2013 than 2012.

CONCLUSIONS: The shares of pharmaceuticals considered in this analysis vary between 0.22% and 398%. No correlation between shares and AB was identified. All results are considered to be true. It is assumed that label restrictions regarding the use of a pharmaceutical, competing alternatives in the same therapeu- tic indication, a pharmaceutical’s life-cycle or overestimation of the EC influence a pharmaceutical’s consumption. This was an observational, cross-sectional study of drug consumption. Further research is needed to confirm these assumptions.

PHP72 PRESCRIBING PATTERN OF ANTIBIOTICS IN NEONATES IN A TERTIARY CARE HOSPITAL Thakur S³, Acharya LD², Lewis LES³, Kumar R³, Kumar S³

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OBJECTIVES: Neonates are among special population group who are more vulnerable to infections due to underdeveloped immunity level at their age (0-28 days of life) and it is a common practice of administering anti- biotics pending bacterial culture results, to sick neonates and to neonates who are more prone to develop infectious diseases; which in turn is gradually pro- moting antibiotic resistance. The objective of the present study was to investigate changing of Candida species (C. spp) distribution and antibiotic susceptibility of different C. spp. and 52 (50.5%) patients in 2011,2012 and 2013 accordingly. Candida parapsilosis was Candida albicans (C.a.), which was isolated in 21 (44.7%), 21 (42%) patients (12.2% of ICU microbiota). In 2011: 47 (19.3%); in 2012: 50 (9.3%); in 2013: 52 (5.2%) patients. In 2011: 47 (19.3%); in 2012: 50 (9.3%); in 2013:

RESULTS: Of the total of 404 admitted neonates, 30% (n =122) were prescribed with antibiotics, among which 76 (62.3%) males and 46 (37.7%) were females. Among n=122 cases, 71 (58.2%) empirically and 51 (41.8%) were pre- scribed in indication of infections. Most commonly prescribed antibiotic class was Aminoglycoside (97.54%), broad spectrum penicillin (66.39%), extended spectrum penicillin (28.68%), 2nd generation cephalosporin (17.1%). Empirical use of ampi- cillin and amikacin were most frequently encountered. Our study showed that Dual antibiotic regimen produced a better outcome (50%) than single/triple/more antibiotic regimen. CONCLUSIONS: The broader outcome of this study would be the potential utility of this data in designing strategies both at level of physicians and administrators for rational prescribing and policy decisions respectively, so that more appropriate use of antibiotics and strategy of antibiotic cycling can provide some better answers for difficulties coming across in management of neonatal infections.”

PHP74 DO QUALITY OR EFFICIENCY INDICATORS INFLUENCE QUALITY OR EFFICIENCY INDICATORS OUTSIDE P4P? Pichetti S, Perronnet M, Sermet C

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OBJECTIVES: Payments for Performance (P4P) schemes are commonly used in many OECD countries in order to incite physicians to improve both quality and efficiency outside the P4P perimeter. In France, a set of 29 indicators has been selected as the P4P perimeter by National Public Health Insurance. Each indicator provides useful information of GPs’ performance, but it is not that easy to combine them all at the same time in order to get a synthetic view of GPs’ performance and their potential influence outside P4P. Other studies (Campbell et al., 2009) tend to show that respecting P4P targets may imply a virtuous effect outside P4P. On the contrary, others (Lavigne et al., 2013) have shown that P4P outside the P4P perimeter (De Pouvourville, 2013). Therefore, respecting P4P targets may have implications for public policy design. If respecting P4P targets imply a virtuous effect outside P4P, there is no need to extend the P4P perimeter. If not, regulatory agency has to increase the number of indicators in order to improve quality and efficiency.
**PHQP7**

**TREND COMPARISON OF THE COLOMBIAN MULTIDIMENSIONAL POVERTY INDEX, INEQUALITIES IN MATERNAL MORTALITY, NEO-NATAL MORTALITY AND GINI COEFFICIENT**

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**OBJECTIVES:** To describe and compare the Colombian multidimensional poverty index (MPI), its trends against Gini coefficient (GC) and inequalities in maternal mortality and neonatal mortality since 1997 to 2011. METHODS: An ecological study was performed. MPI and Gini coefficient were obtained from National Statistics Department’s (DANE) databases. The Maternal Mortality Rate and Neonatal Mortality Rate were estimated and standardized by age and sex respectively. The Attributable Fraction (AF) was estimated as the inequality indicator for these two variables, and AF = 1 indicates the risk by geographical exposure and Punishment” and “A” and behavior among MPI’s Colombian version and health inequities and disparities indicators over time from 1997 until 2011. RESULTS: A substantial change was evident in the MPI 51% decrease (1997-2011) and 40%, (2003-2011) decreasing from 0.6 to 0.4, respectively. The Gini coefficient increased a 3% increase, from 83.4% to 86.2% (2000-2008), and a slight reduction for Neonatal Mortality attributable fraction (NMAF) 1.6% (2000-2008) decreasing from 88.9% to 88.4%. At the same time, GC evidenced a 1% decrease between 2000-2001 and decreasing from 0.57 to 0.54. CONCLUSIONS: The established MPI for Colombia in the last decade had a descending trend and did not resemble the behavioral stage of the major inequity indicators calculated for the country in the same time span. Colombia: What was an undervalued perception over the issues where affected population were not target of requested interventions. It is therefore important to question the validity of measures used to quantify the poverty (MPI)’s Colombian version. In order to identify the strategic gaps, health inequity is an important referent to create control and intervention measures. **PHQP7**

**NURSES VERSUS OTHER HEALTH PROFESSIONALS PERCEPTIONS ON QUALITY AND SAFETY CULTURE ELEMENTS IN GREEK HOSPITALS**

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**OBJECTIVES:** To explore the perceptions of nurses and other health professionals on quality and safety culture elements in Greek hospitals. Quality and risk management together, are prerequisites of patient safety which forms the basis of health care quality management activity. OBJECTIVES: To explore the prevailing organizational climate-in terms of clinical governance “factors-clinical governance” and “safety culture factors” and proactive risk management”, in Greek hospitals and to compare nurses’ perceptions with those of the rest health professionals on the particular factors. METHODS: It is a cross-sectional study, including a representative sample of all specialties of health professionals working in a public and a private Greek hospital. The validated Clinical Governance Climate Questionnaire (GCCQ) was filled by Nn = 261 nurses and Nn= 198 other professionals (response rate 79%). A lower score signifies greater satisfaction in a particular concept. Data mining took place from May to August 2012. Data analysis was performed with the SPSS 19.0 and included factor analysis, t-test, X²-test and regression analysis The two-tailed significance level was set at ≤ 0.05. Significance of “at least bump a blue 1% - 15%” compared with the samples planned and integrated IQ program and proactive risk management”, demonstrated a slightly positive trend (Means: 2.73 and 2.28 respectively) in the total population. Nurses, appear to perceive more negatively the climate related to: i) protected time for Quality Improvement initiatives (p < 0.05), ii) systematic assessment of clinical risks (p < 0.001), iii) sharing of a common vision (p < 0.05), iv) dissemination of Risk prevention policies (p < 0.003), v) proactive risk management (p < 0.05), vi) systematic evaluation of Human Resources development needs (p < 0.001), vii) equal employee’s value regardless of professional background (p < 0.05). CONCLUSIONS: The views of nurses are essential, as they are important and direct factors of care provision. The assessment of climate produces conclusions which if exploited properly, can support the begin the marking and support the effort of continuous improvement of patient safety. **PHQP7**

**PHARMACEUTICAL MARKET ACCESS IN EMERGING MARKETS THROUGH INNOVATIVE PATIENT ACCESS SCHEMES**

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**OBJECTIVES:** Emerging markets are a major priority for pharmaceutical manufacturers, and continue to grow as areas of interest for many firms. However, coverage from 3rd party payers, whether public or private, is often limited, and as a result the patient is the primary payer. Pharmaceutical companies must devise innovative strategies in order to provide access to patients while driving sales. In this study, we aimed to provide an understanding of the current environment outlining the challenges and potential solutions in emerging markets. METHODS: We undertook a secondary research horizon scan of the most relevant literature in the field to provide insights on how companies are addressing the challenges to access in emerging markets. RESULTS: We categorized n = 14 research studies according to their region and categorized in 12 main categories/archetypes: Licensing and Technology Transfer, Differential Pricing and Cost Offset Programs, and Value Added Services based on the primary objectives and characteristics of the scheme. A majority of programs fell under the Differential Pricing and Cost Offset programs (n=8), with the other two categories split up evenly at n=3 each. CONCLUSIONS: Pharmaceutical manufacturers are using innovative patient access schemes to gain access in emerging markets and are doing so by finding ways to drive down overall patient spend. While we were able to archetype innovative patient access schemes into three categories, it is important to note that many schemes incorporate elements from across the categories identified. The design and implementation of schemes into which pharmaceutical companies account is a host of factors including country level dynamics, company assets and strategy, and particulars of scheme design. **PHQP8**

**PATIENT ENVOLVEMENT IN REIMBURSEMENT OF DRUGS IN SLOVAKIA**

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**OBJECTIVES:** To define the possible ways of participation of patients in the decision-making processes in pharmaceuticals. To analyze the current trends in the reimbursement process in Slovakia and to define barriers to the participation. METHODS: To identify the relevant literature, a survey was carried out using a search engine to the literature in PubMed 2000-2013. The survey was carried out with the definition of the key words “Innovations”, “Innovation” or “Pharmaceutical Innovation”. Materials with those keywords were found, as well as through a Web browser. We performed analysis of the Slovak legislation, which regulates the status of patients in the reimbursement process and the comparison of this with other legislative standards, governing the status of citizens in public processes. There has also been evaluated legislative consultation process, which took place during the years 2010 and 2011. RESULTS: Actually the patients can (as the whole public) only view all documents relevant to reimbursement, since they are not a “registered” participant of the process. They are 3 possibilities to comment the process according to relevant legislation: send a written complaint to the MoH, draw up a petition or file a complaint. In the period 2010 – 2011, before the legislation change, the MoH received 318 comments, from that 140 were from public. CONCLUSIONS: The whole process is totally transparent and visible via internet site of MoH. The status of patients (e.g. patient representatives) in the process declined since the last change of legislation from 1.12.2011. Due to the introduction of WTO threshold for ICE/QALY is also the introduction of innovative drugs more restrictive as before, what makes the possibilities of patient participation in reimbursement process even more important. **PHQP9**

**ADVANTAGES OF EXTemporANEOUS dosage FORMS IN UKRAINE**

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**OBJECTIVES:** We evaluated the data of license registry of Ukraine on 01.01.2014. Existing extemporaneous medicines are presented in 426 pharmacies, about 3% of the total number in Ukraine. The range of extemporaneous formulations in Ukraine is significant, it is complemented by modern specifications physicians. METHODS: We analyzed the 1570 prescriptions on extemporaneou", image forms of various doctors in few Lviv pharmacies during 2013-2014. RESULTS: We found that 53 names of substances used active substances and excipients. That should be noted that different formulations are made: medicine, mixtures, solutions, suspensions, drops, ointments, suppositories and other forms. Among the most commonly prescribed by doctors’ prescriptions are liquid dosage forms, topical solution (solution furacin) 0.02% - 500.0; rivanol 0.05%, 0.1% - 500.0; hydrogen peroxide 3% - 500 0; a solution of methylene blue 1% - 10.0; citral alcohol solution. CONCLUSIONS: Extemporaneous medicines are economically available, the average costs of solutions are 4-12 UAH (1 Euro 8), with the other two categories splitting 6-18 UAH, ointments - 5 - 15 UAH, which is 40-85% less than the manufactory prices. Legislation and regulations are necessary that will control the activities of pharmacies. **PHQP80**

**TOWARDS UNIVERSAL HEALTH CARE: A REVIEW OF THE BASIC BASKET OF CARE ASSOCIATED WITH UNIVERSAL HEALTH CARE DELIVERY MODELS**

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**OBJECTIVES:** In 2014, the Irish Department of Health and Children (DoHC) published a paper to outline the development of Universal healthcare by 2019. The impetus for adopting Universal healthcare is multi-faceted; the main driver being a policy document outlining the introduction of Universal healthcare by 2019. The aim of this review was to catalogue what basic care is offered at the population level across Universal delivery models in Europe and document disease-specific resource use and health outcomes as well as organisation around reimbursement structures for purposes of informing policy in Ireland. METHODS: EU-27 countries were classified by health care delivery systems according to data available from

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each country’s department of health. Countries were reviewed under a range of headings including: current delivery models in place, institutions responsible for delivery and organisation of reimbursement system, incentive structures in place, basic bundle of health care covered, additional options for coverage, disease-specific resource use and health outcomes, government contribution to cost of health care and how that expenditure is funded. Results: As of 2013, plans include similar methods on increasing patient access such as off-label use, compassionate use and cross-border health care. Some have outlined further priority on the characteristics of and variation across Universal health care models.

PHP81 NATIONAL RARE DISEASE STRATEGIES: THE CURRENT STATE FOR ORPHAN DRUG MARKET ACCESS IN EUROPEAN UNION (EU) MEMBER STATES Scholen J., Lie X, Kalbausko A, Maervoet J.

Objective: To analyse how the number of patients treated by colony-stimulating factor treatment has been a focus point in the national plans for rare diseases. Congruencies and variations across countries dependent upon the Universal delivery model in place. Conclusions: This review presents characteristics of Universal health care delivery systems across Europe. Basic bundles of health care provision and organisation of reimbursement across countries have been outlined. This paper focuses further priority on the characteristics of and variation across Universal health care models.

PHP82 MEASURING THE EFFICIENCY OF HUNGARIAN HOSPITALS BY DATA ENVELOPMENT ANALYSIS Csakvári T., Turcsányi R, Vajda B, Dankó N, Agoston I, Broncz I

Objective: to analyse the efficiency of the Hungarian acute inpatient-care system. Methods: Data derived from the Hungarian nationwide health insurance database analyzed using technical (C) and scale efficiency (SE) of the Hungarian acute inpatient-care system (2003, 2006, 2010). The number of hospitals included into the study was 133 in 2003, 125 in 2006 and 93 in 2010. We chose four inputs and two outputs: the number of active hospital beds, the number of discharged patients, the number of one-day cases, completed days of nursing (inputs), average length of stay, DRG cost weights (outputs). The method we used for our calculations was Data Envelopment Analysis. Results: In 2003 both the technical and scale efficiency were high (TE: 96.9%; SE: 92.9%). To 2006 the situation deteriorated by some degree (TE: 96.6%; SE: 80.3%). By 2010 technical efficiency still did not show improvement (TE: 94.0%), but scale efficiency increased (SE: 88.2%). Usually the hospitals with higher number of beds are more efficient than the smaller units. Conclusions: The effects of the performance volume limit did not improve the two values; however, the capacity decrease of 2007 did improve the scale efficiency to some extent. The Hungarian health care system needs to reduce the numbers of hospitals and rethink their functions, but needs to increase the size of them.

HEALTH CARE USE & POLICY STUDIES – Formulary Development

PHP83 EXPERIENCES WITH PRICE COMPETITION OF BIOSIMILAR DRUGS IN HUNGARY Horváth I, Nagy Z, Tóth Z, Ágotin I, Endrei D, Csakvári T, Broncz I

Objective: The aim of our study is to analyse the efficiency of the Hungarian National Health Insurance Fund Administration in case of colony-stimulating factor and erythropoietin products. Methods: Data derived from the nationwide pharmaceutical database of Hungarian National Health Insurance Fund Administration. We analysed how the number of patients treated by colony-stimulating factor and erythropoietin products changed before (01.07.2011 - 30.06.2012.) and after (01.01.2012 - 30.06.2013.) the introduction of biosimilar bid in Hungary. Results: In the 12 months before biosimilar bid introduction, patients received erythropoietin treatment, while in the first 12 months after the bid 3647 patients, received colony-stimulating factor treatment, while in the first 12 months after the bid 3647 patients, receiving a 12.5% decline. In the 12 months before biosimilar bid 13974 patients received colony-stimulating factor treatment, while in the first 12 months after the bid 13352 patients, resulting in a 4.5% decline. Conclusions: The analyses of the Hungarian price competition bid of biosimilar products showed a minimal decline in the utilization of both colony-stimulating factor and erythropoietin products while the health insurance reimbursement of these drugs significantly decreased.

PHP84 IMPACT OF PRIOR AUTHORIZATION RESTRICTIONS ON RESOURCE UTILIZATION AND COSTS IN US HEALTH PLANS: A REVIEW OF LITERATURE Shal D, Tontum V, Faly V

Objective: Prior authorization (PA) restrictions have been implemented by US health plans as an effort to ensure appropriate utilization and control costs. A review of published peer-reviewed literature was conducted to evaluate the impact of such PA restrictions on resource utilization and costs. Methods: A targeted review of literature was conducted in Medline from 2009 onwards using the terms ‘insurance claim’, ‘impact’, ‘economic’. Review articles, non-English language studies, non-US studies, papers, and studies evaluating the effectiveness of formulary policies of which PA may be a component were excluded. Impact of PA policies on health care utilization and costs was qualitatively assessed. Results: Fourteen studies were identified which met our inclusion criteria. Majority (57%) of the studies were conducted on Medicaid plans (Medicaid: 8, commercial: 4, Medicare: 1, not clear: 1). Majority (57%) of studies evaluated the impact of mental health medications (anti-depressants, anti-depressants bipolar medications, antipsychotics), two studies were conducted on anti-diabetics, one on a multiple sclerosis drug, one for a lipid-lowering drug, one on an anti-rare disease and one on a vaccine. Few studies were industry-sponsored. Conclusions: Although PA restrictions may result in cost-savings, patient safety and quality of life concerns must also be evaluated while imposing these restrictions. Rigorously designed studies including assessment of PA administration costs as well as indirect costs due to lost productivity should be conducted to better assess the overall economic impact of such restrictions.

PHP85 DO NICE DECISIONS AFFECT DECISIONS IN OTHER COUNTRIES? Hernández-Villafuerte E, Carau M, Devlin N

Objective: The objective is to test the hypothesis whether NICE recommendations on the use of a new drug affect recommendations from other bodies in countries outside England and Wales. To our knowledge, this is the “first attempt to approach this topic quantitatively. Therefore, a sub-objective is to determine the feasibility of gathering a high quality database with sufficient number of observations to test our hypothesis. Methods: A basket of 29 drug/indications pairs and a group of 15 drug/indications pairs were included (Australia, Canada, Denmark, France, Italy, Korea, The Netherlands, New Zealand, Poland, Portugal, Spain, Bosnia, Ecuador, Egypt and Ghana). Information regarding NICE HTA recommendations was extracted from NICE’s website and HTAinSite.com. Moreover, an online-survey of key opinion leaders was carried out to collect information regarding the HTA decision in 10 countries. For the remaining five countries, we used the information from their official webpage. A descriptive analysis was conducted, including an examination of the proportion of NICE decision in countries and the timeline of the decision making about the 29 medicines. Results: There is a lack of comparability between the publically available information. The findings suggest that rejection or restricting the use of a NICE appraisal there is a higher probability that an HTA is undertaken for the same drug in other countries. Furthermore, when NICE has published a negative decision, the tendency of not recommending the drug by another HTA body is much larger after than before NICE’s decision. Conclusions: Issues encountered in the collection of information made it difficult to quantify the effect of NICE recommendations on HTA decisions in other countries. The results suggest that the selected agencies are considering NICE decisions as a factor for rejecting or restricting the use of drugs in which other case would be recommended or reimbursed.

HEALTH CARE USE & POLICY STUDIES – Health Care Costs & Management

PHP87 COMPLICATIONS, COSTS AND RESOURCE UTILIZATION IN REAL-WORLD COMPLEX ABDOMINAL WALL RECONSTRUCTION PATIENTS Mencer M, Reaven N, Funk S, Frain M, Macarios D, DeVito III G

Objective: Little information is available on complication-related resource utilization in patients undergoing complex abdominal wall reconstruction. Under pay-for-performance requirements financial decision-makers need better information to allocate health care resources and budget dollars. This analysis reports complication-related resource utilization and costs over time in a real-world patient population undergoing complex abdominal wall reconstruction. Methods: A cohort of patients with complex abdominal wall reconstructions during inpatient stays between 1/1/08 and 6/30/11 (index event) were followed for 12 months. Related complications, revisions for facility-based care and related costs were evaluated for 30-60-90-365 days after discharge. Insurance claims from the Truven Health
Analytics MarketScan® database, inpatient costs from the Healthcare Cost and Utilization Project (HCUP) and costs reported for Ambulatory Patient Classifications (APCs) were used to estimate costs from the hospital perspective. RESULTS: 13,463 patients were evaluated. Rates of patients experiencing any complication were 17.3% within 30 days, 11.0% within 31-60 days, 8.1% within 61-90 days, and 21.4% within 91-120 days. The most frequent complications over 12 months were infection (16.6%), bowel obstruction/other GI complication (12.6%), skin/connective tissue-related complications (10.7%), and wound complications (8.7%). Complications-related cost over time followed a similar trend; average 12 month cost for patients experiencing an infection was $20,679, $21,558 for bowel-related complications, $14,950 for skin/connective tissue related complications and $19,230 for wound complications. The index event average length of stay for patients was 9.1 days. Patients and patients with complications had a 3.9 (SE 4.4) and 17.0 (SE 19.6), respectively, p < 0.0001. CONCLUSIONS: Health care resource utilization, costs and complications for common hospital diagnoses, such as wall reconstruction patients increase over time. Resource utilization is exacerbated when complications occur. Further study may be required to validate these findings.

PHP58
THE GROWING FINANCIAL AND QUALITY-OF-LIFE BURDEN ASSOCIATED WITH ATRIAL FIBRILLATION (AF), DIABETES, CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND ASTHMA IN IRELAND
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Many people in Ireland suffer from chronic diseases including AF, diabetes, COPD and asthma. With the prevalence of these conditions expected to rise, general wellbeing and quality-of-life will be increasingly affected. Chronic conditions also account for most of the health care resources used, and represent a significant economic burden in the future. Using data from WHO and disease prevalence and 2011 Census data. Estimate the number of patients not achieving target management of their condition and the associated number of preventable events and total costs, using publically available information. RESULTS: Of the estimated 1-4 m patients with AF, diabetes, COPD and asthma in Ireland, 3,563 patients are not receiving appropriate antiagglutination treatment. This results in 531 patients experiencing an avoidable stroke each year, costing the health care system around €1.3m. Amongst the 238,585 patients diagnosed with type 2 diabetes, 17% will not achieve a target HbA1c of 6.5% or less, resulting in an expense of €886m and 12,493 avoidable deaths each year. In addition, 30% of diagnosed COPD patients, and as many as 60% of asthma patients, are not managing their condition effectively, costing the Irish health care system €899m per year in hospital admission costs alone. CONCLUSIONS: Much of the chronic disease burden is caused by preventable risk factors. This is intended as a key policy lever, to elevate chronic diseases on the health and wellness of their employees. This study examined the practices of employers in the US, focusing on the steps employers take to improve health and wellness. OBJECTIVES: To describe the health and wellness programs actively engaged in promoting employee health. METHODS: A study of 18 employers who applied for the Working Well award provided by the Louisiana Business Group on Health in 2013, recognizing employers who are exemplar in their employee health and wellness activities. Applicants completed a survey detailing business policies and programs intended to promote wellness. De-identified data derive from 2013 applications. RESULTS: Over half of the companies had fewer than 500 employees (55.6%), 4 had more than 2000. Health plan coverage was fully (8; 44.4%), non-U. S. pharmaceutical firms also have an adjusted ROE of 11.1%. Non-U. S. pharmaceutical firms also have an adjusted ROE that is comparable to firms from other industries (7.6% pharma vs. 9.6% non-pharma). The implication of these findings is that the capitalization of R&D is more appropriate. OBJECTIVES: To assess the incremental costs, and the incremental cost-effectiveness ratio, for specialty vs. traditional drugs, raising questions of affordability, and whether their clinical benefits are able to effectively treat the disease. METHODS: The incremental costs were estimated by multiplying the incremental costs of specialty drugs, and to mitigate inappropriate use and waste to ensure that effective treatments are affordable to patients.

PHP69
WHAT IS WORKING WELL IN LOUISIANA FOR US EMPLOYERS? A DESCRIPTIVE STUDY OF EMPLOYERS ACTIVELY ENGAGED IN PROMOTING EMPLOYEE HEALTH
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OBJECTIVES: As health care costs continue to rise, employers seek options to improve the health and wellness of their employees. This study examined the practices of employers that are actively engaged in promoting employee health. METHODS: A study of 18 employers who applied for the Working Well award provided by the Louisiana Business Group on Health in 2013, recognizing employers who are exemplar in their employee health and wellness activities. Applicants completed a survey detailing business policies and programs intended to promote wellness. De-identified data derive from 2013 applications. RESULTS: Over half of the companies had fewer than 500 employees (55.6%), 4 had more than 2000. Health plan coverage was fully (8; 44.4%) or self (7; 38.9%) funded. Almost half implemented wellness programs within the last 3 years (44.4%), whereas 4 (22.2%) had programs more than 10 years; all company funded. Annual spend on wellness was split across participating employ- ers with 55.6% spending > $50,000 and the rest $50,000 (8; 44.4%). Rationale most cited for programs: improve employee wellbeing (18; 100%), contain health care costs (17; 94.4%), increase productivity (13; 72.2%), and reduce absenteeism (12; 66.7%). Most employers incentivized program participation (16; 88.9%) through premium reductions (8; 44.4%), cash (8; 44.4%), or PTO (3; 16.7%). Information most reported to help with wellness planning were health risk assessments (HRAs) (15; 83.3%), reductions (8; 44.4%), cash (8; 44.4%), or PTO (3; 16.7%). OBJECTIVES: Throughout Europe, economic conditions are forcing health care system managers to look at ways to reduce costs. One potential driver of health care costs is hospital length of stay (LOS). This study sought to determine which European countries have been most successful at reducing their average LOS for five inpatient admissions. This research also sought to quantify the potential savings for countries that have not already reduced their average LOS in order to budget these savings for their peers. METHODS: A review of hospital LOS and cost per day of hospital stay was conducted in five European countries (France, Germany, Italy, Spain and the United Kingdom), utilizing data published by the World Health Organization (WHO). Additionally, hospital payment systems were assessed in each country through published research to understand systemic motivations of health care providers with regards to LOS. RESULTS: Substantial variability exists in average LOS for the five study admissions. The general finding was that in the UK, the average LOS for three admissions (single spontaneous delivery, cataracts, and pneumonia) are relatively similar across countries. However, the average LOS in Germany for malignant neo- plasm of the breast and acute myocardial infarction are significantly higher than the other four countries. There is little variability, however, in average costs per bed-day in the target countries. A review of payment mechanisms for inpatient hospital stays reveal that hospitals are financially incentivized to minimize LOS in all five countries. CONCLUSIONS: Additional research is needed to understand the reason for the discrepancy between German stays and the other four countries. While there are many potential reasons for the differences, should Germany align their average LOS for malignant neoplasm of the breast and acute myocardial infarction with the other four countries, they could save €744 million per year.

PHP91
R&D INVESTMENTS, INTANGIBLE CAPITAL AND PROFITABILITY IN THE PHARMACEUTICAL INDUSTRY
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OBJECTIVES: Much of the chronic disease burden is caused by preventable risk factors. This is intended as a key policy lever, to elevate chronic diseases on the health and wellness of their employees. This study examined the practices of employers that are actively engaged in promoting employee health. METHODS: A study of 18 employers who applied for the Working Well award provided by the Louisiana Business Group on Health in 2013, recognizing employers who are exemplar in their employee health and wellness activities. Applicants completed a survey detailing business policies and programs intended to promote wellness. De-identified data derive from 2013 applications. RESULTS: Over half of the companies had fewer than 500 employees (55.6%), 4 had more than 2000. Health plan coverage was fully (8; 44.4%) or self (7; 38.9%) funded. Almost half implemented wellness programs within the last 3 years (44.4%), whereas 4 (22.2%) had programs more than 10 years; all company funded. Annual spend on wellness was split across participating employ- ers with 55.6% spending < $50,000 and the rest > $50,000 (8; 44.4%). Rationale most cited for programs: improve employee wellbeing (18; 100%), contain health care costs (17; 94.4%), increase productivity (13; 72.2%), and reduce absenteeism (12; 66.7%). Most employers incentivized program participation (16; 88.9%) through premium reductions (8; 44.4%), cash (8; 44.4%), or PTO (3; 16.7%). Information most reported to help with wellness planning were health risk assessments (HRAs) (15; 83.3%), health care claims and utilization (14; 77.8%), and worker’s compensation claims (8; 44.4%). CONCLUSIONS: In the US, employers are responsible for a significant por- tion of health care spend. Though a small self-selected sample, this analysis reveals that employers actively engaging their employees, using prevention and incentives to promote the health and wellness of their employees, are more likely to have better awareness of efforts that improve employee health and wellness can help attract and retain staff, as well as potentially reducing health care costs.

PHP92
A QUANTIFICATION OF EXPENDITURE ON HOSPITAL STAYS IN 5 EUROPEAN COUNTRIES
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OBJECTIVES: Do specialty drugs offer greater value for money than traditional drugs? METHODS: We searched the FDA website to identify all NDAs approved from 1999 through 2011. We identified published esti- mates of additional health gains (measured in quality adjusted life years (QALYs)) and costs (drug costs, hospitalization costs, etc) associated with specialty drugs compared to existing standard of care at their time of approval, and compared findings with traditional drugs. We compared incremental QALY gains, increment- tal costs, and the incremental cost-effectiveness ratio, for specialty vs. traditional drugs. RESULTS: We found specialty drugs offered greater QALY gains than traditional drugs (p < 0.01 vs. p = 0.17), but were associated with greater additional costs ($10,460 vs. $906, p < 0.01). We found the cost-effectiveness of the different drug types to be broadly similar (p = 0.58). CONCLUSIONS: This research suggests specialty drugs may offer greater health benefits over existing care than traditional drugs, and despite the high costs being associated with greater incremental additional costs were comparable in terms of cost-effectiveness. As payers search for ways to control health care costs it is important to recognize the relative benefits as well as the costs of specialty drugs, and to mitigate inappropriate use and waste to ensure that effective treatments are affordable to patients.
PORTUGAL - THE CASE OF HEALTH CARE AND PHARMACEUTICALS

The price lists with the number of the products, maximum and average ex-factory prices were based on ex-factory prices. A descriptive analysis was conducted on the last price list of each calendar year published by MoH for the years between 2009-2013. The potential impact of patient access to all drugs was assessed. There was an increasing trend for the pharmaceutical consumption in years depending on the taken policies as other health care services. The aim of this study is to review an analysis for the new drug release prices for Turkey in the recent years. METHODS: The data was obtained from the last price list of each calendar year published by MoH for the years between 2009-2013. The year 2014 year data list was limited with the first quarter (Q1). The data classified in this paper which were over 100 TL, over 1000 TL and over 10000 TL. The result was based on ex-factory prices. A descriptive analysis was conducted on the price lists with the number of the products, maximum and average ex-factory prices. The numbers of new released products over 100 TL were; 1, 7, 58, 36 and 52 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The numbers of new released products over 100 TL were as follows: 0, 1, 10, 11 and 13 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The maximum ex-factory prices were 739 TL, 711 TL, 722 TL, 27791 TL, 5512 TL, 4740 TL, 2458 TL, 11000 TL and 2727 TL, respectively. The average ex-factory prices were 178 TL, 329 TL, 28 TL, 314 TL, 36 TL, 93, 497 TL and 612 TL in the years 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016, respectively. The defined daily dose estimates were not uniform for all ATC. The price negotiations. The aim of this study was to estimate the potential annual cost savings (reduced potential budget impact) to the HSE as a consequence of HTA informed price negotiations. METHODS: All NCPE assessments received over a 2 year period were reviewed. Interventions included but initially they had not been recommended for reimbursement, but had subsequently been reimbursed after HTA informed price negotiations. The potential total annual cost saving to the HSE (difference between the original Gross BI (submitted price) and the revised Gross BI (negotiated price)) was estimated. The respective MAH BI models were used for these calculations and additional assumptions fitted to the data. RESULTS: Eighty five NCPEs were classified as either oncology drugs or drugs for orphan diseases. When all such drugs are considered, it is estimated that the cost savings to the HSE, as a result of HTA informed price negotiations is over €19 million per annum. CONCLUSIONS: In Ireland, HTA informed price negotiations lead to considerable cost savings to the Health Payor.

THE TRENDS OF THE PRICES OF NEW MARKETED DRUGS IN TURKEY

Veysel Emri, İpek Koca

Health Transformation Program was started at year 2002 by Ministry of Health (MoH) in Turkey. Today, Turkey has a well established health system mostly dominated by the government on health care provision and payer. This method facilitates access to drugs. In Turkey, there was an increasing trend for the pharmaceutical consumption in years depending on the taken policies as other health care services. The aim of this study is to review an analysis for the new drug release prices for Turkey in the recent years. METHODS: The data was obtained from the last price list of each calendar year published by MoH for the years between 2009-2013. The year 2014 year data list was limited with the first quarter (Q1). The data classified in this paper which were over 100 TL, over 1000 TL and over 10000 TL. The result was based on ex-factory prices. A descriptive analysis was conducted on the price lists with the number of the products, maximum and average ex-factory prices. The numbers of new released products over 100 TL were; 1, 7, 58, 36 and 52 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The numbers of new released products over 100 TL were as follows: 0, 1, 10, 11 and 13 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The maximum ex-factory prices were 739 TL, 711 TL, 722 TL, 27791 TL, 5512 TL, 4740 TL, 2458 TL, 11000 TL and 2727 TL, respectively. The average ex-factory prices were 178 TL, 329 TL, 28 TL, 314 TL, 36 TL, 93, 497 TL and 612 TL in the years 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016, respectively. The defined daily dose estimates were not uniform for all ATC. The price negotiations. The aim of this study was to estimate the potential annual cost savings (reduced potential budget impact) to the HSE as a consequence of HTA informed price negotiations. METHODS: All NCPE assessments received over a 2 year period were reviewed. Interventions included but initially they had not been recommended for reimbursement, but had subsequently been reimbursed after HTA informed price negotiations. The potential total annual cost saving to the HSE (difference between the original Gross BI (submitted price) and the revised Gross BI (negotiated price)) was estimated. The respective MAH BI models were used for these calculations and additional assumptions fitted to the data. RESULTS: Eighty five NCPEs were classified as either oncology drugs or drugs for orphan diseases. When all such drugs are considered, it is estimated that the cost savings to the HSE, as a result of HTA informed price negotiations is over €19 million per annum. CONCLUSIONS: In Ireland, HTA informed price negotiations lead to considerable cost savings to the Health Payor.

SETTING TARGETS FOR PUBLIC SPENDING UNDER EU-IMF ASSISTANCE TO PORTUGAL - THE CASE OF HEALTH CARE AND PHARMACEUTICALS

Rocha L, Fernandes C, Viana R

The 2008 global financial crisis hit Portugal strongly culminating in the resignation of the Health Minister. The Health Service of Portugal (HSE) was faced with a very difficult situation. The Ministry of Health (MoH) has taken several measures to improve the situation. Patient access to all drugs was assessed. There was an increasing trend for the pharmaceutical consumption in years depending on the taken policies as other health care services. The aim of this study is to review an analysis for the new drug release prices for Turkey in the recent years. METHODS: The data was obtained from the last price list of each calendar year published by MoH for the years between 2009-2013. The year 2014 year data list was limited with the first quarter (Q1). The data classified in this paper which were over 100 TL, over 1000 TL and over 10000 TL. The result was based on ex-factory prices. A descriptive analysis was conducted on the price lists with the number of the products, maximum and average ex-factory prices. The numbers of new released products over 100 TL were; 1, 7, 58, 36 and 52 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The numbers of new released products over 100 TL were as follows: 0, 1, 10, 11 and 13 in the years 2009, 2010, 2011, 2012 and 2013, respectively. The maximum ex-factory prices were 739 TL, 711 TL, 722 TL, 27791 TL, 5512 TL, 4740 TL, 2458 TL, 11000 TL and 2727 TL, respectively. The average ex-factory prices were 178 TL, 329 TL, 28 TL, 314 TL, 36 TL, 93, 497 TL and 612 TL in the years 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016, respectively. The defined daily dose estimates were not uniform for all ATC. The price negotiations. The aim of this study was to estimate the potential annual cost savings (reduced potential budget impact) to the HSE as a consequence of HTA informed price negotiations. METHODS: All NCPE assessments received over a 2 year period were reviewed. Interventions included but initially they had not been recommended for reimbursement, but had subsequently been reimbursed after HTA informed price negotiations. The potential total annual cost saving to the HSE (difference between the original Gross BI (submitted price) and the revised Gross BI (negotiated price)) was estimated. The respective MAH BI models were used for these calculations and additional assumptions fitted to the data. RESULTS: Eighty five NCPEs were classified as either oncology drugs or drugs for orphan diseases. When all such drugs are considered, it is estimated that the cost savings to the HSE, as a result of HTA informed price negotiations is over €19 million per annum. CONCLUSIONS: In Ireland, HTA informed price negotiations lead to considerable cost savings to the Health Payor.

Producing a comorbidity index according to ISO-consumption of health resources and their associated costs in routine clinical practice.

The study population consisted of patients assigned to seven primary care centres, two acute care hospitals and one social health centre, all managed by Badalona Serveis Assistencials SA. The following variables were analysed: age (0-100 years), sex, comorbidity (chronic diagnoses) and direct health care costs. We estimated the resource use and gross health care costs attributed to all patients requiring health care in 2013. Subsequently, an expert panel identified the most prevalent chronic diseases (ICD-9). Subgroups were established according to age and number of chronic comorbidities. The main variables and comorbidities associated with the costs were identified using a multivariate model. This allowed a total score to be developed for each patient. Statistical analysis: Spearmans correlation coefficient. Results: in the total population, the correlation coefficient was significant (p < 0.05). The final score was obtained from the logistic model. The score obtained showed a good correlation with age (r = 0.939) and the cost of health care (r = 0.696). The index obtained explained 44.7% of the gross cost. The index was better adapted to the adjusted costs. We described the disaggregated results and the results according to levels of comorbidity (healthy, low, medium, high). CONCLUSIONS: The comorbidity index obtained was shown to be a simple predictive potential of the cost of care and may be applied in routine clinical practice.
A structured discussion of factors influencing PRO choice was held between experts.

**PHP101**

**PATIENT REPORTED OUTCOMES AND THEIR RELEVANCE IN REIMBURSEMENT DECISIONS**


**OBJECTIVES:** Payers need evidence of clinical effectiveness, reasonable cost, and safety. Although, patient-reported outcomes (PROs) are an important component of this evidence it is not always clear which PROs to use and reliance on an incorrect PRO can have negative consequences. The objective was to describe the factors that determine which PROs are most likely to be used.

**METHODS:** A structured discussion of factors influencing PRO choice was held between experts in late phase studies, evidence review, and economic modelling. These were then validated against a sample of published reimbursement decisions across multiple disease areas.

**RESULTS:** Focus of most questions is on whether to use a generic, disease-specific or novel measure. Disease specific PROs are very frequently of value due to the innovative status, defined by a market authorization granted in the five last years. Focus of most questions is on whether to use a generic, disease-specific or novel measure. Disease specific PROs are very frequently of value due to the innovative status, defined by a market authorization granted in the five last years. Focus of most questions is on whether to use a generic, disease-specific or novel measure. Disease specific PROs are very frequently of value due to the innovative status, defined by a market authorization granted in the five last years.

**CONCLUSIONS:** Choosing a PRO, it is important to consider the disease, treatment and payer reimbursement decision context. Disease specific QoL measures may be more sensitive than a generic measure but may also need mapping to a general QoL measure. Acceptance will be contingent on the existence of robust evidence either from published literature or additionally collected data. Reviews of previous HTA submissions and payer decisions should identify requirements / standard practices in key markets and identify common criticisms or problems.

**PHP102**

**INTERVENTIONS AND POLICY MEASURES IN HEALTH CARE AND PHARMACEUTICAL SECTOR TO INCREASE EFFICIENCY AND RECOVERY OF GREEK HEALTH CARE SYSTEM**

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**OBJECTIVES:** Greece is under a very tough and strict memorandum enforced by the European Union and the memorandum in Greek Health system and the Pharmaceutical system should be improved, upgraded or redesigned from scratch in order to be save Greek economy and minimizes its public debt. Also the Greek Health care and Pharmaceutical sector needs in order to better understand expensive drug expenditures.

**RESULTS:** A database on expensive inpatient drugs listed on a national formulary was set up, with information related to drugs - from National and Regional Health authorities- and patients -from our university hospital centre's database (UHC) of the Paris region. A censored regression model, Tobit model, was developed in which the dependent variable was for each drug, the ratio of the number of inpatients not residing in the hospital's region, in order to better understand expensive drug expenditures.

**CONCLUSIONS:** This study represents the first step of modelling significant determinants of hospitals' attractiveness for patient focuses, quite uniquely, on patients and drug factors, and could be extended to other variables.

**PHP103**

**DETERMINANTS OF HOSPITALS’ ATTRACTIVENESS FOR PATIENTS: APPLICATION TO EXPENSIVE DRUGS**

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**OBJECTIVES:** Hospital attractiveness can impact the number of inpatients, and so health care expenditures. The objective is to identify parameters related to patients and geographic factors that influence attractiveness of inpatients not residing in the hospital's region, in order to better understand expensive drug expenditures.

**METHODS:** A database on expensive inpatient drugs listed on a national formulary was set up, with information related to drugs - from National and Regional Health authorities- and patients -from our university hospital centre's database (UHC) of the Paris region. A censored regression model, Tobit model, was developed in which the dependent variable was for each drug, the ratio of the number of inpatients not residing in the hospital's region, in order to better understand expensive drug expenditures.

**RESULTS:** During 2012, 526 091 doses -of the 113 drugs listed- were reimbursed to 99 912 patients. 13% of inpatients come from off the Paris region. According to the Tobit model, three variables positively impact the innovative status, percentage of women and Diagnosis Related Group coded as severe or for diseases with orphan designation. Variables also impact significantly the statistic class. For instance, innovative status, defined by a market authorization granted in the five last years and approved by the public payers in the actual benefits. To benefit from the most innovative treatments, patients tend to be cared in UHC's hospitals.

**CONCLUSIONS:** This study represents the first step of modelling significant determinants of hospitals' attractiveness for patient focuses, quite uniquely, on patients and drug factors, and could be extended to other variables.

**PHP104**

**ECONOMIC IMPACT OF CLINICAL RESEARCHES TO THE RESEARCH CENTERS AND REIMBURSEMENT SYSTEMS IN TURKEY**

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**OBJECTIVES:** Clinical researches are an important tool for the improvement of medicine and significant economic value. The aim of this study was to investigate the economic impact of clinical researches to the reimbursement system in Turkey.

**METHODS:** Budget of clinical trials were calculated from the raw data of the Report of Istanbul Medical Faculty Clinical Researches (ITFAR) network. In addition, the potential cost of the drugs that were approved in the clinical researches for SGK was calculated for showing the cost of medicines acquired with clinical researches. It has been accepted that predicted budgets of researches were not spent for research. Similarly, it has been accepted that the number of patients was not changed during the studies. Thus, approved budgets could be accepted as drug investment of the approval year. For the calculation of drug costs, discounted reimbursement figures of Social Security Administration (SGK) for all medicines were used. If not licenced and imported via Turkish Chamber of Pharmacists, the prices of abroad drug list of SGK were used. Calculations were performed with the drug prices for the year 2013.

**RESULTS:** The average of drug cost savings per patient with participation to the clinical research and clinical research investment per patient were calculated as US$ 21.649 and US$ 8.879. It could be said that total budget of sponsored pharmaceutical researches was US$107 million and the government had a saving close to US$ 311.096.130 due to not reimbursing the cost of drugs of the patients who were included to the clinical researches in Turkey.

**CONCLUSIONS:** However study is based on assumptions, the findings are unique for the literature. The health policy makers can take into account the policy improvements about clinical trials in Turkey.

**PHP105**

**PHARMACEUTICAL DEVELOPMENT: AFRICA AN EMERGENT MARKET**

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**OBJECTIVES:** With population of more than 1 Billion, Africa is the world's second largest continent. The transition that African countries are undergoing is a real challenge for health care authorities. 24% of the global disease burden is accounted for by non-communicable diseases (NCDs). The diseases that prevailed in the 60s and 70s are not appearing in the same levels as they appeared, tuberculosis is still endemic as well as transmissible diseases like HIV/AIDS and Hepatitis still remained as a major problem while some others, such as cancers, cardiovascular and metabolic disorders are dramatically increasing, requiring the implementation of effective and safe pharmaceutical policies that will produce increasing demand for drugs treatment.

**METHODS:** Inventory of the potential of Africa in clinical research. **RESULTS:** In 2012, African Pharmaceutical market revenue was US$ 18 billion and expected to reach US$ 30 billion by 2016. This established countries in both Sub-Saharan and North African countries (South Africa, Nigeria, Cote d'Ivoire, etc.).
Senegal, Egypt, Morocco, Algeria and Tunisia) are contributing 80% of the pharma market in Africa. Despite maintaining regional offices within Africa, many major Pharma and device manufacturers frequently overlook the continent when sponsoring clinical studies. Cultural barriers, political upheaval and uneven infrastructure are certainly causes for the lack of interest. But Africa offers tremendous potential for companies looking to expand their sales volumes to the retail drug stores. In the past, the lack of interest in Africa, due to various factors, has resulted in a general lack of explicit prioritisation activities. The Welsh Government has, on occasion, acted as the funders of last resort. 

**Conclusions:** The assumption that innovative medicines can be subject to significant price cuts could be derived, as many other factors, including the initial price differential, are certainly causes for the lack of interest. But Africa offers tremendous potential for companies looking for cost-effective study sites and appropriate patient drug market populations. Currently more than 45% of the region’s population access public health systems. A worldwide tendency toward “greener” choices when purchasing medicines or not is still debatable, BAS keep making their way to the customer basically through pharmacies. A worldwide tendency toward “greener” choices when purchasing medicines or not is still debatable, BAS keep making their way to the customer basically through pharmacies. 

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attitudes of physicians in Germany towards telemonitoring. METHODS: In the first step of a technology assessment of the entire peer acceptance were identified using a systematic literature review and transferred to a theoretical effect model. This model was used to create a quantitative questionnaire which was then used to interview online 201 outpatient and inpatient physicians from different fields of medical practice in 18 European countries. Pharmacists were additionally surveyed. The empirical data were processed employing a theoretically model based on economic and medical arguments.

RESULTS: The results show a lack of information regarding the financial risks of using telemedical technology, as only 14% of those interviewed said they felt informed about the potential financial risk of using telemedicine technology. The positive effects expected from telemonitoring were rated much better by those who already used telemedical technology, as the four most important reasons for using telemedical technology were: reducing the number of visits, improving the quality of care, saving time, and reducing costs.

CONCLUSIONS: In conclusion, the study shows that only a limited number of physicians have been influenced by telemonitoring. The economic and medical arguments for using telemedical technology are not yet widely accepted. Further research is needed to identify the key factors influencing the acceptance of telemedical technology.

PHP112
EXTERNAL REFERENCE PRICING IMPACT OF THE INTEGRATION OF THE AMNOG DISCOUNT IN THE LIST PRICE
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OBJECTIVES: In Germany, the AMNOG law replaced free pricing by the early benefit assessment (EBA) since 2011. Manufacturers are free to set new drugs’ prices for up to one year after which the price is negotiated between manufacturers and the health care authorities of the EBA. The negotiated price, that is, the price agreed to by the one of the seven states by the manufacturers, is considered as the official list price since April 2014. The objective of this study is to evaluate the impact of this new law on drug prices and to investigate the impact of new reference pricing and technological change on drug prices. A simulation model, developed for the European Commission, was used to simulate ERP’s impact on Boceprevir and Telaprevir prices after five years, following the discount’s inclusion on the official list price in Germany. ERP impact on price was evaluated in Belgium, France, Germany, Luxembourg, Norway, Slovakia, Slovenia, Sweden, Switzerland, The Netherlands and UK for Boceprevir and in Belgium, Finland, France, Germany, Luxembourg, Norway, Poland, Slovakia, Slovenia, Sweden, Switzerland, The Netherlands and UK for Telaprevir. National policy inputs were obtained from a literature review and consultation of international organisations’ representatives. Prices used at the start of the simulation were obtained from IMS. RESULTS: After five years, the relative price variation of Boceprevir between the six European countries will be between -30% and +60% and the price of each country will be lower or equal to the 50% of the list price. The price of the count integrated in the list price was null in Belgium, Luxembourg, Sweden and UK, of -8.1% in the Netherlands, -9.2% in Norway, nearly -10% in Czech Republic, France, Slovakia and Switzerland, and -14% in Slovenia. For Telaprevir, the price variation was null in Belgium, Finland, Luxembourg, Slovakia and the UK, of -0.8% in Slovakia, -2.5% in the Netherlands, -2.9% in Norway, -6.3% in France and -8.6% in Switzerland. CONCLUSIONS: Integrating AMNOG discount in the list price impacts significantly the price in European countries due to ERP.

PHP114
A COMPARISON OF COBB-DOUGLAS, TRANSLOG AND ADDITIVE MODELS OF THE PRODUCTION FUNCTIONS OF HOSPITALS IN PUBLIC HOSPITALS IN GERMANY
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OBJECTIVES: To investigate the adequacy of the widely used Cobb-Douglas and translog models of the production functions of hospital in-patient services.

METHODS: To investigate the adequacy of the widely used Cobb-Douglas and translog models of the production functions of hospital in-patient services, we fitted these and additive models (AM) to 2002-2007 data for the gynaecology and obstetrics, general and digestive surgery, internal medicine, and traumatology and orthopaedic surgery services of 10 public hospitals in Galicia (NW Spain).

Production, measured as admissions weighted in accordance with their diagnosis-related groups (DRGs), was treated as a function of physician full-time equivalents as surrogate labour factor and number of beds as surrogate capital factor. RESULTS: For the General Surgery specialty the findings for the CD model indicate a better fit than the Translog and of the AM, as it is shown by AIC value while R2 (CD = 96.30, Translog = 96.30, AM = 98.30) prefer the flexible AM. This is a good example of using AM as a tool for checking the behaviour of existing parametric models. In this case we can be confident with Cobb-Douglas estimations. Findings for the Internal Medicine specialty indicate responses for the CD (AIC = 17.749) seems to be more “robust” than those based on the AM (AIC = 13.113) and Translog (AIC = 15.939) models, R2 (CD = 95.88, Translog=95.90, AM=97.90) shows better fit for the AM regression estimates. Our results show that while the Cobb-Douglas and translog models suffice to represent the production functions of services with low average DRG weight, the greater flexibility of models such as AMs is required for services with higher average DRG weight.

PHP115
GENDER-RELATED BEHAVIORS IN DRUG CONSUMPTION IN ITALY
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OBJECTIVES: Sex differences in drug use have been demonstrated in several therapeutic areas. However, there is a lack of overviews on sex differences in drug use of entire populations. The aim of this study was to describe difference in prevalence of drug use between men and women. METHODS: We performed a cross-sectional study using 2012 data from the IMS LifeLink Treatment DynamicsTM LrX Database, an Italian-based administrative database that includes all prescribed drugs that are reimbursed by the Italian National Health Service. Groups of interest are classified according to the total volume in Defined Daily Doses were considered. Crude and age adjusted differences in prevalence were calculated as risk ratios of women/men. RESULTS: 31 therapeutic categories were investigated and there are significant differences for 30 of them. The largest sex difference in prevalence was found for thyroid preparations that were more common in women (59.3/1000 women and 10.9/1000 men, respectively). This was followed by antinfiammatory and antirheumatic products (114.9/1000 women and 6.1/1000 men) and antiepileptic agents (26.8/1000 women and 26.8/1000 men). The pharmacological groups with the largest relative differences of dispensed drugs were drugs affecting bone structure and mineralization (RR 4.9), psychoactive substances (RR 4.9) and drugs used to treat women to a higher degree. Antigout-agents (RR 0.4), vasodilators used in cardiac diseases (RR 0.7) and ACE inhibitors (RR 0.7) were dispensed to men to a larger proportion. CONCLUSIONS: This is the first Italian study that shows substantial differences in drug use between men and women. Measures to reduce these differences are needed.
PHP118

PATTERNS AND PREDICTORS OF HOSPITAL READMISSION IN TAIWAN
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OBJECTIVES: Hospital readmissions have been an important issue, as they reflect suboptimal quality of medical care and incur high health care expenditures. However, limited information is available on the patterns of hospital readmission in the entire population to support a thorough planning to prevent hospital readmissions. Therefore, this study aimed to examine the patterns and economic burdens of hospital readmission in Taiwan, and identify predictors of hospital readmissions.

METHODS: This study used the National Health Insurance Research Database of enrollees randomly selected from those enrolled in the National Health Insurance program in 2005. Individuals who were admitted to acute hospitals in 2005 were selected and their readmission patterns one-year after discharge were examined. Cox proportional hazards regression model was adopted to identify predictors of hospital readmission.

RESULTS: The 30-day, 6-month and one-year readmission rates were 11%, 25%, and 34%, respectively. During the one-year follow-up, 52% of total health care expenditures were due to hospital readmissions. Of those who were readmitted to hospitals, 56% were readmitted once and took up 29% of the cost of rehospitalization. However, those readmitted for more than three times (5%) accounted for 30% of the cost. The major disease category of the highest 30-day and one-year readmission rates was neoplasms. The disease of the highest 30-day and one-year readmission rates were cancer of bronchus and lung (36%) and cancer of liver and intrahepatic bile duct (74%), respectively, and the most frequent reason for readmission was the disease itself. Age, gender, place of residence, previous hospitalization, and administrative morbidity, and the year they were estimated were risk factors of hospital readmissions.

CONCLUSIONS: This study identified diseases of higher short-term and long-term readmission rates, causes of short-term and long-term hospital readmissions and predictors of hospital readmission. The information is of importance for planning interventions to reduce hospital readmission rate.

PHP119

SECURE SYSTEM FOR IV ADMINISTRATIONS: HEALTH ECONOMIC IMPACT OF A “SMART” INFUSION SAFETY SYSTEM
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OBJECTIVES: More than half of medication errors are reported during administration. “Smart” Infusion Safety Systems (SISS) have been developed, to avoid medication errors and provide data for continuous quality improvement (CQI). Few data produced by SISS have been analysed. Given the lack of clinical trials, a model was developed in order to assess the economic benefits of SISS from the perspective of the public hospital. Over a period of 3 years, 6 intensive care units (ICU) were analysed. Two types of alerts were defined: hard (absolute) and soft limits. An avoided error was defined as the detection of a scheduled infusion over a hard limit or a scheduled infusion over a soft limit that was later overridden by staff. The severity of consequences was estimated on the HARM INDEX score, which is based on the pharmacologic risk, overdose risk, the probability of an event, and the potential for life-threatening consequences. The model was later overridden by staff. The severity of consequences was estimated on the HARM INDEX score, which is based on the pharmacologic risk, overdose risk, the probability of an event, and the potential for life-threatening consequences. The model was designed to calculate the NPV with the taxes and spending in a lifetime term, and the impact on quality of life.

PHP120

VALUE OF LIFE AND COST OF PRE-MATURE DEATHS WITH THE PERSPECTIVE OF PRODUCTIVITY AS NET TAX REVENUE: A COMPARISON IN FRANCE, GERMANY, ITALY, SPAIN, UNITED KINGDOM
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OBJECTIVES: The Human Capital Theory emphasizes investments to the health care sector as an important element in achieving and sustaining economic development. Investments to health care sector improves macro and micro economic outcomes for the whole society. The aim of this study is to calculate the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for France, Germany, Italy, Spain, UK (UK).

METHODS: Net present value (NPV) of the taxes and spending for each year were calculated. For calculating the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for France, Germany, Italy, Spain, UK (UK). We applied the Human Capital Theory emphasizing investments to the health care sector as an important element in achieving and sustaining economic development. Investments to health care sector improves macro and micro economic outcomes for the whole society. The aim of this study is to calculate the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for France, Germany, Italy, Spain, UK (UK).

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PHP121

SWITCHING PATIENTS WITH PRIMARY ANTIBODY DEFICIENCIES TO HUMAN IMMUNOGLOBULIN: ECONOMIC EVALUATION OF AN INTERPROFESSIONAL DRUG THERAPY MANAGEMENT PROGRAM
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OBJECTIVES: Lifelong immunoglobulin G (IgG) replacement is the standard therapy for patients with primary antibody deficiencies. It can be administered either intravenously (IV IgG) by health professionals in hospital or subcutaneously (SC IgG) by patients at home. However, self-administration requires patients’ education and support over long term to ensure proper adherence and optimal efficacy and safety. Every patient who switches to SC IgG is proposed by the Policlinique Médicale Interprofessionnelle (PMI), a drug therapy management program with a nurse and a community pharmacist including training, coaching and follow-up. The aim of the study was to evaluate if switching to SC IgG at home including the management program was cost-effective compared to IV IgG at hospital.

METHODS: Assuming that both therapies provide similar efficacy, a 3-years cost-minimization analysis based on a simulation model was performed from a societal perspective. Health care costs (€, cost of professionals, infusion pumps and disposables) were derived from the French administrative database and costs of patient support and loss of productivity were estimated. One-way sensitivity analyses were performed. RESULTS: Under base case assumptions, SC IgG at home was estimated at 34,890 CHF per patient per year and 34,270 CHF per year for IV IgG. The total cost savings for a switch to SC IgG at home with the program was 74,940 CHF per patient over 3 years. Results were relatively sensitive to the assumptions. CONCLUSIONS: Home-based SC IgG therapy including an interprofessional therapy management program may be an effective and efficient alternative to hospital for patients with primary antibody deficiencies. Additional costs from purchase of equipment and management program in the first year were offset by hospital costs avoided in short term. Additional studies are ongoing to evaluate the retention in the medium term and the impact on quality of life.

PHP122

GENDER MEDICINE IN GERMANY: WHAT IS SO DIFFICULT ABOUT ITS IMPLEMENTATION? - AN EMPIRICAL STUDY IN GERMANY
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OBJECTIVES: Personalized medicine is currently a popular topic in health care debates. Yet, the basic differentiation between females and males is hardly found in care delivery/health management programs. This study aimed at elucidating the opinion of German Statutory Health Insurance (SHI) managers and internal specialists as to how gender medicine is perceived and reasons for the limitations in the implementation process.

METHODS: Between April and June 2013, a questionnaire on the implementation of gender medicine was sent to all internal specialists and 48 insurance managers of the largest German SHIs, covering over 95% of the market, and approximately 16,000 physicians of the German Society for Internal Medicine (DGIM) were contacted to complete a web-based survey. Descriptive analyses, Chi-square tests, and Pearson correlation coefficient were used to investigate the research objective. RESULTS: According to both, insurance managers (76%) and physicians (60%), gender-specific care is not sufficiently incorporated into standard medical care. Respondents claim the responsibility lies with the ministry of health, physicians and medical staff, as well as their associations. Specifically, more evidence is needed to incorporate gender aspects in treatment guidelines, an idea which is well-supported by insurance managers (65%) and specialists (50%), whereas fewer participants encourage bottom-up mechanisms. CONCLUSIONS: German SHIs expect a significant governmental influence and/or support of self-governing bodies to achieve an incorporation of gender medicine into daily practice. Priority responsibility for the implementation of gender-specific approaches is perceived to lie with physicians. As soon as critical hurdles in the medical field will be removed, the positive perception of both participating parties can be integrated in the implementation process of gender medicine.

PHP123

VALUE OF LIFE AND COST OF PRE-MATURE DEATHS WITH THE PERSPECTIVE OF PRODUCTIVITY AS NET TAX REVENUE: A COMPARISON FOR TURKEY
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OBJECTIVES: Human Capital Theory emphasizes investments to the health care sector as an important element in achieving and sustaining economic development. Investments to health care sector improves macro and micro economic outcomes for the whole society. The aim of this study is to calculate the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for Turkey where the life expectancy was noted 75 years.

METHODS: Net present value (NPV) of the taxes and spending for each year were calculated. For calculating the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for Turkey where the life expectancy was noted 75 years.

RESULTS: The Human Capital Theory emphasizes investments to the health care sector as an important element in achieving and sustaining economic development. Investments to health care sector improves macro and micro economic outcomes for the whole society. The aim of this study is to calculate the possible produced value for a life-time term (VLT) and cost of pre-mature deaths (CPD) from the productivity for Turkey where the life expectancy was noted 75 years.

CONCLUSIONS: However the study was based on a hypothetical model that calculated the NPV with the taxes and spending in a life-time term, the results of each country were parallel.
productivity, and generational accounting, which accounts for a range of other government fiscal transfers to citizens. The possible produced value for a life-time term was assumed as calculating the total NPV depending on the life expectancy. CPD was assumed as the difference between NPV on the year of life expectancy and each decades as life years 50, 40, 30, 20, 10 and new born. The economic values for the model were derived from the World Bank, OECD, UNESCO or WHO. RESULTS: Possible produced value for a life-time term for Turkey was calculated as US $483,298. Cost of pre-mature death per person was calculated as US $ -102,064, US $ -271,716, US $ -641,679, US $ -583,726, US $ -518,753, US $ -483,866 for the life years new born, 10, 20, 30, 40 and 50 respectively. CONCLUSIONS: However, the study was based on a hypothetical model that calculated the NPV with the taxes and spending in a life-time term, cost of premature death was calculated as the highest in early ages and was decreasing up to the retirement age. The results may be reference for the decision makers. Health policy makers may improve the access to the treatments in the early life years for the possible increased cost of deaths in Turkey.

PHP124 EXPOSURE TO POTENTIAL DRUG-DRUG INTERACTIONS IN TEACHING HOSPITAL OF SOUTH PUNJAB, PAKISTAN
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OBJECTIVES: Drug-drug interaction is a common error in poly-medication and contributes a major part in adverse drug reactions. The aim of the present study was to evaluate the percentage of potential drug-drug interactions in the prescription in the region of South Punjab Pakistan prescribed by the medical practitioner. METHODS: A cross sectional study was performed in Nishter Hospital Multan, Pakistan, the 3rd oldest medical institution of Pakistan, which has a capacity of 1800 beds and has a best facility to handle large number of emergency cases. During the period 3 months, drug interaction was taken as an indicator to see the Drug - Drug interactions and compared with the standard reference of important DDI’s. The potential drug-drug interactions were categorized according to their severity level using mechanism. Results: Out of a total of 100 prescriptions (543 medicines), 41% of prescriptions have potential DDI’s. Mostly prescribed drugs were the antibiotics (38%), and the drugs belonging to class analgesic were found to contribute mostly in drug-drug interactions (26.50%). The survey showed the total number of interactions and their severity level accounting as major (20.10%), moderate (63.4%) and minor (15.90%). The mechanism by which the drugs interact with one another showed that there were pharmacokinetic (60.5%), pharmacodynamic (38.6%) and few of them interact by the mechanism which was not specified in the available literature (0.9%). CONCLUSIONS: Drug-drug interactions occur in poly-medication and need to be evaluated and monitored for the positive impact on the medication use system and improvement of quality of patient care. A clinical pharmacist with accurate knowledge of drug, their effect on human beings and their interaction with other can monitor and manage these drug interactions.

PHP125 VALUE OF LIFE AND COST OF PRE-MATURE DEATHS WITH THE PERSPECTIVE OF PRODUCTIVITY AS NET TAX REVENUE: A COMPARISON IN ARGENTINA, BRAZIL AND MEXICO
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OBJECTIVES: The Human Capital Theory emphasizes investments to the health care sector as a major determinant in achieving high economic productivity. However, investments to health care sector improves macro and micro economic outcomes for the whole society. The aim of this study is to calculate the possible produced value of economies and their productivity level accounting as major investments to health care sector. RESULTS: The total number of interactions and their severity level accounting as major investments to health care sector were calculated as 40% (63.4%) and few of them interact by the mechanism which was not specified in the available literature. CONCLUSIONS: Drug-drug interactions occur in poly-medication and need to be evaluated and monitored for the positive impact on the medication use system and improvement of quality of patient care. A clinical pharmacist with accurate knowledge of drug, their effect on human beings and their interaction with other can monitor and manage these drug interactions.

PHP112 COST-EFFECTIVENESS OF TELERADIOLOGY: LESSONS TO LEARN FROM AN INTERNATIONAL REVIEW
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OBJECTIVES: At the global level the large deployment of telemedicine raises needs for cost-effectiveness evaluations. The objective of this literature review is to explore what extend telemedicine innovations that were implemented in many countries were cost-effective. Specifically, we explore whether the cost-effectiveness can be adapted to the evaluation of telemedicine innovations. So, what answers can a review of the international literature relating to the medico-economic evaluation of telemedicine provide? Method: A systematic reading of 286 articles published between 2000 and 2013, 74 studies that implemented economic evaluation of telemedicine were analysed. Three axis of analysis are explored: the act concerned by the teleradiology, the telemedicine intervention, the medical speciality, the economic evaluation method implemented. RESULTS: The descriptive analysis showed significant heterogeneity in studies characteristics: economic analysis method, telemedicine applications, medical specialities, and organisational practices. The qualitative analysis underlines that most studies face methodological issues and provide reduced evidence of the economic impact of the telemedicine interventions. The telemedicine technologies are too individualised (by the context and the organisation) to be evaluated by the standards of cost-effectiveness analysis. CONCLUSIONS: This literature review did not allow proposing a classification for telemedicine practices identified as efficient, depending on the strategies compared, field of application or specialty, types of telemedicine or an organisation of care model. Despite all this, one focus can be the management of chronic diseases that remains a central topic at the international level. The increase in the number of medical specialities or fields of application concerned with telemedicine and the increased volume of activity necessitate the dissemination of methodological recommendations to promote the coherent development of economic evaluations. Our literature review shows that there is need to develop innovative methods to assess the cost-effectiveness of telemedicine technologies.

PHP129 ASSESSMENT OF VALIDITY OF AN INDICATOR MODULE IN IDENTIFICATION OF ADVERSE DRUG EVENTS IN PATIENTS OF MEDICINE DEPARTMENT
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OBJECTIVES: An indicator is a clue that helps a health care organization to identify adverse drug events and assess the overall harm that occurs from medical care within that organization. The main aim of the study was to investigate use of an indicator list for identification of adverse events in the health care setting studied. METHODS: The study was a prospective observational study in a tertiary care teaching hospital. The study mainly involves the review of medical records of patients in general medicine department who were admitted due to drug related problems with the help of trigger tool. When the presence of indicator is identified, those cases were thoroughly scrutinized to identify adverse drug events and confirm

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such events in the light of available evidence and discussion with the treating physi-
cians. 1275 patients were included in the study for case review as per the study criteria. Out of 275 patients, 150 patients had at least one indicator (55%) and detection of adverse events was about 19.2%. Ratio of actual adverse event detected to the presence of indicators was calculated as true positives. The average true positive rate was 33%. Average number of patients per patient was determined to be 3.82. The harm categorization was carried out for the observed adverse events as per National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The study showed that indicator tool could be used to review the cases prospectively and identify adverse events. The identified indicators showed the pattern and frequency of adverse events. Findings of our study supported the idea of making the indicator tool as a practical aid for identification of adverse events.

PHP130
BARRIERS OF PHARMACEUTICAL CARE IN COMMUNITY PHARMACIES: EVIDENCES FROM EMERGING COUNTRIES

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The pharmaceutical care concept has been popular in the world during past dec-
dades, but it did not reach well to its maturity in some countries, so the investigation on barriers to the implementation of the pharmaceutical care in these countries would be great of interest. OBJECTIVES: The aim of the study was to identify and prioritize barriers to the provision of pharmaceutical care in Iranian community pharmacies based on Tehran community pharmacists’ perceptions. Setting The pre-
sent study was performed with participation of community pharmacists settled in Tehran, the capital city of Iran. METHODS: A cross-sectional descriptive study was performed using an anonymous questionnaire between August and November 2013. 55% community pharmacists expressed their perceptions on items by a 5-point Likert-type scale. Besides descriptive analysis, data was also analyzed through structural equation modeling. Main outcome measured was the importance of barriers perceived in it. In case of 5-point Likert-type scale, the number of indicators presented by pharmacists varies from country to country based on the pharmacists’ perceptions, and corrective actions should be made accordingly.

PHP131
COSTS AND EFFECTIVENESS OF THE MEDIGUIDE TECHNOLOGY IN THE CONDITIONS OF THE CZECH REPUBLIC

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OBJECTIVES: MediGuide technology is designed to monitor the position of diagno-
istic and therapeutic catheters equipped with a sensor MediGuide and navigation in vascular and interventional procedures. Which comprises technologies of electrophysi-
otherapy. MediGuide compared to conventional technology, offers the 3D display on the live fluoroscopy or recorded background. It is realised in the new version of the MediGuide system. The aim of the study is to determine the economical and cost-effectiveness of new technologies MediGuide in the Czech Republic. Results of the analysis are being compared to the studies of the German Cardiac where technology is positively evaluated. METHODS: The study is based on the costs-effectiveness analysis, which comprises technology system MediGuide. The comparator angiography Siemens Artis Zee. Value of the effect was determined by the cost of power at the treatment of 100 patients was in the first year to CZK 181,711; mortality in the Czech Republic 7.5±4.5min; Germany 34±9min and the cost of one second images of the technique were used: radiation burden, which in the Czech Republic reached values of 3±3.2 Gy. MethOds: Through meta-analysis of the data from different sources, a network of experts, systematic literature searches and expert workshops, the five most relevant crises from different disciplines (medical, HR, supply and IT) were identified. These survey data were supplemented with the results of telephone interviews with managers. Further data were collected on these crises, their management and influencing factors. The results on medication errors presented here are based on the survey data using a linear regression model. RESULTS: The analysis was based on fully com-
pleted data from 100 hospitals. 70% of the hospitals stated that crises due to medical errors occurred in the last 5 years, which could not be handled with established risk management tools. Although the crisis-appearence was lower in private hospitals (28%) compared to publicly funded (31%) and nonprofit (41%) hospitals, this difference was not significant. We recognized that a high frequency in the occurrence of medical errors was significantly associated with a lower evalua-
tion of risk management issues (e.g. the presence of a staff member responsible for risk management, scenario analysis and crises trainings). CONCLUSIONS: Our study confirms that German hospitals have to expand their targeted risk man-
agement activities in order to prevent the occurrence of hospital crises especially due to medical and medication errors. All survey results will be incorporated in a decision-making and benchmarking-tool for hospital managers to improve crisis management in German hospitals.

PHP134
COMPARISON OF EXPECTED VERSUS ACTUAL COST ACTUAL VERSUS CONSEQUENCE OF REIMBURSED DRUGS IN THE NETHERLANDS BETWEEN 2009 AND 2013

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OBJECTIVES: A Budget Impact Analysis (BIA) analyses the financial consequence associa-
ted with the uptake of a new treatment option in the market; which can improve the drug development and forecasting and influence changes to pharmaceutical and health care budgets. Therefore, BIA forms a key consideration of the Dutch Health Care Insurance Board (ZINL) when making a reimbursement decision regarding a new treatment intervention. The current study presents an analysis of forecasted data specific to new drugs reimbursed under list 18 between 2009 and 2013. Results of this analysis will be communicated to hospital managers and healthcare stakeholders. The presented method of performing a BIA is based on 3 years of data from the Drug and medical devices Information Project database Forecasted data specific to new drugs reimbursed under list 18 between 2009 and 2013 was extracted from drug reim-
bursement reports available from the ZINL website. Actual data of the selected drugs were extracted from the Drug and medical devices Information Project database (GIP database). Per year and cumulative (between 1 and 5 years) data on total drug cost, total number of users and total cost per patient were compared between the forecasted values and the actual values. RESULTS: In total 20 drugs were included in the analysis, of which 12 presented data for 3 years or more. Compared to the actual data, the expected total drug cost was overestimated for 14 drugs, total number of users was underestimated for 12 drugs and for 10 drugs the total cost per patient was underestimated. Total number of users was most accurately estimated, presenting a pooled cumulative overestimation of 5 times the actual number of users. Total drug cost was least accurately estimated (pooled cumulative overestimation of 13 times the actual total cost), since the total drug cost includes the uncertainty reflected in both the total number of users and total cost per patient. CONCLUSIONS: The expected cost of 18 drugs is underestimated in 15 compared to the actual data. The expected cost of 2 drugs is overestimated in 2 compared to the actual data. The overall overestimated the actual budget presented in the GIP database between 2009 and 2013.

PHP125
PREDICTED VERSUS ACTUAL BUDGET IMPACT OF HIGH-COST DRUGS IN IRELAND

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OBJECTIVES: Budget impact analyses are an essential component in the economic evaluation of new drugs. These analyses allow the health care payer to avoid the likely impact of the drug on the payer’s budget, and to plan for short- and long-term
resource allocation. The objective of this study is to compare the company-predicted budget impact with the actual budget impact of high-cost drugs reimbursed in Ireland.

METHODS: All drugs submitted to the health service executive (HSE, health care payer in Ireland) for reimbursement under the high-tech drug scheme (a scheme used to administer high cost drugs) from 2009 to 2012 were included in the review. Company estimates of the likely budget impact of the drug in 2013 were extracted from submissions and compared with actual expenditure in 2013 from the health service executive-primary care reimbursement service (HSE-PCS). Only drugs for which budget impact was provided in the submission and for which there was available data and cost information in the HSE in 2013 were included in the analysis.

RESULTS: Ten drugs were included in the analysis, including six cancer drugs, two immunomodulators for multiple sclerosis and rheumatoid arthritis, and two orphan drugs for cystic fibrosis and idiopathic thrombocytopenic purpura. The cumulative expenditure on these drugs in 2013 was €3.8 million compared with a predicted gross budget impact of €3.4 million, representing a 24% million underestimation in company submissions. The most significant underestimation related to the drug for cystic fibrosis ( €2.9 million). The average rebate related to the orphan drug for cystic fibrosis (€2.9 million).

CONCLUSIONS: Company submissions have been shown to both under- and over-estimate budget impact predictions. It is important that budget impact estimates are as realistic as possible in order to effectively inform decisions on resource allocation or reimbursement.

PHP136

REDEL STUDY: DIFFERENCES IN REIMBURSEMENT DELAYS IN CEE COUNTRIES
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OBJECTIVES: The dynamic of the reimbursement processes shows a very different picture in different countries. The REDEL study examined the elapsed time from marketing authorization to the starting date of reimbursement of the original medicines in Central and Eastern European Countries (Austria, Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia).

METHODS: The basis of comparison were 216 products and their ATC codes selected from the database of the European Medicines Agency which were granted market authorization between January 1, 2007 and December 31, 2013. In the case of these products the research studied the dates, when countries adopted them into their reimbursement system. The adoption was the subject of the study between January 1st, 2010 and 1st July 2013. The following three different indicators were calculated for each product:

- REDEL - the time between marketing authorization date and reimbursement date, INNREIMB - the number of reimbursed INNs according to a specific country or MAH, SR - Success Rate as the ratio of reimbursed INNs to examined INNs.

RESULTS: While an average of 403 days elapsed between the authorization and the starting date of reimbursement in Slovenia (mean of 76 days), the same period was 1295 days in Poland (mean of 21 adoptions). The top three in the ranking of REDEL of active substances products, the same period was 1295 days in Poland (mean of 21 adoptions). The top three in the ranking of REDEL of active substances products, the same period was 1295 days in Poland (mean of 21 adoptions).

CONCLUSIONS: While an average of 403 days elapsed between the authorization and the starting date of reimbursement in Slovenia (mean of 76 days), the same period was 1295 days in Poland (mean of 21 adoptions). The top three in the ranking of REDEL of active substances products, the same period was 1295 days in Poland (mean of 21 adoptions). The top three in the ranking of REDEL of active substances products, the same period was 1295 days in Poland (mean of 21 adoptions).

PHP137

BLACK BOX AMINO REBATES: WHAT IS DRIVING THE PRICE IN THE NEGOTIATION OF A GKV-SPITZENVERBAND?
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OBJECTIVES: Price negotiations of a pharmaceutical company with the German GKV-Spitzenverband (Association of Statutory Health Insurance) after early benefit assessments can be considered a black box. This analysis aims at providing insights into how the GKV-Spitzenverband drives the final rebate to predict future pricing decisions and to enhance the negotiation strategy and therefore secure optimal pricing.

METHODS: Published benefit assessments from the G-BA (Federal Joint Committee) website and the products’ prices as listed in the German pharmacy selling system were used as a basis for research. The latter allows a comparison of launch prices (manufacturer selling prices) and prices after the negotiation with the GKV-Spitzenverband (reimbursement prices). The following parameters were analyzed: Rebate size, rebate by added benefit rating, and rebate by therapeutic area.

RESULTS: By June 2014, 36 products had been through price negotiation, with the rebate of the launch price ranging from 5-71% (average: 25%). The rebate of products with considerable benefit rating ranged from 10-35% (average: 21%). Products with minor added benefit reached rebates between 5-48% averaging at 23%. Products with no quantifiable benefit yielded rebates ranging from 31-44% (average: 24%). Products with no additional benefit had a rebate between 5-71% averaging at 37%. Products in oncology yielded an average rebate of 27%, followed by endocrinology (23%), central nervous system (22%), cardiovascular (21%), and infectious diseases (16%).

CONCLUSIONS: The better the added benefit rating of a product, the lower is its associated rebate. However, only marginal average differences were observed. The rebate per therapeutic area did not reveal obvious patterns: Assessments for oncology products resulted in above average rebates, while rebates for products for infectious diseases were far below the average.
controlling for characteristics of the analysed population. Results highlight the high that chronic diseases significantly drive health care expenditures. Using secondary are similar to those observed in other countries. Our findings show in particular among the employed to delay care seeking. The relative underutilization of care by schemes is not equal. Differences between the UE/URBMI and the uninsured may levels of health service utilization was com-

average used 2.7% less outpatient services (p<0.05) but 1.2% more inpatient ser-

the increased coverage rate has improved access to care. Past studies using the health care expenditures using pharmaceutical data regarding about 2

ine in the database, chronic diseases are mainly estimated using drugs prescription on public health care expenditures. Without explicit diagnoses of diseases in the database, chronic diseases are mainly estimated using drugs prescription (reimbursed medications only) for a treatment of at least 90 days/year. A multi-

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ning reimbursement was investigated. Objectives: To investigate quantitatively, which influence the chosen EU price weighting method has in a theoretical framework model of pharmaceuticals price negotiations. Methods: Three components theoretically determine the reim-

prices are theoretically feasible. When defining the 15 EU basket countries the

1999 to present day. Results: The payer’s perspective is considered after a drug has been granted market access and launched. This is often too late as payers may not want to reimburse expensive drugs, especially if the current gold standard is cost-

9

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is, 6 times greater than the ones without any chronic conditions (r(23) vs. r(7)). All chronic diseases (except psoriasis) have a significant impact on health care (at 1 level). The last months of life, developing or living with cancer, chronic renal failure, rare disease and mental disorder are the factors having the greatest impact on monthly reimbursed health care expenditures. All things being equal, a person at the end of life costs more than €2,236 per month to the health insurance compared to a person not at the end of life. Respectively this amounts to €3,557, €3,008, €2,042 and €1,151 for people living with a rare disease, chronic renal failure, mental disorder and cancer. Conclusions: Results found in this study are similar to those observed in other countries. Our findings show in particular among the employed to delay care seeking. The relative underutilization of care by schemes is not equal. Differences between the UE/URBMI and the uninsured may levels of health service utilization was com-

years of death. In the matched cohort, the average health expenditure was in 2009 new health reform. Methods: An analysis was conducted on 2009 and 2011 data from the CHINS (sampling totally 23202 people from 9 prov-

To control for confounding factors, propensity score matching models were developed controlling for relevant factors such as age, gender, income, educational level and health status. The level difference of health service utilization was com-

mARkET ACCESS PATHwAy fOR mEdICAL NUTRITION IN EUROPE ANd THE US

METHODOLOGY: This analysis aims at presenting different market access path-

results

high impact, with a frequently high importance of the U. K. as an EU country being launched relatively early. Conclusions: The chosen weighting method of EU prices has a high impact on results of EU average price, which is an important component of German price negotiations. No undisputed method exists at the time of market entry.

MARKET ACCESS PATHWAY fOR mEdICAL NUTRITION IN EUROPE ANd THE US

in the US or Germany, there are reimbursed categories for medicines under AMNOG conditions in Germany. Creating new reimbursed categories linked to new MN linked to composition of the product and dedicated to patients with inability to have their nutritional needs covered by normal food intake (set by CMS in the US and G-BA in Germany). Creating new reimbursed categories linked to new

market access pathways for granting reimbursement or coverage of the medical nutrition category are very heterogeneous between the analyzed countries.

A Literature review was conducted on Ovid MEDLINE to establish a whether a clear and internationally validated definition of market access has been proposed. Included were articles and/or reviews con-

Market access can be thought of as either gain-

results

results

1999 to present day. Results: The payer’s perspective is considered after a drug has been granted market access and launched. This is often too late as payers may not want to reimburse expensive drugs, especially if the current gold standard is cost-

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is overlap in the criteria to qualify for funding. Many countries consider drugs for additional funding if a drug can be used in more than one indication and cannot be grouped to a specific DRG. Other criteria identified relate to, for example, drug prices and indications. Some countries grant additional reimbursement for drugs prior to assessment by a national reimbursement process, while others only grant additional reimbursement after the drug has been available for a certain period of time and funding decisions are based on historical data. In most countries, additional reimbursement is considered annually. Hospitals and expert groups can suggest additional reimbursement for expensive drugs to the responsible authority.

**CONCLUSIONS:** Many countries have adapted to the need for additional funding for expensive drugs, and have established systems to grant this funding to hospitals. There are differences in criteria to qualify for, and timelines for receiving, additional funding after drugs are launched.

**PHP148**

**PAY-FOR-PERFORMANCE: BALANCING COST AND CARE**

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**OBJECTIVES:** Initiatives aimed at improving both the quality and efficiency of United States health care are commonly grouped under the broad category of "pay-for-performance" (P4P) programs. Typically these programs award bonuses to providers that attain pre-determined quality and cost goals, but may also impose financial penalties on those that fail to meet those goals. Funded by the Affordable Care Act, P4P programs have recently expanded significantly within the public sector and are expected to grow. This project was designed to review Medicare P4P cost measures, explore the implications for providers pursuing P4P, and recommend possible alternatives. **METHODS:** Two P4P programs, both well known under the health reform law and having potential to impact a large portion of the Medicare population, were selected: 1) Accountable Care Organizations (ACOs), and 2) the Physician Value Based Payment Modifier (VBPMM). Each program's cost measures, components, and methodology were isolated, described, and evaluated to determine if and how they influence the cost of the care and the patient experience. The researchers determined whether the Medicare ACO and VBPM programs are based on payments made under Medicare Part A (Hospital Insurance) and Medicare Part B (Supplemental Insurance) but do not include Medicare Part D (Prescription Drug Benefit) costs. Whether performance is measured against the provider's historic costs, or compared to national benchmarks, only Medicare Part A and B costs are included. **CONCLUSIONS:** Medicare Part D costs are not included in the cost measurement, thereby eliminating prescription drug expense from the performance rating. This methodology may encourage providers to shift Part D drug costs to Part D, thus limiting patient access to therapies that may only be covered under Medicare Part B.

**PHP149**

**REVIEW OF PRICING AND REIMBURSEMENT SYSTEMS IN SOUTHEASTERN EUROPE**

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**OBJECTIVES:** To provide an up-to-date description and comparative analysis of pricing and reimbursement policies in South-Eastern Europe (SEE), and to identify factors influencing reimbursement decisions. **METHODS:** Payers and decision makers in Slovenia, Croatia, Romania and Bulgaria were interviewed by questionnaire. An additional interview is ongoing covering country specific policy and legislation (Pumbed 2009–2014), and relevant documents from web sources including national hospital insurance funds, drug agencies, ministries of health, Eurostat, pharmaco- economics and outcome conference proceedings for Economic Co-operation and Development, and Business Monitor International. **RESULTS:** The four countries spent 5.1%–8.8% of GDP on pharmaceuticals. Four country package agreements based on outcomes are finance-driven. To gain a better understanding of the pricing and reimbursement processes, discuss the implications for provider prescribing patterns, and recommend possible alternatives. **METHODS:** Two P4P programs, both well known under the health reform law and having potential to impact a large portion of the Medicare population, were selected: 1) Accountable Care Organizations (ACOs), and 2) the Physician Value Based Payment Modifier (VBPMM). Each program's cost measures, components, and methodology were isolated, described, and evaluated to determine if and how they influence the cost of the care and the patient experience. The researchers determined whether the Medicare ACO and VBPM programs are based on payments made under Medicare Part A (Hospital Insurance) and Medicare Part B (Supplemental Insurance) but do not include Medicare Part D (Prescription Drug Benefit) costs. Whether performance is measured against the provider's historic costs, or compared to national benchmarks, only Medicare Part A and B costs are included. **CONCLUSIONS:** Medicare Part D costs are not included in the cost measurement, thereby eliminating prescription drug expense from the performance rating. This methodology may encourage providers to shift Part D drug costs to Part D, thus limiting patient access to therapies that may only be covered under Medicare Part B.

**PHP150**

**PRICING AND REIMBURSEMENT ENVIRONMENT FOR A BIOTECHNOLOGY COMPANY IN SOUTHEASTERN EUROPEAN COUNTRIES**

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1RTI Health Solutions, Manchester, UK; 2Novartis Pharma AG, Basel, Switzerland; 3Merck Antwerp Solutions LLC, London, UK; 4Market Access Solutions LLC, Rancho, NJ, USA

**OBJECTIVES:** To gain a better understanding of the pricing and reimbursement process for innovative medical devices and treatments in Southeastern European countries. **RESULTS:** In the UK and France, pricing and reimbursement is agreed at a national level, with few restrictions at regional and local levels. In the UK, NHS England is likely to be responsible for funding of new biologics and relies on guidance from NICE before adopting a product in a new indication; therefore, demonstrating cost-effectiveness is critical. In France, the ANSM also has the responsibility to approve a new product on a national level, subsequent requirements vary by region and sometimes specific location. Similarly, in Spain, once approved nationally, regions develop their own recommendations, and local decisions are made by hospital formularies. Evidence requirements in Italy and Spain vary at a national, regional, and local levels. **CONCLUSIONS:** A biologic obtaining a license in a new indication must undergo the same procedure as a new product. The process and restrictions for biologics may be stricter than for other medications due to the perceived high cost. The level of national, regional, and local requirements and restrictions varies; it is important that appropriate evidence is submitted to decision makers at each level.
OBJECTIVES: Switzerland’s regulation of prices for reimbursed drugs is based on referencing across countries and within the therapeutic class for products with comparators. The SwissHTAi initiative involving all key stakeholders in the health care systems (sickness funds, industry, physicians, academia, Kantons) has published consensus papers for new benefit criteria and measurements. METHODS: A comparative analysis of the cost-effectiveness and adverse events impact and the impact on the value of the drug as evidenced by the submission requirements of Scotland and the Netherlands look similar, the cost-effectiveness impact assessment is performed on the variables related to additional clinical benefit; variables that also significantly influence G-BA’s decision.

PHIL154 A COMPARISON OF ADDITIONAL BENEFIT SCORES IN GERMANY (G-BA) AND FRANCE (HAS)

Seyhun O.1, Erdogdu F.1, Casamayor M.2, Van Engen A.2

OBJECTIVES: In Germany, the manufacturer’s comments in 56% (40/71) and 28% (29/71) of submissions, respectively. The final scope implemented all and some of the manufacturer submission requirements of Scotland and the Netherlands look similar, the cost-effectiveness impact assessment is performed on the variables related to additional clinical benefit; variables that also significantly influence G-BA’s decision.

PHIL155 A COMPARISON OF FACTORS INFLUENCING REIMBURSEMENT AND COVERAGE DECISIONS IN SCOTLAND (SMC), THE NETHERLANDS (N2I AND GEMZYME) (G-BA)

Charkopoulo M.1, Alleman CJ1, Verlegger K.2, Spoorenndonk JA1, Schmidt R.1, Schoeman O.1, Heeg B.1

MethOds: This study aims to compare factors that influence the reimbursement recommendation by SMC and N2I in Germany, the submitted evidence is used to assess the drug’s additional benefit, followed by price-rebate negotiations with the GKV-Spitzenverband. In Scotland and the Netherlands, the submitted evidence is evaluated for reimbursement decision. This study aims to compare factors that influence the reimbursement recommendation by SMC and N2I in Germany, the submitted evidence is used to assess the drug’s additional benefit, followed by price-rebate negotiations with the GKV-Spitzenverband. In Scotland and the Netherlands, the submitted evidence is evaluated for reimbursement decision.

RESULTS: Sixteen (84%) of the materials submitted to the EMA have been considered by HTA agencies. The SMC has approved 100% of the biosimilars it has considered (n=19); the largest positive reimbursement rate amongst the SMC was observed for AMNOG, a sustainable change to the reimbursement of new drugs in Germany. The G-BA assessed the additional benefit of the drug, to an appropriate therapeutic. AMNOG law is perceived to be one of the toughest drug evaluation process in Europe. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance. A comparison is made with Turkey’s existing reimbursement scheme also for Turkey. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance.

RESULTS: In Germany, univariate analyses demonstrated that (positive) economic evidence. In Germany, univariate analyses demonstrated that (positive) economic evidence. In Germany, univariate analyses demonstrated that (positive) economic evidence.

PHIL156 PRODUC'T QUALITY ASPECT IN REImBURSEmENT Of mEdICAL dEvICES:

OBJECTIVES: The SwissHTAi initiative involving all key stakeholders in the health care systems (sickness funds, industry, physicians, academia, Kantons) has published consensus papers for new benefit criteria and measurements. METHODS: A comparative analysis of the cost-effectiveness and adverse events impact and the impact on the value of the drug as evidenced by the submission requirements of Scotland and the Netherlands look similar, the cost-effectiveness impact assessment is performed on the variables related to additional clinical benefit; variables that also significantly influence G-BA’s decision.

RESULTS: In Germany, a total of 76 completed early benefit assessments. From the best available score perspective, the G-BA assessed the additional benefit as considerable in 20% of drugs assessed (score 2), as minor in 30% of drugs assessed (score 3) and as unimportant in 40% of drugs assessed (score 4) and none in 18% of drugs assessed (score 5). No drug has been granted a major additional benefit (score 3) and 4% of drugs were directly assessed to a reference price group. In France, the French agency committed to a major improvement (IA) in 0.2% of cases (IA abortion), an important improvement in 1.3% of cases (IA II), a moderate improvement in 2.5% of cases (IA III), a minor improvement in 9.2% of cases (IA IV) and no clinical improvement (IAF) in 86.8% of cases. Our Results show in addition that the G-BA assigned an additional benefit (scores from 1 to 4) to more than half of drugs whereas the HAS granted an additional benefit rating to less than 14% of cases. This study suggests that there is a more favourable benefit rating in Germany than in France.

PHIL157 HITA STATUS OF BIOSIMILARS ACROSS THE UK AND IRELAND

Mildred M.1, Davies K 1 Boehringer Ingelheim Ltd, Bracknell, UK

OBJECTIVES: The SwissHTAi initiative involving all key stakeholders in the health care systems (sickness funds, industry, physicians, academia, Kantons) has published consensus papers for new benefit criteria and measurements. METHODS: A comparative analysis of the cost-effectiveness and adverse events impact and the impact on the value of the drug as evidenced by the submission requirements of Scotland and the Netherlands look similar, the cost-effectiveness impact assessment is performed on the variables related to additional clinical benefit; variables that also significantly influence G-BA’s decision.

RESULTS: In comparison to HTA systems in Germany and the UK the SwissHTAi recommendations seem to be more pragmatic and would follow a broader multi-criteria decision making approach.

PHIL158 DOES NOT REACHING AN AGREEMENT ON THE FINAL NICE SCOPE HAVE ANY IMPACT ON THE FINAL APROALIS OF A DEVICE?

Camassaro M.1, Meenstra L.2, Van Engen A.2

OBJECTIVES: Identifying the right patient population, comparator and endpoints is key to increase the likelihood of reimbursement. Manufacturers do not always agree with payers’ views on these items. Disagreement may lead to funding rejection. We assessed the rate of mismatches between manufacturers and NICE and their impact on the final scope.

RESULTS: The NICE’s APM has considered biosimilars in 69% for AMNOG, a sustainable change to the reimbursement of new drugs in Germany. The G-BA assessed the additional benefit of the drug, to an appropriate therapeutic. AMNOG law is perceived to be one of the toughest drug evaluation process in Europe.
Rejection was more common for manufacturer’s comments on outcomes (6/8, 75%) and manufacturer suggestions to the final scope does not decrease the likelihood of being granted funding.

**PHP159**
**AN EXAMINATION OF THE REGULATORY AND REIMBURSEMENT PROCESSES FOR BIOBETTERS AND COMPARISON WITH BIOSIMILARS**

**de Silva SJ, Dimova M, Bending MW**

**Methodology:**
- Biobetters and biosimilars are both biopharmaceuticals, with the former having a unique molecule and the latter being highly similar to an existing product.
- The study aimed to compare the regulatory and reimbursement approaches to the appraisal of biobetters and biosimilars.

**Results:**
- Biobetters and biosimilars of the same product class were identified, and qualitative analyses of the recommendations found that biosimilars were more likely to be approved based on clinical evidence.
- The evidence requirements for biobetters were found to be more stringent, particularly in terms of clinical trial data.

**Conclusions:**
- Biobetters and biosimilars are subject to distinct regulatory processes and decision drivers for reimbursement. Biobetters face a higher evidentiary burden compared to biosimilars.
- The study highlights the need for a standardized approach to regulatory and reimbursement processes across countries.

**PHP160**
**TIME LIMITS RESTRICTION IN GERMANY**

**Thivolet M, Rousi P, Kornfeld M, A. Torumi M, György A**

**Methodology:**
- The study aimed to examine and compare the regulatory and reimbursement approaches to the appraisal of biobetters and biosimilars.
- The research team used available regulatory and HTA reimbursement decision documentation to examine and compare the approaches.

**Results:**
- As of June 1st 2014, 76 EBAs were concluded and time limits, from 1 to 5 years, were imposed on 28/217 (67%) of the decisions.

**Conclusion:**
- Time limits for the approval of biobetters and biosimilars are set and can vary widely from one to five years. The study highlights the need for a standardized approach to regulatory and reimbursement processes across countries.

**PHP162**
**GLOBAL HTA ASSESSMENTS OF ULTRA-ORPHAN PRODUCTS: A CASE STUDY OF Eculizumab (Soliris) and Idunorabe-2-Sulfatase (Elaprase)**

**Paul A1, Morawski J, Spinner DJ2, Doyle JI3, Faulkner EC, Ransom JF6**

**Methodology:**
- The study aimed to assess the HTA evidence requirements and reimbursement decisions for ultra-orphan medicines and comparatively evaluate key decision drivers across geographies.

**Results:**
- The study found that HTA agencies and payers have modified evidence requirements and opportunity for very high prices. The study also identified the need for health technology assessment (HTA) review of biobetters and biosimilars to ensure their approval.

**Conclusion:**
- The study highlights the need for a standardized approach to regulatory and reimbursement processes across countries for health economic, clinical, and value-based criteria.

**PHP163**
**EVIDENCE-BASED MARKET ACCESS VALUE RESOURCE: NAVIGATING THE Hurdles FOR A BIOLOGIC OBTAINING A LICENSE IN A SECOND INICATION IN KEY EUROPEAN COUNTRIES**

**Hoque S1, Bjoerke B, Walker A, Raipur MM, Fernandez M, Quijano M, Ling CS, Heyes AK1**

**Methodology:**
- The study aimed to develop a resource for manufacturers and decision makers to navigate the challenges of obtaining a second indication for a biologic.

**Results:**
- The study found that the process for obtaining a second indication can be complex and time-consuming. The study also highlighted the importance of demonstrating clinical and economic value.

**Conclusion:**
- The study provides a valuable resource for manufacturers and decision makers to navigate the challenges of obtaining a second indication for a biologic.
engagement. CONCLUSIONS: The evidence-based market access value resource approach provides a clear, concise, and globally integrated value story that will assist in market access and form the basis of consistent communication regarding value at the national, regional, and local level across external stakeholders (e.g., payer decision makers, physicians, patient advocates). Access for a biologics will be compared regarding key, decisions and adoption of a new technology are diverse and dispersed across and within countries, with varying levels of required evidence.

PHP164
MEDICARE PROVIDER UTILIZATION AND PAYMENT DATA: THE BOOK TO BILL GAP

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Doyle P1

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The utilization of Medicare claims data provides a snapshot of all other top 10 developed nations, with no increases in life expectancy. Increasing transparency in health care spending could help address this cost to outcomes gap. CMS’ recent release of Medicare Part B Utilization and Payment data, covering 880,000 providers and $77 billion in Medicare pay- ments, is a significant step toward this goal. OBJECTIVES: Understand differences in billed versus paid amounts for provider and procedure types reported in Medicare data. METHODS: Descriptive and inferential statistics were run on provider specialties representing greater than 2% of claims to describe the differences between maximum allowed Medicare payment amount, amount billed by providers, and the amount reimbursed. Geographical variation was also explored. RESULTS: Amount billed is at least double the amount paid and double the maximum allowable amount for all of the specialties explored, amount billed versus paid varies significantly by specialty, with some specialties billing as much as six times what they are paid. Largest discrepancies were in anesthesiology (on average billing $4883, being paid $191, allowed $110 paid). Other specialties with significant disparity include cardiology, diagnostic radiology, emergency medicine, ophthalmology, and orthopedic surgery, within certain specialties, specific procedures showed ranges of billed versus paid that were as much as six to 12 times the average amount reimbursed. The data shows that 90% of maximum allowable, and each state is represented in line with census data for the Medicare population; state differences in amount paid versus billed and allowed is not significant. CONCLUSIONS: In analyzing payer and provider data to increase transparency in the health care spend, we recognize there is heterogeneity between what is paid versus billed across specialty. There is an opportunity to focus attention on narrowing this gap for high-value procedures through evidence and education of patients, payers, and providers to ensure patients receive appropriate treatment, and providers are appropriately reimbursed.

PHP165
CLAIMS REIMBURSEMENT ANALYSIS OF THE NATIONAL HEALTH INSURANCE SCHEME IN GHANA

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National Health Insurance Scheme, Accra, Ghana

OBJECTIVES: To assess the value and service quality of the National Health Insurance Scheme (NHIS) benefits. METHODS: A review method was employed to analysis medical claims for the 2011 to 2013 period. The medical claims were retrieved from the database of the Ashiedu Keete District NHIS Office. The incurred claims ratio, promptness of claims settlement, and claims rejection ratio indicators of benefit value and service quality were analyzed. RESULTS: A total of 421,574 medical claims were analyzed. Cost of GH¢7.3 million (US$11 million) were analyzed. These claims came from thirteen accredited health care providers-three public health facilities, four private clinics and six community pharmacies. The incurred claims ratio increased significantly from 4.3 to 7.2 over the period, 2011-2013. The proportion of claims settled beyond 90 days increased consistently from 26% to 90% over the same period. Although, the proportion of claims rejected increased from 0.9% to 3.6% over the period under review, overall, it was low. The reasons for rejection included provision of benefits to ineligible subscribers and breach of sub- limit on certain expense category. CONCLUSIONS: There is increased awareness and utilization of health services; however, there are considerable delays in claims settlements. It would be necessary for management of the NHIS to settle claims in time to ensure that health care providers are financially resourced to render service to subscribers.

PHP166
NATIONAL HEALTH INSURANCE FUND DRUG EXPENDITURE IN BULGARIA, 2007-2012: REFERENCE BASED PRICING ALONE OR IN COMBINATION WITH OTHER APPROACHES TO PRICING

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OBJECTIVES: Our team wanted to compare the economic effect of restricted market access and reference based pricing (RBP) vs. RBP alone in two consecutive periods, 2007—2009 and 2010—2012. METHODS: We used the officially published cash flows for reimbursement to calculate the cost of GH¢7.3 million (US$11 million) were analyzed. RESULTS: While restricted market access and RBP has been applied between 2007 and 2009, the NHIF drug expenditure increased with 15% (from EUR 144 mln to EUR 166 mln). For that period, the drug expenditure was generally 100% within the budget. From 2010 to 2012, while RBP has been applied, a 20% increase in drug expenditure was recorded with 62% (from EUR 187 to EUR 303 mln). For the period, the drug expenditure exceeded the NHIF budget with 5% in 2010, 2011, 2012, 2013. CONCLUSIONS: RBP alone cannot control the drug expenditure in a long-term. Additional measures are needed together with RBP Performance-based pricing, differential pricing, comparative pricing, profit control and performance volume agreements may be considered as additional to RBP measures for pricing and budget control.

PHP167
EVALUATION OF SOCIAL WELFARE PART OF HUNGARIAN DRUG PROVISION (2007—2012)

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Healthware Consulting Ltd., Budapest, Hungary

OBJECTIVES: The part of Hungarian drug provision system, which is available on social welfare list, changed several times and in different extents in recent years. The introduction of drug budget in 2006 and simultaneously the abolition of social welfare drug list implied the most significant change. The chief aim of our analysis was to give a comprehensive overview about the main trends on this field examining the range of available products on social welfare list based on different aspects, also concerning the trends of demand, product structure, expenditures and utilization of health services; however, there are considerable delays in claims settlement, and providers are appropriately reimbursed.

PHP168
ANALYSIS OF NEW MODEL OF THERAPEUTIC POSITIONING REPORTS AS A P&R DECISION-MAKING TOOL IN SPAIN

Rodriguez T,
Izmirli A,
Ando G

OBJECTIVES: This study aims to determine if the recently proposed model for thera- peutic positioning reports (IPTs) in Spain is actually being used as a supportive tool for pharmaceutical costing and reimbursement (P&R) decisions whilst delivering innovative and market access and regional market access frameworks. RESULTS: Primary research was conducted with regional payers on the proposed model of IPTs, which contain a comparative evaluation on effectiveness and safety, as well as generating considerable consequences regarding to potential ways of future structural changes, considering both interests of entitled patients (right to access innovative therapies) and the Health Fund (increase savings, improve efficiency). This analysis based on real world (patient level) data may result in complex investigation opportunities of this patient segment and reimbursement category.

PHP169
REFERRAL UTILIZATION RATE: LINKING HOUSEHOLDS TO HEALTH CARE SYSTEM; KENYAN RURAL SETTING EXPERIENCE

Mugore DM1,
Loum CS2,
Kaseje D3

1Moi University, Eldoret, Kenya, 2Great Lakes University of Kigoma, KIGOMA, Kenya, 3Great Lakes University of Kigoma, Kigoma, Kenya

OBJECTIVES: Referral utilization is defined as the number of patients referred and seen by physicians. The objective was to establish referral utilization rate among sick persons and households based and residents in the health care. METHODS: A cross sectional study carried among 200 households in two sub- locations in rural Kenya. Sick persons identified were issued with referral and counter slip to the hospital. RESULTS: The part of the study total 322 patients were identified, advised and referred, with a referral response rate of 93% (298/322). Seventy percent were five years and above. The study showed that 82% (263/322) of the patients attended in hospital with referral slip the same day

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP169
REFERRAL UTILIZATION RATE: LINKING HOUSEHOLDS TO HEALTH CARE SYSTEM; KENYAN RURAL SETTING EXPERIENCE

Mugore DM, Loum CS, Kaseje D

Moi University, Eldoret, Kenya

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HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

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they were referred, 5% (15/322) arrived second day, 6% (20/322) third day and over 7% (34/322) did not arrive in the hospital. CONCLUSIONS: The study provides evidence that community health workers if properly trained, equipped and supported would identify sick persons in the households, counsel and refer them to hospitals for specialized care. Patient referral arrival rate on same day is reasonably high because households received trained and well equipped CHWs who referred them to seek care. Similar studies carried out in the US and Great Britain suggest that in a population of 1000 adults, 750 will experience an episode of illness, of these 250 will consult a physician of whom 6 will require to be referred to the physician.

PHP170 PROVINCIAL ENTRY OF NEW DRUGS IN CHINA

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OBJECTIVES: To improve health care provision whilst containing cost at the same time, China follows the entry of new drugs at provincial level. Whilst different provinces have different economic situation and needs, it is essential for pharmaceutical companies to strategize provincial drug entry. The purpose of this research is to explore province(s) that may provide the best chance for new drug entry. We compared the reimbursement status of these drugs against the Chinese database.

RESULTS: 245 new formulations were identified, among them 35 of them are alternative formulations of 26 new drugs. Among the 23 provinces and 4 municipalities provinces, Anhui (48%) followed by Jiangsu (20%) approved most new drugs without restrictions. Whereas, Jilin (62%) was the province approved most drugs associated with restrictions. The number of approved new drugs was not correlated to regional GDP per capita (r = 0.18, r2 = 0.03) but not the 2009 NDLP multiple databases including the two NDLPs, Adis Insight and the Chinese database. Provincial reimbursement status of these drugs was identified using the Chinese database. Provincial population and economic data (including gross domestic product (GDP), health expenditure and consumer price index (CPI)) in 2011 were captured on the National Statistical Database. The relationship between the numbers of provincially reimbursed drugs (with/without restrictions) and GDP per capita, and between the numbers of provincially reimbursed drugs (with/without restrictions) and regional health expenditure, were investigated. All databases were accessed in September 2013.

Conclusions: We found no relationship between the reimbursement status of new drugs approved on a provincial level, the provincial economic status and the number of new drugs approved in provinces. 

PHP171 USING THE ISPOR 2013 EUROPEAN CONGRESS AS A BIG DATA CASE STUDY

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OBJECTIVES: The availability of concentrated big data sets can help researchers analyze current trends in an industry and drive future growth. Over 1,600 poster presentations related to pharmacoeconomics and outcomes research were presented at the 2013 ISPOR European meeting. We analyzed the titles of the posters to find trends in research. METHODS: We analyzed the titles and associated sections of all the poster presentations accepted for the ISPOR European meeting held in Dublin, Ireland. The distribution by sector (research on methods, health care use & policy studies, cancer, cardiovascular, etc) was calculated in addition to the type of study (cost, P&O & patient preference, clinical outcomes, etc.) We also searched the titles of poster presentations for key words to divide them into the following five categories: cost-effectiveness, budget-impact, burden of illness and literature review. RESULTS: In total, 1,679 poster title were analyzed. For the sector distribution, the top three sectors were as follows: research on methods (44, 18%), health care use & policy studies (217, 12.92%) and cancer (210, 12.51%). The top four typical types of studies were: cost studies (617, 36.75%), patient reported outcome & patient preference studies (217, 12.63%), and clinical outcomes studies (200, 11.91%). Of all the posters, cost-effectiveness studies made up 43% (705; 24.87%), budget-impact studies made up 12% (212; 12.63%) and clinical outcomes studies (200; 11.91%). CONCLUSIONS: Analyzing trends at conferences may help researchers and key stakeholders understand the current issues in the field. The most common type of study for the 2013 ISPOR European was cost studies. The cost-effectiveness studies were concentrated in cancer, cardiovascular disorders and infections.

PHP172 COMMON ILLNESSES IDENTIFIED BY COMMUNITY HEALTH WORKERS IN THE HOUSEHOLDS AND REFERRED TO PRIMARY HEALTH FACILITIES FOR CARE

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OBJECTIVES: To determine common illnesses identified and referred to the health facility for care by community health workers during routine household visitations

METHODS: The clinical evaluation study was carried out in two sub locations in rural Kenya where one hundred community health workers were trained on community based referral and counter referral model and issued with referral tools. The community health workers were instructed to regularly visit them in order to identify sick persons counsel and refer them to link hospitals. One hundred villages comprising 2209 households with a population of 11,000 people were covered where the counter referral model was implemented. RESULTS: In total the community health workers identified sick persons and referred 322 sick persons to health facilities for care. Those identified for referrals were categorized as either below or above five years. Under five referrals accounted for 30% (97/322) whereas the top five reasons for referrals included; general illnesses for under five, 5% (18%), postnatal care for infant, 30% (93), immunization defaulters

3.1%, malaria, 3.9% and diarrhea, 3.9%. Top five reasons for above five refer-

The study concludes that CHWs are trained and supplied with referral tools and regular support supervision, they have the capacity to identify common ailments at household level and provide advice on the appropriate health action required to be taken. It is the view of the authors that community health workers referral model be scaled up.

PHP173 AN EVALUATION OF PATIENT SATISFACTION IN PAFOS, CYPRUS WITH THE "EUROPEP" INSTRUMENT

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OBJECTIVES: To evaluate patients’ satisfaction with the general practice care pro-

vided at the Pafos General Hospital outpatient units. METHODS: The EUROPEP ques-
tionnaire, standardized and validated into Greek, was distributed to outpatients, and consisted of random sampling and filled out with personal interviews, from February to April 2014. EUROPEP includes 23 items and 5 dimensions regarding doctor – patient relationship, medical care, information - support, organization of care and accessibility. The sample size was based on 50% of annual outpatients’ visits. For the assessment of the questionnaire internal consistency, the coefficient a Cronbach was used. Subjects’ t-test and analysis of variance have been performed in order to determine the significant differences between the dimensions and sociode-

PHP174 CLINICAL TRIAL ACTIVITY IN GREECE FROM 2010 TO 2012: STILL MISSING THE OPPORTUNITIES?

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1National School of Public Health, Athens, Greece, 2Sanofi - aventis AERE, Athens, Greece

OBJECTIVES: Clinical trials (CTs) lead to innovative medical treatments, and pre-

vent/ cure most of the major diseases. CTs are a cooperative effort between researchers, funders, pharmaceutical companies (SPEF). Each company was requested to return a structured questionnaire for each interventional CT approved by the National Ethics Committee (NEC). The study aimed at portraying the CT activity in Greece for 2012, built upon a previous survey conducted in 2010, and at highlighting any discrepancies. METHODS: The survey was conducted by the Hellenic Research and Educational Association of Pharmaceutical Companies (SPEL). Data on 70 interventional CTs were received. The majority was phase-III trials (64.3%) as in 2010 (68.3%) with a mean duration of 36.3 months (regardless of phase). Most CT sites were affiliated to a university or NHS hospital (45.7% and 42.3% respectively). A contractionary phase in the CT activity was observed compar-

PHP175 PREDICTORS OF WORKING MOTIVATION IN JOB SATISFACTION AMONG NURSES IN CYPRUS

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1University of Cyprus, Pafos, Cyprus, 2University of Peloponnese, Corinth, Greece

OBJECTIVES: To investigate factors affecting nurses’ working motivation on job satisfaction in public and private hospitals in Pafos. METHODS: The study included all hospitals in Pafos, with 410 nurses out of which a random sample was col-

lection of data in January to May 2013. A self-administered, instruments have been used. The first questionnaire refers to working motivation in terms of recognition, responsibility, personal development, job interest, working relationship-

ships etc. developed by Evered and Morris (1999). The second questionnaire refers to job satisfaction by Spector (1985). Both instruments score 1: “agree/satisfied very

0.004), medical care (p

organization of care (p

0.001) and organization of care (p

0.001). Patients’ health condition was found significant with the doctor – patient relationship (p = 0.004), medical care (p = 0.007) and accessibility (p = 0.001).

Conclusions: Patients were satisfied with the provision of general practice and sociodemographic characteristics appear to be significant predictors of satisfaction. Also, problems of accessibility can be solved through the forthcoming reform of primary health care in Cyprus.

2010, as demonstrated by the basic characteristics of approved CTs, i.e. average number of patients/trial: 35 vs 98, average number of patient per partici-

5% (0.05; 15 of 30). CONCLUSIONS: Variations in patient referral rate reveals the getting enough patient into clinic, the practice and waiting time was scored much lower (2.3 ± 0.8), meaning “dissatis-

fied”. Statistically significant differences were found between gender and doctor – patient relationship (p = 0.019), information - support (p < 0.001) and organization of care (p = 0.004). Gender stereotype was related to information – support (p < 0.001) and organization of care (p < 0.001). Patients’ health condition was found significant with the doctor – patient relationship (p = 0.004), medical care (p = 0.007) and accessibility (p = 0.001).

Conclusions: Patients were satisfied with the provision of general practice and sociodemographic characteristics appear to be significant predictors of satisfaction. Also, problems of accessibility can be solved through the forthcoming reform of primary health care in Cyprus.

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much” to 4 “disagree/disatisfied very much”. Correlation analysis was performed to identify the relationship between working motivation and job satisfaction. Also, multivariate regression analysis with stepwise method was conducted between overall job satisfaction and various working motivation dimensions. RESULTS: 141 out of 150 nurses filled out the questionnaire (88.4%). The majority of the sample (68% of the nurses) (20-30 years old) (p < 0.01) and belonged to the 21-30 years old group. Working motivation scoring was ranged from 2.54 to 2.04, meaning positive, except from working relationships (1.8 ± 0.7). Also, the mean of overall job satisfaction was 2.3±0.6, meaning satisfied. Positive correlation was found between working motivation and job satisfaction (p<0.01), with the exception of salary and working relationships. Personal development (β = 0.227), job interest (β = 0.254), responsibility (β = 0.149) and recognition (β = 0.154), were significant predictors of overall job satisfaction (p<0.05). Reporting high motivation from work was positively and significantly related to higher job satisfaction. CONCLUSIONS: Working motivation of health professionals contributes to the enhancement of their job satisfaction and consequently to the improvement of health services provision.

PHP176
FACTORS INFLUENCING JOB SATISFACTION AMONG NURSES OF PAFOS GENERAL HOSPITAL IN CYPRUS
Nikolaou M1, Latou D2, Geitona M3
1Neapolis University, Nicosia, Cyprus, 2University of Paphos, Paphos, Greece
OBJECTIVES: To assess the job satisfaction of the nursing staff of the Pafos General Hospital in Cyprus. METHODS: A cross-sectional survey was conducted in April 2014. All 150 nurses (NR=100%) working at the General Hospital of Pafos filled out a standardized, self-administered questionnaire with a 5-point Likert scale, regarding the assessment of their job satisfaction, working conditions and personal well being as independent variables, multiple linear regression analysis was performed with backward method. Also, correlation analysis, using Spearman rank coefficient was conducted to quantify the strength of association among job satisfaction and independent variables. RESULTS: The majority of the sample (64.7%) was female and permanent employees (60.7%). The mean age was 33.7 (SD 9.7) years. The personal well being score was 4.1 (SD 0.6), which means satisfied. The working conditions and job satisfaction scores were 2.2 (SD 0.7) and 2.9 (SD 0.9), showing low and moderate satisfaction respectively. Age (β = -0.321, 95% CI -0.650, -0.008), permanency of job (β = 0.346, 95% CI 0.005, 0.667), satisfaction of working conditions (β = -0.532, 95% CI -0.331, -0.730) and personal well being (β = 0.444, 95% CI 1.188, 0.700) were significant predictors of overall satisfaction (p<0.05). Positive correlation was found between job satisfaction and working conditions (r = -0.394, p ≤ 0.001) and personal well being (r = -0.185, p = 0.024) respectively. CONCLUSIONS: The assessment of nurses’ working conditions appears to contribute to the improvement of job satisfaction, the enhancement of productivity and nursing care outcomes.

PHP177
LEGAL AND ETHICAL IMPLICATIONS OF USING DATA FROM SOCIAL MEDIA WEBSITES
KhanhLe1, Abogunrin S, Martin A
1Evidra, London, UK
OBJECTIVES: Most social media (SM) sites have common terms and conditions dictating how data from the sites may be used, but how these relate to healthcare research is usually unclear. We analyzed studies included in two separate systematic literature reviews to assess whether researchers have evaluated the legal and ethical implications of using data from SM sites to be used in health care research. MethOds: In the first review, MEDLINE and Embase were searched for English language studies on the use of SM in the context of adult vaccination. We assessed whether any of the individual studies considered the legal and ethical implications of using SM sources. RESULTS: The first review identified 3,232 unique abstracts; 36 reported on interactive, internet-delivered programs, Facebook, and mobile apps, for improving health outcomes of patients with cancer, or inflammatory, mental health, musculoskeletal, neurologic, ophthalmologic, or sexual health-related disorders. The second review identified 1,264 publications, of which 32 used SM to communicate with patients, analyze content, or recruit patients for studies related to perceptions of adult vaccines. Among these 68 publications, no study reported whether the legal or ethical implications of using SM content were considered prior to conducting research. CONCLUSIONS: The evidence suggests that legal and ethical implications of utilizing data from SM websites are not reported, and may not be considered, in current SM research. It is unclear whether this reflects the lack of clarity about what these restrictions mean for health care research, or whether researchers are not aware that such restrictions may exist. An informed debate to raise awareness of these issues and come to an understanding of the best way forward is urgently needed.

PHP178
PHENOMENON OF INAPPROPRIATE DRUG MANUFACTURING IN CHINA - PAST AND PRESENT
Wardh AA
GFR NOP, London, UK
OBJECTIVES: It was an unspoken fact that Chinese manufacturers copying patent-protected drugs inappropriately (e.g. arigripazole (neurology), penetrated (oncology), and sumatriptan (respiratory)). The purpose of this study is to review this phenomenon among the drugs currently included in the National Drug Lists (NDLs) and trends in the recent years. MethOds: Reimbursed drugs from three therapeutic areas (neurology, oncology and respiratory) were identified from the 2012 NDLs. The marketing years of the import (originator) drugs and local ‘branded’/generic drugs were found using the online Drug Future Chinese Marketed Drugs Database (accessed December 2013 to January 2014). RESULTS: New drugs for neurological diseases, 106 drugs for oncology and 76 drugs for respiratory diseases were identified; 92, 42 and 26 drugs respectively had the marketing years of both import brands and local ‘branded’/generic versions. 32 (~35%) neurological drugs, 13 (31%) oncology drugs and 11 (42%) respiratory drugs had local ‘branded’/generic versions before the imported (originator) version. Most of these drugs in all three therapeutic areas were marketed between 2002 and 2003, whilst their imported (originator) versions were marketed 1-7 years later. Since 2009, no originator drug has been found marketed later that their local ‘branded’/generic versions. CONCLUSIONS: The low number of local ‘branded’/generic drugs marketed before the imported drugs in recent years suggests that the IP issue in China might have improved since the 2000s. Positive Results also suggest that respiratory medicine is the most popular for inappropriate local manufacturing. It is yet to find out whether this observation was related to the costs of the originator drugs, the market demand, difficulties in licensing new molecular entities due to their complexity, or both. These results may act as the basis to further explore future IP issues in China.

PHP179
THE ECOLOGY OF MEDICAL CARE IN JAPAN VISITED
Takashashi D, Ohde S
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OBJECTIVES: Studies on the ecology of medical care have provided a framework for health care systems, medical education, and clinical research. Ten years ago, Fukui et al. reported the ecology of medical care in Japan. However, medicine and health care organization has changed since then. In the current study, we conducted an updated evaluation and core analysis of the observed data to identify current health care seeking behaviors of people in Japan. MethOds: A population weighted random sample from a nationally representative panel was used to estimate the number of activity, health problems, self-care, and health care utilization per 1,000 individuals based on a prospective health diary recorded for one month. Variations in terms of age and gender were also examined. RESULTS: Based on 6,548 persons (3,741 males and 1,807 females), 3,837 persons (2,283 males and 1,554 females) reported on the data from 2003, health care seeking behaviors of people with symptoms in Japan are remarkably similar, with the exception of an observed increase in the use of CAM. Results of this study would be useful for further delineation of health care seeking behaviors of people in the context of a health care system unique to Japan.

PHP180
WHAT IS THE PROPORTION OF PATIENTS WHO RETURN COUNTER REFERRAL SLIPS TO THE ORIGINAL REFERRAL SERVICE FOR CONFIRMATION OF ARRIVAL TO THE HOSPITAL?
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1Great Lakes University of Kisumu, Kisumu, Kenya, 2Great Lakes University of Kisumu, Kisumu, Kenya
OBJECTIVES: Counter referral success rate is defined as number of patients received back at the request of the counter referral slips divided by the total number of patients referred and received at the referral hospital. Study objective was to determine the number of patients who returned counter referral slips to the original referral service for confirmation of arrival to the hospital. MethOds: Questionnaire referral study was conducted in two rural health centers, where 100 community health workers were trained on community based referral and counter referral model and issued with referral tools. Each was assigned 25 households, instructed to regularly visit them in order to identify sick persons and refer them to link hospitals. One hundred villages comprising 2,029 households with a population of 11,000 people were covered where the counter referral model was implemented. RESULTS: During the 12 months of implementation, a total of 322 patients were identified, counseled and referred to link hospitals of whom 93 (298/322) arrived at the hospitals with referral and counter referral slips. The study showed that forty six percent (130/288) of counter referral slips had the name, signature and date of referring health worker, only 12% (35/288) indicated CHW’s telephone contact. Forty one percent (121/285) had the name and signature of attending physician of which 96% (116/121) had hospital stamp. Further, forty seven percent (140/286) of the returned counter referral slips defined the original referral service for confirmation of arrival at the referral hospital. Fifty one percent (117/228) were satisfied with referral and counter referral process. CONCLUSIONS: It is concluded that referral and counter referral model is both feasible and acceptable. However, referral protocols and other resources are necessary for the process to be successful. Further, both ends should be willing and prepared to receive those being referred there.

PHP181
WHAT IS THE PATIENTS’ MEDIAN DELAY FROM THE REFERRING COMMUNITY HEALTH WORKER TO ARRIVAL IN THE LINK HEALTH FACILITY?
Mogere DM1, Loum C2, Kaseje D3
1Great Lakes University of Kisumu, Kisumu, Kenya, 2Great Lakes University of Kisumu, Kisumu, Kenya
OBJECTIVES: Median delay could be defined as time taken in days from referring health facility for arrival at receiving link health facility. The purpose of the study was to determine the amount of time (in days) patients take to arrive at the link health facility for health care after being referred from the household by community health workers. MethOds: Quasi-experimental study was carried out in two

A434 VALUE IN HEALTH 17 (2015) A433–A466
CHOOSING IMPORTANT HEALTH OUTCOMES FOR COMPARATIVE EFFECTIVENESS RESEARCH: A SYSTEMATIC REVIEW

Garson E1, Gurung B1, Medley N1, Altman D1, Blazevic E1, Clarke M1, Williamson PJ1

1University of Liverpool, Liverpool, UK, 2University of Oxford, Oxford, UK, 3University of Bristol, Bristol, UK, 4Queen’s University, Belfast, Ireland

OBJECTIVES: A core outcome set (COS) is a standardised set of outcomes which should be measured, reported, as a minimum, in all effectiveness trials for a specific health area. This will allow results to be compared, contrasted and combined as appropriate, as well as ensuring that all trials contribute usable information. The aim of this review was to identify the following which outcomes or domains to measure in all clinical trials in a specific condition, and to describe the methodological techniques used in these studies. METHODS: We developed a multi-faceted search strategy for electronic databases (MEDLINE, EMBASE, Cochrane Library). Three hundred and six studies were identified. CONCLUSIONS: COS will facilitate comparing and summarizing information of greater relevance to patients in their own therapeutic decisions. This review has brought together the existing research in a single place. COS will provide a framework for trials to measure outcomes relevant to patients.

THE COST-EFFECTIVENESS OF CLINICAL CARE?

MethOds: In-depth interviews with 20 respondents in each of the four areas (USA, UK, Brazil, Bangladesh). The interviews were conducted between June 2006 and September 2006. Results: Respondents estimated the economic benefits of healthcare reform in terms of increased access to healthcare services and improved health outcomes. The respondents also identified the challenges related to implementing healthcare reform, such as financing, quality assurance, and public perceptions. The results suggest that healthcare reform can provide significant cost savings and improve the quality of care. The findings also highlight the importance of involving patients in the decision-making process.

HEALTH REFORM IN CHINA AND THE UNITED STATES: A TALE OF TWO NATIONS SEEKING TO IMPROVE ACCESS TO AFFORDABLE CARE

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OBJECTIVES: Traditionally, drug repurposing has been considered as a cost-effective alternative to the development of new drugs. Currently little is known and documented regarding efficiency of repositioning strategies in drug development. The objective of this article is to assess the meaning of this process with focus on CNS area. We aim to identify the repositioning strategies that conducted to the discussion of new indications for drugs. Currently little is known and documented regarding efficiency of repositioning strategies in drug development. The objective of this article is to assess the meaning of this process with focus on CNS area. We aim to identify the repositioning strategies that conducted to the discussion of new indications for drugs. Currently little is known and documented regarding efficiency of repositioning strategies in drug development.

PHP182

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PHP182

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need for political unity, substantial financial investments, and adaptability when faced with obstacles and suboptimal results.

**PHP187**

**THE FUTURE OF EDUCATION IN HTA AND HEALTH ECONOMICS**

**Carolyn Beckford C.**

The University of Sheffield, Sheffield, UK

**OBJECTIVES:** An increasing range of online education is available to those working in the field of health technology assessment (HTA) and pharmacoeconomics. The aim of this study was to explore the market for free online education in HTA and to assess the practicalities of delivering a free, interactive short-course.

**METHODS:** We delivered a 5-week online course at the end of 2013 following the principles of the Massive Open Online Course (MOOC) approach. The HTA MOOC programme covered the key areas of HTA: What is it, how new technologies are evaluated, the key principles of assessing clinical effectiveness and cost-effectiveness, and the role of HTA in decision-making processes. The programme was open-access, with materials adapted from an existing online MOOC programme. Descriptive statistics of participants were recorded and a survey was conducted of participants' experiences.

**RESULTS:** 2039 individuals registered for the HTA MOOC, of which 1508 completed a voluntary survey giving basic sociodemographic data about themselves. Participants were from Europe (55%), Asia (16%) and North America (13%) and accessed the MOOC to gain knowledge about the subject (78%) and specifically for career development (56%). 531/2039 (26%) of those registered in Week 1 completed the MOOC (i.e. submitted all required weekly assessments by the end of Week 5), compared to an average of 3-6% for MOOCs delivered in 2013. Students strongly supported the principal strengths of the programme to be the quality and usefulness of the learning materials, and the principal issue to be time required (workload was considered by some to exceed the four hours/week intended).

**CONCLUSIONS:** The MOOC approach offers scope for delivering flexible, effective and accessible education to small or large international cohorts of professionals, patients and providers working within HTA and pharmacoeconomics.

**PHP190**

**PHARMACOECONOMIC EDUCATION IN BRASILIAN SCHOOLS OF PHARMACY**

Fratini R,1 Capone B,1 Mallesini G,1 Alessandrini G,12
departments of pharmacoeconomics at the University of Florence, Italy and the University of Padua, Italy.

**OBJECTIVES:** The objective of this study was to survey the pharmacy schools in Brazil to determine the extent of education in pharmacoeconomics offered during the school year 2012-2013.

**METHODS:** A questionnaire based on previous studies was developed. This was emailed to 55 pharmacy schools in Brazil during October and December 2013. The schools were selected from the Ministry of Education website. Public and private University schools (only those that have high concepts in the National Examination Performance of Students) were included. In addition, a search was made in the database directories of research groups from National Council for Scientific and Technological Development (CNPq).

**RESULTS:** Of the 55 questionnaires sent, 16 were returned (29%). Only two schools do not address the concept of pharmacoeconomics in their curriculum. Most of the schools address some concepts in different subjects (8 hours).

**CONCLUSIONS:** Brazil has 17,000 patients in 2010. Despite this development, the number of CT submissions to ANSM (French Regulatory Agency) decreased from 1,000 in 2008 to 895 in 2013.

**PHILIP191**

**APPLICATION OF A ‘NICE POST-HOC B/S ANALYSIS’ TO THE NICE APPRAISAL PROCESS**

Macaulay R

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**OBJECTIVES:** Post-hoc subgroup analyses are still used in clinical trials of medical technologies to identify patient populations in whom greatest benefits can be achieved, despite this being derided as an analytical approach. Indeed, using such an approach, aspirin has been shown to be ineffective versus placebo in acute myocardial infarction patients born under the star signs of Libra and Gemini (ISIS-2, 1988, Lancet) and endarterectomy is only efficacious in treating symptomatic stenosis patients born on a Monday, Wednesday, or Friday (ECST group, 1998, Lancet).

**Method:** This research aimed to determine what effect the name of a drug has on its cost-effectiveness and how HTA is used within different health systems to inform reimbursement decisions. The course was provided by the Coursera, a free-open-access, education platform.

**Results:** Of those registered in Week 1, 17% completed the MOOC (i.e. submitted all required weekly assessments by the end of Week 5), compared to an average of 3-6% for MOOCs delivered in 2013. Students strongly supported the principal strengths of the programme to be the quality and usefulness of the learning materials, and the principal issue to be time required (workload was considered by some to exceed the four hours/week intended).

**Conclusions:** The MOOC approach offers scope for delivering flexible, effective and accessible education to small or large international cohorts of professionals, patients and providers working within HTA and pharmacoeconomics.

**PHP192**

**IMPACT OF STORY BOOKS ON PROMOTING KNOWLEDGE AND BEHAVIOR OF 4TH STAGE ELEMENTARY STUDENTS ABOUT RATIONAL USE OF MEDICINES IN KERMANSHAH PROVINCE OF IRAN 2008**

National Committee on Rational Drug Use, Tehran, Iran

**OBJECTIVES:** Evaluation of the impact of children's stories on promotion of the knowledge and behavior of 4th stage elementary students about rational use of medicines in the Kermanshah elementary schools.

**METHODS:** 64 elementary schools were selected in Kermanshah province of Iran. The schools were categorized into 3 groups (rich, medium and poor level) based on their students’ economic level. Both boys and girls were involved. Two checklists were designed in order to evaluate students’ knowledge and behavior before and after the intervention. A story book which was published by National Committee of Rational Drug Use (RUD) conveyed to the students as the intervention.

**RESULTS:** The correlation between pre and post intervention and the schools economic levels and the gender of students were obtained. The knowledge change rates were 21.83%, 22.26% and 17.40% for rich, medium and poor schools respectively. The change rate for girls was greater in comparison to that of boys.

**CONCLUSIONS:** It is concluded that children stories as an educational intervention can have valuable positive changes on students’ knowledge and behavior regarding hygiene and medicine. Implementing such interventions among Children, result in promoting rational use of medicines in future of the society.

**PHP193**

**CLINICAL TRIALS IN FRANCE: AN UNDEREXPLOITED OPPORTUNITY**

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**OBJECTIVES:** Despite high-performance infrastructures and recognized expertise, Clinical trials (CT) are declining in France. Health Professionals deploy the burden of the French administration that leads to a real concern regarding the international scientific competition. In addition patients are reluctant to participate in CT especially after the benfluorex scandal. One of the witnesses of the competitiveness of France in CT is the activities among Clinical Investigation Centers (CIC).

**METHODS:** These are platforms fully dedicated to clinical and scientific research acting as an interface between INSERM units (Public National Institute of Scientific Research) and CHU (University Hospital).

**RESULTS:** There are 54 CIC in France. They have been created between 1992 and 2009. CICs are located in university hospitals and are situated in the most important regions of the country. The specific needs of CHU and researchers have led to implement several types of CICs: multi-topics (24 CIC-F), Clinical Epidemiology (CIC-E), integrated in biotherapy (11 CIC-BT) and technological innovations (8 CIC-IT). During the last quadrennium, CIC-P supervised about 1000 protocols, of which 2/3 were therapeutic and 1/3 on physiopathology. 25% of protocols conducted in CIC-P were translational in collaboration with INSERM units, 20% were for rare diseases, 35% were funded by industry and 36% by the PHRC (Academic funding). The AP-HP (Academic Hospitals of Paris area) is the major sponsor in France and one of the first in Europe, with 500 clinical trials enrolling more than 17,000 patients in 2013. Despite this development, the number of CT submissions to ANSM (French Regulatory Agency) decreased from 1,000 in 2008 to 895 in 2012. ANSM approved 705 protocols in 2012 versus 790 in 2008.

**CONCLUSIONS:** Despite appropriate structures and willingness to encourage scientific production, failure in promotion in pharma remains unexploited due to different causes which need to be deeply evaluated.

**HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs**

**PHP194**

**WILL VALUE BASED ASSESSMENT (VBA) REVOLUTIONISE THE NICE APPRAISAL PROCESS?**

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**OBJECTIVES:** In March, the National Institute for Health and Care Excellence (NICE) revealed their plans to implement Value Based Assessment (VBA) in their Technology Appraisal process: VBA will replace NICE’s end-of-life criteria. Instead wider societal impact (WSI) and burden of illness (BOI) will be systematically included in the assessment through absolute and proportional Quality Adjusted Life Year (QALY) shortfall.

**Method:** This was then transformed into a hypothetical willingness to pay (WTP) threshold ranging from €20,000 for the drug with the lowest rating to €50,000 per QALY for the most patients in need. Despite this development, the number of CT submissions to ANSM (French Regulatory Agency) decreased from 1,000 in 2008 to 895 in 2012. ANSM approved 705 protocols in 2012 versus 790 in 2008.

**Results:** Despite appropriate structures and willingness to encourage scientific production, failure in promotion in pharma remains unexploited due to different causes which need to be deeply evaluated.
life criteria or even QoL impact on family. CONCLUSIONS: This analysis presented a possible scenario for the implementation of VA. None of the drugs with a negative recommendation would get a positive recommendation under this scenario. The products at most risk are those currently accepted using end-of-life criteria. However, how the new value elements will be weighted has yet to be determined.

PHP195
THE EVOLUTION OF INTERNATIONAL REFERENCE PRICING: AN ANALYSIS OF 39 COUNTRIES
Lockwood C, Mariotini G, Ando G
IBS, London, UK
OBJECTIVES: To characterise country-level changes to international reference pricing (IRP) policy frameworks across 39 markets, and understand how countries amend this tool. METHODS: Qualitative interviews were conducted with 50 stakeholders across 39 markets, representing 37 payers or payer influencers and 13 industry stakeholders. The interviews focused on IRP methodology for the past and present. Extensive secondary research of government websites and existing literature was also conducted. A qualitative and semi-quantitative analysis of these findings was undertaken to identify key trends in how IRP has been modified and amended. RESULTS: IRP has remained comparatively stable – in terms of both the countries comprising the reference basket and the underlying formula for determining the reference price. However, how the new value elements will be weighted has yet to be determined. A number of stakeholders have made substantive changes to the IRP formula and framework, with notable changes made in the United States, Canada, and European countries. These changes have been driven by a range of factors, including political and regulatory changes, as well as efforts to align with international practices. The analysis suggests that the new MTA and STA processes will foster greater engagement and transparency, and enable patients to guide the appraisal process.

PHP196
MAKING SENSE OF NICE’S ‘NEW’ MTA AND STA PROCESS GUIDE: A NARRATIVE SYNTHESIS
Uhlich M, Mildred M
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OBJECTIVES: NICE’s guide to the process of Multiple Technology Appraisals (MTA) and Single Technology Appraisals (STA) provide a valuable source of information to enable stakeholders to engage in Health Technology Appraisals (HTAs). NICE recently conducted a review of the process guides which has implications for all stakeholders involved with MTAs and STAs. The objective of this analysis was to identify the number and type of amendments within the guides in order to highlight the most important changes for consultees and commentators. METHODS: Narrative synthesis was used to systematically identify, classify and explore the impact of the proposed amendments to the MTA and STA process guides. The hypothesis was that the amalgamation of the MTA and STA guides would simplify both TA processes whilst increasing rigour and transparency. Sources of reference were the MTA and STA process guides, NICE’s consultation on the review of the MTA and STA process guides, EAB meeting minutes from 2009 onwards, and the 2009 MTA and STA process guides. RESULTS: Amendments were classified as relating to the process itself (26%), data and confidential information (6%), and others (15%). Of the 27 amendments to the current process, 19 (70.4%) were identified as major amendments which warrant specific appreciation. Major amendments included: (1) the STA decision process – a single TA meeting will be held in the STA process, (2) the MTA methodology – the MTA process shall be based on a best evidence synthesis, and (3) the STA process – the STA process shall be based on a best evidence synthesis. The analysis suggests that the new MTA and STA processes will foster greater engagement and transparency, and enable patients to guide the appraisal process.

PHP197
METHODOLOGICAL REQUIREMENTS REGARDING QUALITY OF LIFE MEASUREMENT IN THE EARLY ASSESSMENT OF BENEFIT IN GERMANY
Brimme C, Augustin M, Lohrbig D
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OBJECTIVES: In Germany, an early assessment of benefit (EAB) is required for new medicines since January 2011. The pharmaceutical manufacturer submits a dossier on additional benefit over comparative treatment which is subsequently evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG). Stakeholders can comment on the evaluation in a formal comments procedure. The final decision on additional benefit is made by the Federal Joint Committee (G-BA). It provides the basis for price negotiations between manufacturer and statutory health insurance funds. Quality of life (QoL) is one of four criteria for benefit evaluation. This qualitative study aims to determine methodological requirements for QoL measurement in the German EAB. METHODS: A qualitative content analysis according to Mayring was conducted. Documents of all EABs completed until December 2013 (including dossier, IQWiG evaluation, protocol of the oral hearing, and G-BA decision) were searched for the term QoL or synonyms. The interviewees were interviewed via telephone or via email. The data was analyzed using a range of methodological requirements regarding QoL assessment, analysis, and interpretation emerged. Dominant topics included: the appropriate level of disease specificity of QoL instruments, required evidence on an instrument’s validity and on the validity of a minimal important difference; appropriate duration of QoL assessment; consequences of potential bias due to unblinded study design or missing data; interpretation of results that differed between subscales of an instrument; and acceptance of surrogates. The analysis suggests that the new MTA and STA processes will foster greater engagement and transparency, and enable patients to guide the appraisal process. On QoL can have high impact on the additional benefit determined by the G-BA. Therefore, QoL assessment and analysis in clinical studies shall that enter benefit dossiers should confirm with a range of methodological requirements.

PHP198
EXPLORING THE FLAWS IN COST-EFFECTIVENESS MODELS THAT LEAD TO REJECTION OF NICE SUBMISSIONS
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OBJECTIVES: New health technologies are required to demonstrate both clinical and cost-effectiveness before recommendation by the National Institute for Health and Care Excellence (NICE) for reimbursement in England; however, a large proportion of submissions are rejected due to non-robust economic analysis. Published NICE evidence reviews state that the majority of rejected submissions contained economic flaws. The objective of this study was to explore the flaws in the economic models that lead to rejection of NICE submissions and to identify areas of weakness early in the process. RESULTS: Of 44 rejected economic models, 44% contained data and confidential information issues, 7% contained terminology issues, and 22% contained other issues. Of the 27 amendments to the current process, 19 (70.4%) were identified as major amendments which warrant specific appreciation. Major amendments included: (1) the STA decision process – a single TA meeting will be held in the STA process, (2) the MTA methodology – the MTA process shall be based on a best evidence synthesis, and (3) the STA process – the STA process shall be based on a best evidence synthesis. The analysis suggests that the new MTA and STA processes will foster greater engagement and transparency, and enable patients to guide the appraisal process.

PHP199
IS IT POSSIBLE TO PREDICT THE MARKET ACCESS OF A NEW PHARMACEUTICAL IN GERMANY? A SYSTEMATIC EVALUATION OF FEDERAL JUDICIAL COMMITTEE DECISIONS ON EARLY BENEFIT ASSESSMENTS ACCORDING TO THE GERMAN LAW FOR REFORMING THE MARKET OF PHARMACEUTICALS
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OBJECTIVES: As of 1st January 2011 the German drug market is regulated by the act of the reorganization of the pharmaceutical market (AMNOG). Since then the pharmaceutical industry is burdened with a new pharmaceutical market access assessment by the joint federal committee (G-BA) which determines the additional benefit level. According to AMNOG any specification of the reimbursement price shall be based on the economic assessment. Hence a focus on the critique of the economic evidence. RESULTS: The present study aims to determine methodological requirements for QoL measurement in the German EAB. On QoL can have high impact on the additional benefit determined by the G-BA. Results also indicate that the new MTA and STA processes will foster greater engagement and transparency, and enable patients to guide the appraisal process.
2005-2011 for new drugs and new indications for existing drugs were identified from the European Medicines Agency (EMA) website. Two reviewers independently took an appraisal was obtained from the NICE website and NIHR Horizon Scanning Centre records, and the associations between this and the characteristics of the drug and intended patient population were then determined. RESULTS: For 2005-2011, we identified 196 drugs (172 drugs) or new indications (24 indications) of which 72 (54%) were selected for appraisal. The decision to undertake an appraisal was significantly associated with an MA granted 2009-2011 (OR = 2.3, p < 0.01), the drug being a biological agent (OR = 3.9, p < 0.01), administered on a 1:1 basis (OR = 0.8, p < 0.05), indicated for a patient population < 1 in 1,000 (OR = 2.1, p < 0.05), or for malignant disease (OR = 5.1, p < 0.01). It was not associated with an indication for more severe disease (OR = 2.0, p = 0.06), an MA issued for a new indication (OR = 1.4, p = 0.2) or NICE involvement (OR = 1.8, p = 0.10). The review identified several characteristics associated with the decision to undertake an appraisal relating to both the drug and intended patient population that do not contribute to the selection process and are required to determine which are the most relevant factors in this decision.

PHP201
Determination of Cost-effectiveness threshold for Malaysia
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OBJECTIVES: The cost-effectiveness (CE) of health care technologies usually creates an argument especially when alternatives are more expensive but more effective. In this situation, external criterion in the form of CE threshold or willingness-to-pay for a quality-adjusted life-year (WTP/QALY) need to be applied to decision-making in the health care sectors. The lack of CE thresholds in Malaysia, one of the most important barriers in using health technology assessment for decision making. This study was mainly done to determine the CE thresholds for the Malaysian health system.

RESULTS: A qualitative narrative synthesis. A total of 387 evaluations studies published in MEDLINE, EMBASE, LILACS, SCIeLO, NHS EED, HTA Database, EMBASE, Cochrane Library, and BVS ECOS from 1980 to 2013 were included. In our review, we identified several characteristics associated with the decision to undertake an appraisal relating to both the drug and intended patient population that do not contribute to the selection process and are required to determine which are the most relevant factors in this decision.

PHP202
SYSTEMATIC REVIEW OF ECONOMIC EVALUATION OF HEALTH TECHNOLOGIES DEVELOPED IN BRAZIL FROM 1980-2013
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OBJECTIVES: The aim of this study is to review published economic evaluation of health technologies conducted in Brazil. METHODS: Systematic review of economic evaluations studies published in MEDLINE, EMBASE, LILACS, SCIeLO, NHS EED, HTA Database, Embase, Cochrane Library, and BVS ECOS, from 1980 to 2013. Full (Cost consequence analysis - CCA, Cost minimization analysis - CMA, Cost-effectiveness analysis - CEA, Cost-utility analysis - CUA, Cost-benefit analysis - CBA) and partial (cost-utility or cost-effectiveness) studies were analyzed. Studies were included if at least one of the authors was Brazilian and was affiliated to a Brazilian institution. Two independent reviewers screened full-text articles for relevance and carried out data extraction. Disagreements were resolved through discussion or consultation with a third reviewer. We performed a qualitative synthesis of the results. RESULTS: We identified 9196 records and 557 met inclusion criteria. One hundred and ninety (34%) were full (of these, 56.6% CEA, 20.3% CCA, 12.7% CIA, 5% CMA, and 4.7% CBA), and 367 were partial economic evaluations.

PHP203
A LITERATURE REVIEW OF PATIENT ADVOCACY GROUP (PAG) INVOLVEMENT IN HTA
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OBJECTIVES: Patient input is an important part of the assessment process, yet sometimes seen as having a low evidence base. Previous work by the authors shows more research is needed on how the patient group contribution is impacting decision-making. This study was to review the methodological approaches, and outcomes to summarize tables. RESULTS: We identified 21 articles out of a total of 18,829 studies. Articles covered multiple subject areas. Process improvements were most common (4 studies) followed by current perceptions (3 studies), comparison of patient mediated specific type of patient input, and recommendations, comparison of patient pathways and specific type of patient input (3 studies). Conclusions were required to determine which are the most relevant factors in this decision.

PHP204
TRENDS AND KEY DECISION DRIVERS FOR REJECTING AN ORPHAN DRUG SUBMISSION ACROSS FIVE DIFFERENT HTA AGENCIES
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OBJECTIVES: Access to orphan drugs is often inconsistent, and is hindered by difficulties in demonstrating value in HTA appraisals due to the small patient populations and insufficient data. To inform future submissions, we examined the trends and key decision drivers for rejected submissions across the HTA agencies. METHODS: The Orphanet database was searched for orphan drugs with a marketing authorisation between 2002 and 2014. To assume a certain level of competition between orphan and conventional, rare diseases for which two or more orphan drugs were available were selected. Decisions from five HTA agencies were considered: AWMSG (Wales), CADTH (Canada), NICE (England), PRAC (Australia), and the Scottish Medicines Consortium. RESULTS: A cross-sectional, contingent valuation study was conducted using stratified multistage cluster random sampling technique in the state of Malaysia. The sample was stratified into three groups across Malaysian population, estimated in terms of societal WTP for a QALY. METHODS: A cross-sectional, contingent valuation study was conducted using stratified multistage cluster random sampling technique in the state of Malaysia. The sample was stratified into three groups across Malaysian population, estimated in terms of societal WTP for a QALY. Objectives: The aim of this study is to review published economic evaluation of health technologies developed in Brazil from 1980-2013. The number of orphan drugs assessed, and rejection rates, varied by HTA agency. PRAC and SMCG had the lowest rejection rates (4/18; 22% and 62/227, 27%, respectively), while NICE had the highest rejection rate with 40% (4/10). Uncertainties regarding clinical efficacy, and concerns over the robustness of economic evidence were the two key decision drivers that led to a rejection. Examination of data by disease type indicated a trend towards higher rejection rates for diseases with a higher prevalence rate. CONCLUSIONS: The proportion of rejected submissions varied by HTA agency, particularly within the HTA bodies in the UK, highlighting inconsistencies in decision making. An association between prevalence rate and the proportion of rejected submissions was found, with lower rates of disease prevalence correlating with higher acceptance rates. This is most likely due to the lower budget impact incurred in smaller patient populations.
market authorization was retrieved from the EMA or MRHA. NICE positive decisions were compared with market authorizations. A decision that included restrictions that restricted the population eligible for reimbursement for a given therapy was categorized as “recommend with restrictions.” NICE positive decisions that were not more restrictive than the market authorization were categorized as “recommend.” Negative decisions were categorized as “do not recommend.” Restrictions were quantified and categorized. RESULTS: NICE issued “do not recommend” decisions in 32% of the reviews from 2007-2013. The overall rate at which NICE issued “do not recommend” decisions (market authorization) within the same year, but did not pass the traditional levels of statistical significance (p = .21). NICE issued positive decisions in 68% of reviews, but the decision was more restrictive than the market authorization in 52% of the positive decisions. NICE’s restrictiveness has decreased since 2007, with the exception of 2013 where 60% of NICE’s positive decisions were “recommend with restrictions.” For the “recommend with restrictions” reviews, there are 1.7 restrictions on average (range 1-4, s.d. 1) added to the market authorization. The most prevalent type of restrictions were contraindicated or intolerant. In 2014 were included in our analysis. The rationale for the decisions was analyzed for both positive and negative recommendations. Reasons for recommending or rejecting a technology were summarized into categories. RESULTS: In total, 101 publications were identified: 67 of those assessed drugs, 12 a procedure or pharmaceutical for their incremental benefit vs. an appropriate comparator to inform price negotiations with Insurers. This study summarizes the rationale underlying the German authorities’ (G-BÄ) final assessment of manufacturers’ submissions following successful approval by regulators. METHODS: G-BÄ decisions (1/2011 to 6/2013) were evaluated (full, partial, or minimal) on the basis of data included in the manufacturers’ development programs and expectations concerning: (1) target population; (2) comparator; (3) clinical endpoints, including indirect comparisons. Also addressed was the role of safety and how the G-BÄ addressed the potential for bias. RESULTS: Of 69 completed submissions, 3 were resubmissions and 7 lacked a dossier. 59 completed submissions were subjected to a detailed review. Ten (17%) exercises required reevaluation. Major discrepancies (≥18%) were identified in 17% of which (16%) were considered fully inadequate, and 20 (34%) inadequate for significant subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%). For 34 (92%) the assessment was partially inadequate, and 20 (54%) inadequate for specific subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%). For 34 (92%) the assessment was partially inadequate, and 20 (54%) inadequate for specific subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%). For 34 (92%) the assessment was partially inadequate, and 20 (54%) inadequate for specific subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%). For 34 (92%) the assessment was partially inadequate, and 20 (54%) inadequate for specific subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%). For 34 (92%) the assessment was partially inadequate, and 20 (54%) inadequate for specific subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%]), wrong endpoint 6 [16%] and use of historical controls 5 (11%).
of the HTA process in Japan, which is excluded from this analysis. NICE, PRAC and the SMU all use a number of patients with the same disease to obtain evidence. A clear statement of patient numbers eligible for treatment per year for 5 years. Beyond this, the requirements of the Australian PBC and the SMU were similar, specifying prevalence, incidence and mortality data, whereas NICE requires a measure of diseaseness level (not clearly defined) and life expectancy among those with the disease. The epidemiology requirements did not differ by disease area. CONCLUSIONS: HTA bodies stipulate the inclusion of epidemiological data to estimate economic impact of interventions. Some requirements are more formal than others, and there are also some important differences. Specific epidemiological data needs for individual agencies must be considered by drug developers when planning and gathering information for HTA submissions.

PHP212 INCLUSION AND CONSIDERATION OF PATIENT PREFERENCES IN AMNOG EARLY BENEFIT ASSESSMENTS

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OBJECTIVES: To explore the inclusion and evaluation of patient preference data in AMNOG value dossiers. This perspective is becoming increasingly important in health care decision making. Health technology assessment (HTA) agencies include patient views in their appraisals in different ways and to various extents. Patient views and preferences can be captured either by engaging patient organisations, patients themselves, or informal carers in the HTA process (as is done for example in the UK or Canada). Such patient aspects can be also explored in qualitative and quantitative studies which are considered as part of evidence documentation in the assessments. We have reviewed value dossiers and corresponding benefit assessments in Germany from 1st January 2011 to 31st March 2014. Types of patient preference data included in the value dossiers and their consideration in the assessments were collected and summarised.

RESULTS: A total of 68 dossiers were reviewed. 18 dossiers (26%) included data on patient preferences. Those data related to: a) relevance of different treatment endpoints from the patient’s perspective; b) patient’s experiences; c) patient preference for specific drug administration route (e.g. oral vs. injections), administration system (e.g. different inhalation systems), or administration frequency; c) patient preference for therapy duration or type of therapy. In none of the assessment reports did the evaluating committee explicitly address the evidence on patient preferences. A comment on patient preference data was stated in one assessment report only (for aciddeniumbromid).

CONCLUSIONS: About a quarter of value dossiers referred to data on patient preference. Surprisingly, it appears that the evidence on patient preferences has not been considered in the AMNOG benefit assessments despite the fact that benefit to the patient is the central criterion of the AMNOG early benefit assessment.

PHP214 RAPID RELATIVE EFFECTIVENESS ASSESSMENT OF PHARMACEUTICALS: TRANSFERABILITY AND COMPLETENESS OF INFORMATION DERIVED FROM GLOBAL VALUE DossIERS TO COMPLETE A EUEnET SUBMISSION

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OBJECTIVES: EUEnET is currently evaluating the applicability of the Core Model® for Rapid Transferability Evaluation of Pharmaceuticals to selected drugs for which a market authorization is intended between 2013 and 2015. A global value dossier (GVD) represents an important tool for pharmaceutical manufacturer (PM) to communicate with the national HTA bodies. The evaluation considered the management of the dossier, the clinical, epidemiological, as well as health economic outcomes. The current study is intended to quantify the information that may be transferable from a well prepared, comprehensive GVD to EUEnET submission via gap analysis of the GVD. This approach is based on the EUEnET database comprising 4 different models. Description of the health problem, 2. Technical characteristics of technology and appropriate comparative (s), 3. Clinical effectiveness, and 4. Safety of the new drug. METHODS: A GVD, developed for a pharmaceutical product, was used as data source to evaluate the feasibility to address all questions in the four EUEnET modules. RESULTS: In modules 1 and 2 about 60% of data are required to complete the EUEnET submission are missing from the GVD. Most of this information (e.g. implementation of the new drug, current use of the drug) may be easily obtained from other documents held by PM. In modules 3 and 4 about 70% of queries cannot be answered without additional assessments (e.g. complementary evidence synthesis, study quality assessments), systematic searches (e.g. on-going unpublished studies) and additional sources. CONCLUSIONS: A GVD can be a useful pool of knowledge for a new drug in a specific indication. Despite this large body of evidence, a considerable part of the information that is required for a EUEnET submission may be missing from GVDs and needs to be derived from existing clinical study reports, extensive systematic literature searches and additional evaluations. Applying of validated and systematic methods during the GVD development process may reduce additional work for assessment reports.

PHP215 ENCePP-HTA WORKING GROUP SURVEY ON CAPACITY TO CONDUCT RESEARCH IN SUPPORT OF HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: We have reviewed value dossiers and corresponding benefit assessments in Germany from 1st January 2011 to 31st March 2014. Types of patient preference data included in the value dossiers and their consideration in the assessments were collected and summarised. RESULTS: A total of 68 dossiers were reviewed. 18 dossiers (26%) included data on patient preferences. Those data related to: a) relevance of different treatment endpoints from the patient’s perspective; b) patient’s experiences; c) patient preference for specific drug administration route (e.g. oral vs. injections), administration system (e.g. different inhalation systems), or administration frequency; c) patient preference for therapy duration or type of therapy. In none of the assessment reports did the evaluating committee explicitly address the evidence on patient preferences. A comment on patient preference data was stated in one assessment report only (for aciddeniumbromid).

CONCLUSIONS: About a quarter of value dossiers referred to data on patient preference. Surprisingly, it appears that the evidence on patient preferences has not been considered in the AMNOG benefit assessments despite the fact that benefit to the patient is the central criterion of the AMNOG early benefit assessment.

The Working Group’s current focus is on establishing baseline data to shape the network’s activities in the context of AMNOG. A future activity will be to map and test different benefit assessment frameworks. The Working Group is currently providing advice on the conduct of some benefit assessments. In order to provide evidence on the feasibility of far more complex benefit assessments, the Working Group is currently providing advice on the conduct of some benefit assessments. The Working Group is currently providing advice on the conduct of some benefit assessments.

PHP216 WHAT THE ENGLISH COULD LEARN FROM THE IRISH: MAKING THE NICE APPROVAL PROCESS MORE COST-EFFECTIVE

Macaulay R

PHP217 GOING BEYOND THE QALY IN ASSESSING THE BENEFITS OF MEDICAL DEVICES


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OBJECTIVES: Many medical devices offer improvements over current care that may be difficult to assess using standard methods of benefit such as the quality-adjusted life-year (QALY). The objective of this research was to identify whether these benefits could be measured and valued by alternative approaches, such as contingent valuation (willingness-to-pay) or conjoint analysis (discrete choice experiments). METHODS: We undertook a systematic review of the literature from 1996 to 2013 to identify empirical studies of the benefits of medical devices using the following methodologies: willingness-to-pay (WTP), discrete choice experiments (DCEs), multi-criteria decision analysis (MCDA) and subjective well-being (SWB). We recorded the number and category of individuals surveyed, the attributes explored and the key findings of each study. RESULTS: The search resulted in 2772 hits, of which 2016 were considered not relevant and 76 were duplicates. On further examination, 47 of the remaining 680 papers were found not to meet our inclusion criteria, 240 were methodological papers and 363 involved non-device technologies. Thus, there were 128 relevant studies of which 18 were WTP and 126 DCEs. The devices studied included hearing aids, hip and knee implants and colostomy bags. Comfort, convenience or ease of use was the most common attribute explored other than effectiveness and quality of the device. Where benefits were shown, patient preferences sometimes differed from those of physicians. CONCLUSIONS: This research demonstrates that it is feasible to measure and value the benefits of devices using alternative approaches to QALYs, but that the literature is quite small as compared with that for non-device technologies.

PHP218 REALITY IN MARKET ACCESS IN GERMANY AND FRANCE – COMPARATIVE ANALYSIS OF ADDED BENEFIT DECISIONS IN INNOVATIVE PHARMACEUTICAL THERAPIES

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OBJECTIVES: To explore the inclusion and evaluation of patient preference data in AMNOG value dossiers. This perspective is becoming increasingly important in health care decision making. Health technology assessment (HTA) agencies include patient views in their appraisals in different ways and to various extents. Patient views and preferences can be captured either by engaging patient organisations, patients themselves, or informal carers in the HTA process (as is done for example in the UK or Canada). Such patient aspects can be also explored in qualitative and quantitative studies which are considered as part of evidence documentation in the assessments. We have reviewed value dossiers and corresponding benefit assessments in Germany from 1st January 2011 to 31st March 2014. Types of patient preference data included in the value dossiers and their consideration in the assessments were collected and summarised. RESULTS: A total of 68 dossiers were reviewed. 18 dossiers (26%) included data on patient preferences. Those data related to: a) relevance of different treatment endpoints from the patient’s perspective; b) patient’s experiences; c) patient preference for specific drug administration route (e.g. oral vs. injections), administration system (e.g. different inhalation systems), or administration frequency; c) patient preference for therapy duration or type of therapy. In none of the assessment reports did the evaluating committee explicitly address the evidence on patient preferences. A comment on patient preference data was stated in one assessment report only (for aciddeniumbromid).

CONCLUSIONS: About a quarter of value dossiers referred to data on patient preference. Surprisingly, it appears that the evidence on patient preferences has not been considered in the AMNOG benefit assessments despite the fact that benefit to the patient is the central criterion of the AMNOG early benefit assessment.
OBJECTIVES: The German market access system for drugs have been changed significantly in the last years, by introducing a sharper focus on benefit assessment and reimbursement of orphan drugs. However, the system for orphan drugs has remained largely similar. METHODS: The German market access system from 2008 to 2013 was reviewed. A descriptive analysis was conducted to identify those products that have been processed in both systems between Jan 2011 and Dec 2013. This year of comparison was chosen, as it is the first year of introduction of the new system. The number of positive recommendations in NICE HTA decisions for medicines from 2008 to 2013 was assessed. The research question remains whether they produce consistent results in terms of additional benefit (AB) for pharmaceuticals which have passed the assessment in both systems. METHODS: The G-BA and IQWIG as well as the National Health Care Institute (NZi) in the Netherlands were asked to identify those products, which have been processed in both systems between Jan 2011 and Dec 2013. For further comparison a data grid consisting of 26 items for evaluation has been developed, outlining the HTA criteria, assessment of critical endpoints, health related quality of life inclusion. RESULTS: Overall, 140 new therapies have been assessed in France by TC, and 80 in Germany by the G-BA. According to inclusion criteria, 44 products could be identified which have passed through both systems including 7 orphan drugs. Thirty-three products (92%) received a recommendation for list 1B or EDL evaluation by the NZi. However, varying magnitudes appeared to be the greatest difference (n = 17 (39%) remaining drugs), conditioned by lacking concordance of both scale grade systems. CONCLUSIONS: Differences in both countries show partial heterogeneity in determining criteria like benefit levels (ASMR and AB). Although the evidence package for initial assessment in both countries is largely similar, preliminary results suggest their contextualization and scales are different. Further analysis based on results of the grid is needed to better assess criteria leading to different benefit levels and their reimbursement impact.

PHP219
FACTORS INFLUENCING DUTCH DRUG REIMBURSEMENT RECOMMENDATIONS; A DATABASE ANALYSIS
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OBJECTIVES: In the Netherlands, manufacturers need to apply for reimbursement of orphan drugs in a drug dossier. In addition, an expert committee decides on reimbursement of expensive drugs, hospitals can receive additional reimbursement if the drug is included on the expensive drug list (EDL). Pharmacoeconomic evidence is only required for list 1B and EDL evaluation. The National Health Care Institute (NZi) evaluates the reimbursement recommendations and makes (provisional) reimbursement recommendations to the Dutch government. The aim of this study was to identify explanatory variables for the recommendation by NZi. METHODS: A database of published evaluations from February 2006 to March 2014 was created, containing the final reimbursement recommendation and a range of corresponding explanatory variables such as the therapeutic indication, clinical and economic characteristics. Univariate analyses were performed to assess the impact of the individual explanatory variables on the recommendation by means of odds ratios. RESULTS: In total 262 applications were included; the number of positive recommendations by NZi were 121/122 (99%) for 1A, 77/107 (72%) for 1B and 19/28 (68%) for EDL. Pharmacoeconomic analysis was reported in 36/107 (34%) 1B evaluations, of which 27 (75%) were recommended. For the EDL category, pharmacoeconomic analysis was reported in 20/28 (71%) evaluations, of which 17 (85%) received a positive recommendation. Univariate analyses performed for the 1B subgroup showed that NZi rejected significantly (p=0.05) influenced by clinical trials with life-saving primary endpoint (positive), non-inferior trial outcomes compared to placebo (negative) and budget impact below €2,500,000 (positive). Whereas, the univariate analyses for the EDL, clinical evaluation demonstrated that ATC-code L (antineoplastic and immunomodulating agents), clinical trials with life-saving primary endpoint and reporting of economic analysis outcomes had a significant and positive impact on the final NZi recommendation. CONCLUSIONS: These univariate analyses demonstrate that for 1B and EDL, clinical and economic factors impact the NZi reimbursement recommendations.

PHP221
COMPARISON OF INTERNATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEMS – DOES THE PERFECT SYSTEm EXIST?
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OBJECTIVES: The purpose of this study is to answer the question of whether the National Institute for Health Technology Assessment (HTA) that have been published by organizations representing the field. These components include: clear processes and decision-making, including for pragmatic approaches and appeal, transparency in methodology, value judgments and decisions; and a facility for stakeholder involvement. The objective of this study was to compare international HTA systems to rank their performance against the ideal components of HTA. Information was also collected on the level of user feedback, on the level of involvement of stakeholders, and on the transparency of the decision-making process. RESULTS: A survey was designed to collect information on the HTA systems across the United Kingdom, France, Italy, the Netherlands, Sweden, Central Eastern Europe, Canada, Australia, New Zealand (NZ), Korea and Taiwan. Questions were grouped under the topics: process, methods, data, societal input and transparency. The survey was completed by 9.0% affiliates with first-hand experience working with the HTA system in their country. RESULTS: The majority of countries consider rare diseases and low budget impact with leniency in decision making and/or process. Transparency in decision-making is lacking in many of the countries surveyed. However, consumer members sit on decision-making committees in several countries, only the UK involves a group of citizens in setting the decision making criteria applied by the committee. Combined regulatory-payment scientific advice is only available in European countries. Austria is the only country offering high diagnostic treatments for both costs and a not recommended decision, while UK and NZ have routine disinvestment reviews. CONCLUSIONS: Each country is performing reasonably well in some elements of their HTA system, but none met all the requirements of an ideal HTA system. HTA systems need to learn from the experiences in other countries when considering improvements to processes and efficiency.

PHP223
TRENDS IN EARLY ENGAGEMENT BETWEEN INDUSTRY AND HTA: ANALYSIS OF SCIENTIFIC ADVICE SERVICE PROVIDED BY NICE SINCE 2009
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OBJECTIVES: Regulatory Scientific Advice (SA) provided by EMA, FDA, MHRA and other agencies is highly demanded by manufacturers but health technology assessment (HTA) scientific advice is still far from becoming a routine step in the product development cycle. NICE has been running an advisory service for 5.5 years. METHODS: This work presents analysis of requests to the programme: types of advice projects, number and type of requests per company, clinical indication, stage of clinical development when the advice is sought, reason for seeking advice and current development and regulatory status of products. RESULTS: Between 2009 and 2014 NICE conducted 109 advisory projects (107 medicinal products and two diagnostic tests). 23 of these projects were done in parallel with regulatory agencies and/or other HTA bodies. 78% of all requests were in the following four therapeutic areas: oncology, neurology, rheumatology and cardiology. Majority of products (61%) were in phase II of clinical development. 80% of the advice projects were linked to the early stages of product development. The research question remains whether or not advice projects are linked to the early stages of product development in 5.5 years. RESULTS: The majority of countries consider rare diseases and low budget impact with leniency in decision making and/or process. Transparency in decision-making is lacking in many of the countries surveyed. However, consumer members sit on decision-making committees in several countries, only the UK involves a group of citizens in setting the decision making criteria applied by the committee. Combined regulatory-payment scientific advice is only available in European countries. Austria is the only country offering high diagnostic treatments for both costs and a not recommended decision, while UK and NZ have routine disinvestment reviews. CONCLUSIONS: Each country is performing reasonably well in some elements of their HTA system, but none met all the requirements of an ideal HTA system. HTA systems need to learn from the experiences in other countries when considering improvements to processes and efficiency.

PHP224
EXPLORING UNCERTAINTY IN ECONOMIC EVALUATION OF MEDICINES: A REVIEW OF THE FIRST MANUFACTURERS’ SUBMISSIONS TO THE FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)
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OBJECTIVES: Since October 2013, HAS is required to provide the inter-ministerial Economic Committee on Health Care Products (CEPS) with an economic evaluation on innovative medicines likely to have a significant budget impact on the national health insurance scheme. HAS economic evaluations are based on critical appraisals of cost-effectiveness analyses (CEA) submitted by manufacturers. Exploration of uncertainty around incremental cost-effectiveness ratios is critical to assess the robustness of CEA. Objectives was to assess how uncertainty in the health economic evaluations has been undertaken by manufacturers, using HAS guidelines on economic evaluation as an analytical framework. METHODS: Manufacturer economic evaluations of medicines (n=13) were reviewed. Three sources of uncertainty were considered: uncertainty around model input parameters, uncertainty around model structure and methodological uncertainty. RESULTS: Manufacturers did not report all types of uncertainty. Sensitivity analyses were not performed for all model parameters. probabilistic sensitivity analysis (PSA), as well as overall compliance with HAS guidelines. RESULTS: Model input parameters were the most frequently explored source of uncertainty. Both DSA and PSA were systematically used. However, reporting of PSA was not comprehensive, and sometimes the type of parameter was not described. CONCLUSIONS: The choice of distribution was not systematically justified and lacked consistency across similar parameters. Most submissions failed to consider parameter correlations. Exploration of uncertainty around model structure was rarely presented. Where applicable alternative approaches
lating health outcomes were reported in two-thirds of the submissions. However, worst-case scenarios were hardly presented in line with HAS guidance for exploring methodological uncertainty (e.g. perspective, discounting, time horizon) was fair. However, the choice of the comparator(s) – an essential component of a CEA – was considered problematic in nearly 40% of submissions. **CONCLUSIONS:** Overwhelming support of DSA and FSA is confirmed with HAS guidance. All stakeholders need to explore uncertainty, in particular, to account for correlations between model input parameters and to enhance the analysis of structural uncertainty.

**PHP228**

**VALUE-BASED ASSESSMENT: WILL SCOTLAND’S SMC ADOPT IT IN THE SAME WAY?**

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**BACKGROUND:** In May 2010 the UK government set out its intentions to reform the current method of pricing branded medicines and introduced a new system of value-based pricing (VBP). This was to replace the Pharmaceutical Price Regulation Scheme (PPRS), which expired in 2009. PPRS was difficult to implement, and the PPRS was renewed until end of 2018, it has been indicated that VBP will no longer relate to medicines’ pricing, but instead will be a reshaping of the Health Technology Assessment (HTA) model employed by the UK in its appraisal of new medicinal and renamed Value Based Assessment (VBA). As medical assessment is devolved in the UK, performed by NICE in England and the SMC in Scotland, we seek to understand whether the SMC will adopt the same approach to VBP as NICE. **METHODS:** The research was conducted through in-depth secondary research and interviews with stakeholders, including payers and IOs, in UK. **RESULTS:** Both NICE and the SMC have indicated they will continue to use QALY as a measurement of clinical and cost effectiveness while also incorporating issues such as burden of disease, patient outcomes and preferences in their assessment. However, their approach to conducting such assessments may differ with the SMC suggesting using a new system of patient and clinician engagement (PACE), currently in use for the appraisal of medicines for end of life or rare conditions (orphans), as a wider process to determine Scotland’s requirement for a value based approach to assess all new medicines. **CONCLUSIONS:** Manufacturers would be encouraged to closely follow the outcomes from the new PACE system, incorporated into the SMC assessment process to ensure a fair and effective evaluation of their medicines.

**PHP229**

**DISCREPANCY BETWEEN NATIONAL DRUG RECOMMENDATIONS AND LOCAL UPTAKE IN THE SWEDISH INPATIENT SECTOR**

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**OBJECTIVES:** The current study seeks to assess discrepancies between national inpatient drug recommendations issued through the cost-effectiveness pilot project (klinikkodesprojektet) in local and national level and the outcomes from the new PACE system. **RESULTS:** From 2011 on an increased number of resolutions and especially cancer drugs were conditional. Only in a few a drug was recommended in the resolution but not to be shown in the re-assessment. In these cases the recommendations concerning further evidence were not part of the G-BA voting. As currently just one drug was re-assessed, no conclusions can be drawn how re-assessment changes the extent or certainty of additional benefit.

**PHP226**

**PHYSICALLY ADDITIONAL BENEFIT IN GERMANY**

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**OBJECTIVES:** Gemeinsame Bundesauschuss (G-BA) assesses the additional benefit of G-BA determined appropriate comparator. As part of the submission, manufacturers provide annual drug cost estimates. This research tests whether manufacturers submit higher annual costs for drugs that provide greater additional benefit, that is, whether added benefit is priced. **METHODS:** The influence of G-BA’s additional benefit assessment on the manufacturer’s estimated per patient annual drug cost was estimated via ordinary least squares based on 73 reviews. The model also included controls for the (log) size of the target population and the annual cost of the comparator. These variables were collected from the Federal Gazette publication or the “Beschluss” document. **RESULTS:** Our model explains three-quarters of the variation in annual drug cost (R2 = 0.76). Some of the target population and the cost of its comparator, a drug assessed as having unquantifiable or minor added benefit is estimated to have an annual per patient cost that is 9 times greater (p = 0.01). There is evidence of a “quantity discount”: doubling the size of the target population is estimated to reduce the per-patient annual cost by 18% (p < 0.01). There could be attributed to the funding system, where local payers are responsible for funding inpatient drugs.

**PHP227**

**RISK OF BIAS IN TRIAL-BASED ECONOMIC EVALUATIONS**

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**OBJECTIVES:** The objective of our research is to give first an overview of the risks of bias in trial-based economic evaluation, and second to identify how key sources for bias can be revealed and overcome (bias-reducing strategies) in future trial-based economic evaluation in the fields of general practice and health psychology. **METHODS:** A scoping review was performed using PubMed and the NHS Economic Evaluation Database. **RESULTS:** The most assessed dimensions were Efficacy, Safety, and Costs. There was a significant association between the cost dimension and the study bias. Only 40% of the included studies had a cost dimension. **CONCLUSIONS:** Manufacturers would be encouraged to closely follow the outcomes from the new PACE system, incorporated into the SMC assessment process to ensure a fair and effective evaluation of their medicines.
shows a positive development within the region’s HTA. The Regional Decrees were introduced, however the HTA reports are not fully compliant to the scoping document and it is central to understand the reason behind the challenge.

**PHP231**

**QUALITY OF LIFE – A RARELY ACKNOWLEDGED KEY CATEGORY WITHIN THE AMNOG PROCESS IN GERMANY**

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Increasingly, quality of life becomes a more important part of the HTA assessments of new products. Assessing quality of life is trickier than changes in clinical parameters as changes of quality of life tend to occur slower and with a high level of variance. Additionally, it is sometimes necessary to assess quality of life indirectly, especially in cognitive disorders. However, the available data are often driven by the requirements for marketing authorization and rarely fit to the requests of HTA agencies. In addition, a high quality of life among mortality, morbidity and level of health-related quality of life outcomes categories in the AMNOG (Arzneimittelmarktneuordnungsgesetz). Law on the Reorganization of the Pharmaceutical Market) process in Germany. OBJECTIVES: Our focus was to review the impact of quality of life data presented by manufacturers since the introduction of the AMNOG in 2011 on the level of additional benefit claimed by the manufacturer and the evaluation by the Federal Joint Committee (G-BA) and the Institute for Quality and Efficiency in Healthcare (IQWiG).

**METHODS:** We screened the IMS HTA database and the assessments published on the G-BA website for assessments including additional benefit claims based on quality of life. We compared these with the corresponding IQWiG reports and the final decision of the G-BA (if available). RESULTS: Data on quality of life was part of 36 additional benefit claims. In most cases, IQWig (n=23) and G-BA (n=28) considered quality of life data as well. However, in six cases IQWiG and G-BA assessed quality of life, even though the manufacturer didn’t include these data. There are few nuances to note. For example, in Costa Rica, where the G-BA decision was based on quality of life. CONCLUSIONS: Even though quality of life is seen as a highly relevant factor for the HTA assessment of a new drug or technology, it is rarely taken into consideration.

**PHP232**

**UNDERSTANDING THE ROLE OF SUBGROUP ANALYSIS AND TESTS FOR HOMOGENEITY OR INTERACTION IN THE AMNOG Dossier**

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OBJECTIVES: Although subgroup analysis in clinical trials is often criticized, it is still considered an important part of the AMNOG Dossier when describing effect modification in different patient groups. An identification of effect modification in the subgroups will allow for a more tailored or weakened harm and an additional benefit of a drug. The purpose of this article is to give a detailed background with regard to the statistical inference in subgroup analysis and a brief review of the effect of tests for homogeneity/interactions on the final grading of the additional benefit, according to the decision from IQWiG.

**METHODS:** This article covers: Understanding tests for homogeneity, individual versus pooled data and influence of subgroup analysis on recent IQWiG benefit assessment. A research of the recently published AMNOG Dossiers was performed. A description was given to the number of drugs that had an additional benefit and the subgroups that were involved. Clustering analysis was performed to investigate the hidden structure in the subgroups. Regression models were used to describe the relationship of the drug and benefit levels in the presence of an additional benefit. RESULTS: Some subgroups such as age, gender and weight play a major role in the AMNOG assessment. Other subgroups are more specific for certain disease areas or contraindications. Differences in the benefits do not necessarily disappear when a certain subgroup is taken into consideration. CONCLUSIONS: Subgroups exert a profound influence upon the overall effect of a drug. Despite of the weakness of the statistical inference, subgroup analysis plays an important role in the AMNOG Dossier. Some subgroups are frequently related to the overall effect of a drug and some might even change the whole story in the AMNOG Dossier. In conclusion, subgroup analysis should be understood properly and the results should be interpreted carefully.

**PHP233**

**THE INVERSE CORRELATION BETWEEN INTERNAL AND EXTERNAL RISK UNDER INTERNATIONAL REFERENCE PRICING: AN ANALYSIS OF SIX EUROPEAN COUNTRIES**

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OBJECTIVES: To index six countries on the basis of the risk they pose to pharmaceutical prices with regards to international reference pricing (IRP), from both an internal (how IRP is used by the country) and external (how other countries use this country for IRP perspective). OBJECTIVES: To index six countries on the basis of the risk they pose to pharmaceutical prices with regards to international reference pricing (IRP), from both an internal (how IRP is used by the country) and external (how other countries use this country for IRP perspective).

**METHODS:** Details on IRP method lifetimes were obtained from primary and secondary research. Achievable drug price levels in Bulgaria, France, Germany, Portugal and Romania were derived from these markets’ perceived maximum acceptable drug price levels in their reference markets (based on existing literature). Furthermore, based on the IRP formulas and relative drug price levels of each of the markets referencing these five and the United Kingdom, the markets most likely influenced by the six were identified. The headroom method combined with the return on investment.

**Objectives:** The headroom method combined with the return on investment.

**Conclusions:** The headroom method combined with the return on investment.

**Results:** The headroom method combined with the return on investment.

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**Objective:** To understand the potential commercial viability of two disruptive and four incremental medical devices in different stages of development.

**Methods:** The headroom method combined with the return on investment.

**Results:** The headroom method combined with the return on investment.

**Conclusions:** The headroom method combined with the return on investment.

**Objectives:** The development process of medical devices strongly depends on financial resources available and the expected return on investment.

**Methods:** The headroom method combined with the return on investment.

**Results:** The headroom method combined with the return on investment.

**Conclusions:** The headroom method combined with the return on investment.

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The health care context and the Romanian legislation covering HTA were studied to consider the reasons behind HTA introduction, the key players involved in critical appraisal of HTA reports and the decisions taken by the Ministry of Health (MoH). RESULTS: The introduction of quick-HTA began mid-June 2013 when MoH released the legislative text. The HTA Unit was set up to deliver quick-HTA recommendations based on a scorecard method with 6 criteria. The HTA model was based on a "scorecard" system with 6 criteria. HAS (France) opinion, NICE/SMC/AVMSG (UK) opinion, the number of EU countries with reimbursement, relative efficacy, relative safety and relative patient-reported-outcomes (PRO), but no role for economic sustainability impact. From October 2013, 13 HTA reports were delivered by the HTA Unit with an acceptance rate of above 80%. Most of the drugs accepted for reimbursement were oncological (23%), other main therapeutic areas were diabetes (16%) and cardiovascular (15%). Independent experts receiving positive evaluations, comparisons of HTA unit (14), haematology (8) and neurology (7). The HTA included also biosimilars, all 4 of them received positive decisions. Unfortunately, early 2014, the new Government abrogated this HTA legislation and the already-published HTA reports, claiming that the process did not fulfill the criteria set at the beginning. A literature survey between 2000 and 2014 was conducted in English, Spanish and Portuguese in PubMed/Medline, Science Direct, LilACS and Scielo. Epidemiological and socio-economic data was retrieved from national health accounts as well as WHO/PAHO, OECD and World Bank. For the Brazilian National Committee for Incorporation of Technologies (CONITEC), available reports on the incorporation of medicines into the National Unified System (SUS) for the first two years of operation (2012 and 2013) were analyzed. A matrix containing quantitative and qualitative criteria was elaborated to analyze reports by the outcome of decision, therapeutic class, author(s) of the request and public consultation. RESULTS: A total of 92 available CONITEC reports for 2012 (n=38, 33 for medicines) and 2013 (n=54, 42 for medicines) were analyzed. 45% of reports on medicines recommended incorporation into the SUS. Most of the positive recommendations were clearly related to public health priorities as identified by the government, translating a strong commitment for improved access to medicines within the SUS i.e. anti-cancer drugs. Overall, the creation of the CONITEC represents a substantial step forward toward the institutionalization of HTA, with more transparency and accountability in decision-making processes, considering ethical, organizational, health and legal aspects. CONCLUSIONS: Whereas lowest in Russia, India and South Africa, and at a transitional stage in China, Brazil has a comparable degree of institutionalization of HTA as countries with a long-lasting HTA experience. In best practice assessment, the area of HTA within the BRICS has still to be elaborated. Transferability of lessons learned might be a strong tool for improving HTA development within the BRICS.

PHP243

IS G-BA STRATEGICALLY DISCOUNTING THE BENEFIT ASSESSMENT OF RELATIVELY HIGH COST DRUGS?

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PHP242

HTA IN THE BRAZILIAN HEALTHCARE SYSTEM AND POTENTIAL LESSONS LEARNED FOR OTHER BRICS STATES

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†Stuwe L, Bellanger MM, Picon PD

OBJECTIVES: The objective of the study was to provide an external assessment of recent HTA institutionalization in Brazil, and identify a set of lessons learned potentially applicable to BRICS States. METHODS: This research is based on a quantitative and qualitative assessment. A literature survey between 2000 and 2014 was conducted in English, Spanish and Portuguese in PubMed/Medline, Science Direct, LilACS and Scielo. Epidemiological and socio-economic data was retrieved from national health accounts as well as WHO/PAHO, OECD and World Bank. For the Brazilian National Committee for Incorporation of Technologies (CONITEC), available reports on the incorporation of medicines into the National Unified System (SUS) for the first two years of operation (2012 and 2013) were analyzed. A matrix containing quantitative and qualitative criteria was elaborated to analyze reports by the outcome of decision, therapeutic class, author(s) of the request and public consultation. RESULTS: A total of 92 available CONITEC reports for 2012 (n=38, 33 for medicines) and 2013 (n=54, 42 for medicines) were analyzed. 45% of reports on medicines recommended incorporation into the SUS. Most of the positive recommendations were clearly related to public health priorities as identified by the government, translating a strong commitment for improved access to medicines within the SUS i.e. anti-cancer drugs. Overall, the creation of the CONITEC represents a substantial step forward toward the institutionalization of HTA, with more transparency and accountability in decision-making processes, considering ethical, organizational, health and legal aspects. CONCLUSIONS: Whereas lowest in Russia, India and South Africa, and at a transitional stage in China, Brazil has a comparable degree of institutionalization of HTA as countries with a long-lasting HTA experience. In best practice assessment, the area of HTA within the BRICS has still to be elaborated. Transferability of lessons learned might be a strong tool for improving HTA development within the BRICS.

PHP240

AN UPDATE ON CLINICAL AND EVIDENCE REQUIREMENTS FOR ADDITIONAL THERAPEUTICAL PRODUCTS IN EUROPE

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OBJECTIVES: Advanced-therapy medicinal products (ATMPs), such as gene therapy, cell therapy and tissue engineering are a class of medicines in the biotechnology sector, which offer prospects in prevention and treatment of fatal and/or chronic debilitating diseases where no effective treatments exist. However, with complicated mechanisms of actions and benefits often being anticipated in the longer term, it is challenging to demonstrate hard clinical evidence and create robust cost-effectiveness models that Payers have come to expect at the launch of pharmaceuticals. Thus, across EUS, Payers are yet to be convinced about the ATMPs and may not be able to realize their full potential. This paper aims to use case studies of ATMPs launched in EUS to outline access pathways and review the clinical and economic evidence requirements. METHODS: Secondary research identified ATMP approv- als in EUS and a framework was created to develop hypotheses on clinical and economic evidence requirements, considering alternative routes to market. Hypotheses were then validated during in-depth interviews with key stakeholders across EUS. RESULTS: Payers are yet to be convinced about the ATMPs and are reluctant to pay premium prices if they are not sure about long-term efficacy and safety. Additionally, in their cost-benefit analyses, Payers tend to consider only the direct costs associated with a condition, ignoring broader societal benefits and long-term effects in the long run. Therefore, price negotiations are sometimes lengthy. Risk sharing and novel payment-by-result schemes are often agreed to mitigate these risks. CONCLUSIONS: Payers are not yet familiar with the potential value of ATMPs, and require the same principles and criteria as non-atypical medicines. One way of investing in educating Payers on the huge differences between ATMPs and traditional therapies, particularly to show that manufacturing costs are substantial, and work together to identify relevant measures for clinical and economic evaluations of this new therapy class.

PHP237

TEN YEARS OF DEVELOPMENT STUDIES IN HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL: PROFILE OF STUDIES AND OPERATIONAL INDICATORS

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BACKGROUND: The Department of Science and Technology (DECT) at the Ministry of Health (MoH), since 2003, has financed studies to support demands from the MoH technical areas regarding the decision making process about health technologies. OBJECTIVES: To analyze DECT performance in financed Health Technology Assessment (HTA) studies to improve the capacity building of HTA in Brazil. METHODS: A retrospective descriptive study based on the analysis of documents and official records built in a single database in Excel containing the studies promoted from 2003 to November 27, 2013. The variables pre-classified and linked to the term’s usage. During analysis, a system of codes was built by two researchers, relevant text passages were extracted and linked to QoL and synonyms. In a process of independent analysis and joint consensus building by two researchers, relevant links to QoL and synonyms. In a process of independent analysis and joint dossiers, IQWiG evaluations, G-BA decisions and the protocols of the oral hearing for assessment (11.2011-12.2013). We conducted a qualitative content analysis screening the HTA landfield. A preliminary screening of documents with a variety of studies types, specialty in pharmacotherapy. However, evaluation demands do not always correspond to health needs of promotion and prevention.

PHP238

THE DEFINITION AND ROLE OF QUALITY OF LIFE IN GERMANY’S EARLY ASSESSMENT OF DRUG BENEFIT

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OBJECTIVES: Since January 2011, pharmaceutical manufacturers are obliged to submit detailed prospective economic benefit assessments (EBA) to the MoH for new products in the German pharmaceutical market. These EBA are usually evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the definitions given in their site and a subsequent EBA study of the IQWiG-Guidelines Development Board (G-BA) in 2012, IQWiG decides on additional therapeutic benefit related to mortality, morbidity, quality of life (QoL) and side effects. As QoL is among the more contested of these criteria and remains comparably unspecified, this qualitative study’s aim was to analyze definitions and the role of QoL in early assessments of benefit (EBA) in Germany. METHODS: As most of the documents are freely available on the G-BA website, this study included all relevant documents of the first completed 66 assessments (11.2011-12.2013). We conducted a qualitative content analysis screening the dossiers, IQWiG evaluations, G-BA decisions and the protocols of the oral hearing for relevant links to QoL and synonyms. In a process of independent analysis and joint consensus building by two researchers, relevant text passages were extracted and reduced to key content on the term’s usage. During analysis, a system of codes was developed accounting for a wide variety of recurring QoL-related definitions and references and its importance. RESULTS: Even though key players did not necessarily share the same QoL-definition, the concept’s relative importance was highlighted in numerous references. G-BA decisions criticize the lack of or the inadequate presentation of QoL data in the manufacturer’s dossiers. G-BA and IQWiG apply a narrow understanding of QoL, while manufacturers failed to establish basic assumptions of QoL linking factors such as patient satisfaction to the concept. CONCLUSIONS: QoL, in a particular sense is of pivotal importance in Germany’s early assessment of benefit. The demand for relevant QoL data is growing.
OBJECTIVES: Gemeinsame Bundesausschuss (G-BA) states that it assesses additional costs of comparator, and clinical grounds, but it also requires that manufacturers submit drug and comparator costs. This raises the possibility that G-BA assessment might be influenced by price, possibly to provide leverage during subsequent price negotiations. This research tests the hypothesis that high cost drugs (relative to the comparator) are more likely to receive reimbursement through the health technology assessment (HTA) process. The following variables were collected from the Federal Gazette publication or the “Beschluss” document: additional benefit assessment, annual cost per patient of drug, and the comparator. This analysis was conducted to test the hypothesis that G-BA reimbursement might be influenced by price.

RESULTS: In this analysis, the variable most strongly correlated with G-BA reimbursement was the cost differential relative to the comparator. A one-percentage-point increase in the drug-to-comparator cost differential was associated with a 0.19 percentage-point increase in the likelihood of reimbursement. The influence of drug cost relative to the comparator on the likelihood of reimbursement was also found to be statistically significant. These findings suggest that G-BA reimbursement decisions are influenced by price, possibly to provide leverage during subsequent price negotiations. This raises ethical concerns about the potential for price to influence the assessment of health technologies.

PHP246
DEVELOPMENT OF HTA IN TURKEY

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OBJECTIVES: The aim of this study was to assess the development of HTA in Turkey, with a particular focus on HTA regarding obesity surgery in the treatment of obesity. In addition to all these three issues like obesity, KOAH etc., instead of certain health technologies and publishes the General Directorate of Pharmaceuticals and Medical Devices. This committee is under the payer institution called SSI. The HTA committee was established in 1998, and it has the responsibility of HTA. The most important of these is the HTA committee in Turkey.

METHODS: The applicants must submit valid data on the potential of the method in question to assess the applicability of end-of-life treatment criteria and the likelihood of NICE guidance. The new legislation will require a PAS in the UK is not restricted to end-of-life treatment criteria (most of which are for oncology indications), as expected, many of them are subject to a PAS in the UK. However, the opposite correlation does not hold true - i.e., the requirement for a PAS in the UK is not restricted to end-of-life treatments.

PHP244
DISEASE BURDEN IN BRAZIL AND HEALTH TECHNOLOGY ASSESSMENT: A RETROSPECTIVE OF TEN YEARS OF SUPPORTING

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BACKGROUND: Defining health technology assessment priorities has been a challenge for the Department of Science and Technology who adopted a prioritization criteria strategy (epidemiologic relevance, services/policy relevance, state of the art, operational feasibility and social demand) for demands from MoH technical areas. However, evaluation demands do not always correspond to health needs. OBJECTIVES: To analyze the relationship between projects financed from 2003 to 2013 and disease burdens in Brazil. METHODS: Systematization of the summaries from financed projects through searches in the information from www.saude.gov.br/rebates and http://presaissaudae.saude.gov.br/bdgc/ and categorization according to the twenty sub-groups of diseases and injuries of disease burden (Dalys) research in Brazil (SHARMM ET AL, 1998). RESULTS: 284 HTA projects financed between 2003 and 2013. Of these, 24% (68/284) apply to the twenty main causes of loss of life years according to the DALY. A positive correlation was found between the number of HTA projects financed and the Burden of Disease. The three main HTA criteria (most of which are for oncology indications), as expected, many of them are subject to a PAS in the UK. However, the opposite correlation does not hold true - i.e., the requirement for a PAS in the UK is not restricted to end-of-life treatments.

PHP248
THE COSTS AND EFFECTS OF POST-AUTHORISATION SAFETY STUDIES FOR NEW ACTIVE SUBSTANCES

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OBJECTIVES: At market entry, there is usually uncertainty regarding a new medicine’s benefit-risk profile. Therefore, regulatory authorities may request additional postmarketing (PM) studies. Regulatory Authorities can request a Post-Authorisation Safety Study (PASS) such as a registry, database study, survey, or clinical trial to reduce the uncertainty regarding certain safety risks. We aimed to assess the costs and effects of PASS for centrally approved new active substances (NAS) in Europe in 2007. METHODS: We compared two scenarios for all NAS (n=47): (1) Full regulation: routine PhV activities (spontaneous adverse drug reaction (ADR) reporting) with additional PASSs for some NAS, (2) Limited regulation: only routine PhV activities. For a follow-up period of six years after marketing we assessed the safety-related labeling changes for NAS and identified the source of these changes (PASS, spontaneous ADR reporting or other). Data on labeling changes was extracted from the Development Medicine Database, which contains information on medical drugs to evaluate the potential of new examination and treatment methods as essential treatment alternatives. In most cases this is not possible and will decrease the level of evidence of available clinical data for new examination and treatment methods due to grey zones and loopholes in the legislation.

PHP247
CORRELATION BETWEEN END-OF-LIFE STATUS OF A TREATMENT AND LIKELIHOOD OF A PATIENT ACCESS SCHEME IN THE SETTING OF A NICE REVIEW IN THE UK

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OBJECTIVES: This study aims to assess the existence of a correlation between the applicability of end-of-life treatment criteria and the likelihood of NICE requiring a Patient Access Scheme (PAS) to recommend the treatment for funding. METHODS: A review of all patient access schemes in existence as of May 2016 and the NICE guidance and PASS, spontaneous ADR activities. Our results indicate that there is a correlation between end-of-life treatment criteria and the likelihood of NICE requiring a PAS. This analysis was made for different criteria’s like study and endpoint design, certainty of results of the studies and others. We used our business case as template to extract the key-learning’s and identify the pitfalls in the new process. RESULTS: The new legislation will have a strong impact on the study design and evidence to show the potential of new examination and treatment methods as essential treatment alternatives. A lot of evaluation criteria’s came from the drug assessments but are not sufficient to provide the potential of new examination and treatment methods.
Failure pathologies concerning a large number of patients with important average health research interest to link their data to other data sources were more likely to have previously extracted for the 3 iHPIs, avoiding multi-collinearity, generated regions with different country composition. Both Malta and Georgia became isolated; Finland and Portugal shifted from their respect for the impact of health care policies across regions and countries. After extracting 8 correlated HPIs linked to direct health care policies from a published set of HPIs, factor analysis allowed us to convert these into 3 independent components, which were subject to further multivariate analyses to identify potential additional factors.

**PHP252**

**IMPACT OF ECONOMIC CRISIS ON THE GREEK HEALTH CARE SYSTEM AND ON THE POPULATION HEALTH**

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Laoulidou I.1

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Open University of Cyprus, Latsia, Nicosia, Cyprus, Hippokration Hospital of Athens, Athens, Greece.

OBJECTIVES: The aim of the paper is to map the impact of economic crisis on the Greek health care system and on the population health. METHODS: A systematic literature review was conducted in databases PubMed, Embase and Scopus for the years 2008-2013, focusing mainly to the impact of the economic crisis in Latin America, Eastern Europe and Eastern Asia. In order to assess the impact of crisis in Greece, Hellenic Statistical Authority (EL. STAT), Hellenic Center for Disease Control and Prevention (EL. CDC), OECD, Eurostat and World Bank database were used. RESULTS: Greece entered a deep economic crisis in 2009 and in only four years lost more than 25% of its GDP. Unemployment rate exceeded 27% of the population. 18% of uninsured population reached 2 million according to the Ministry of Labour (2014) whereas the rate of population at risk of poverty or social exclusion has increased from 27.6% in 2009 to 34.6% in 2012. Total current spending fell by 5.4 billion Euro. The health expenditure fell by a greater proportion, 25.2% or 44 billion from 2009 to 2012. At the same time the use of public services (e.g. hospital admissions) and waiting times increased. Regarding the health outcomes, an increase in the incidence of HIV/AIDS per million population, 1.3% by reducing expenditure. However, health-promoting policies providing equitable access, especially regarding the vulnerable groups, and infectious diseases prevention should be considered as a more cost-effective alternative.

**PHP253**

**ESTIMATION OF STRESS RESISTANCE OF MEDICAL STUDENTS IN LVIV**

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OBJECTIVES: High demands for speed and amount of students’ trainings in health care education one of the stress causes. Presence of stress can negatively affect the state of progress and level of physical health of medical students. METHODS: Testing of 275 students III-IV years of studying at medical faculty (145 girls, 130 boys) registered. Formation of skills for stress resistance by implementation of health-saving technologies in student lifestyle is necessary. RESULTS: The 7 European regions differed significantly for 7 of the 8 initial HPIs ‘incidence’. The 7 iHPIs loaded respectively on ‘mortality’, ‘prevention’ and ‘AIDS incidence’. The 7 European regions differed significantly for 7 of the 8 initial HPIs and for each of the 3 iHPIs (p always < 0.02). Cluster analyses based on the 3 iHPIs, avoiding multi-collinearity, generated regions with different country composition. Both Malta and Georgia became isolated; Finland and Portugal shifted from their respective regions. CONCLUSIONS: The impact of health care policies across regions and countries. After extracting 8 correlated HPIs linked to direct health care policies from a published set of HPIs, factor analysis allowed us to convert these into 3 independent components, which were subject to further multivariate analyses to identify additional factors and insights.
allergic rhinitis, cow’s milk allergy, eczema and obesity). RESULTS: Of 100 studied children 64% were breastfed (BF), while 36% had artificial nutrition (AN), xBF = 0.48, xAN = 0.52. Gastroenteritis xBF = 0.42 diseases/child/6 months, D/CH/L, xAN = 1.64 D/CH/L, xBF = 0.84 D/CH/L, xAN = 0.64 D/CH/L, xBF = 0.79 D/CH/L, xAN = 0.20 D/CH/L. Laryngitis: xBF = 3.73 D/CH/L, xAN = 4.86 D/CH/L, xBF = 0.83 D/CH/L, xAN = 0.03 D/CH/L. Pneumonia: xBF = 0.11 D/CH/L, xAN = 0.31 D/CH/L, xBF = 0.00 D/CH/L, xAN = 0.00 D/CH/L. Allergic rhinitis: xBF = 0.16 D/CH/L, xAN = 0.21 D/CH/L, xBF = 0.19 D/CH/L, xAN = 0.00 D/CH/L. Cow’s milk allergy: xBF = 0.11 D/CH/L, xAN = 0.17 D/CH/L, xBF = 0.00 D/CH/L, xAN = 0.16 D/CH/L, xBF = 0.00 D/CH/L. Eczema: xBF = 0.01 D/CH/L, xAN = 0.02 D/CH/L, xBF = 0.01 D/CH/L, xAN = 0.00 D/CH/L. Obesity: xBF = 0.03 D/CH/L, xAN = 0.17 D/CH/L, xBF = 0.05 D/CH/L, xAN = 0.00 D/CH/L. CONCLUSIONS: Results of the analysis indicated that breastfed children showed less frequent incidence of all the studied diseases compared to children who had artificial nutrition. Breastfeeding and even more the method of breastfeeds are important in the child’s health, lower the occurrence of the diseases, frequency of medication use and overall total expenditure on health care.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP255 EVALUATION OF MEDICATION PRESCRIPTION PATTERN USING WORLD HEALTH ORGANIZATION PRESCRIBING INDICATORS IN IRELAND: A CROSS-SECTIONAL STUDY

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OBJECTIVES: To quantify the specialists’ prescription pattern in Iran. MATERIALS AND METHODS: A retrospective cross-sectional study was carried out on the claim data of 870,158 patients received antibiotics, 41% of patients received injectable forms of drugs, and antibiotics. Concomitant use of antibiotics and an injectable form of medicines was observed among general practitioners, 100 patients within a specified period. Prescribed drugs and diagnoses were then conducted (March–June 2011). Two geographical areas (rural and semirural) in Crete were considered and the World Health Organization prescribing indicators were applied to identify and score the variability related to main uncertainties involved: (1) efficacy/effectiveness uncertainty; (2) budget uncertainty; (3) budget impact; and (4) incremental cost-effectiveness ratio (ICER) and willingness to pay. Final score gives the best type of agreement to be selected accordingly. RESULTS: The results in this study were similar to published guidelines in Spain. METHODS: This guidance was designed with the main aim of identifying uncertainties, helping select the pharmaceuticals most eligible to be included in an agreement (PSA) / per prescription scheme (PRS) to be implemented between the Catalan Health System (CatSalut) and health care providers/pharmaceutical companies in Catalonia. RESULTS: For a given agreement, it identifies and quantifies the cost differentials. Four variables related to main uncertainties involved: (1) efficacy/effectiveness uncertainty; (2) budget uncertainty; (3) budget impact; and (4) incremental cost-effectiveness ratio (ICER) and willingness to pay. Final score gives the best type of agreement to be selected accordingly. CONCLUSIONS: The steps outlined in this first guidance in Spain, although not compulsory, will provide useful practical tips for how to go about designing and reporting of an EA or a BIA for pharmaceuticals in Catalonia (Spain).
PROVIDER UNDER THE NEW HEALTH CARE LEGISLATION AND PRICE POLICY

10 YEARS EVALUATION OF COSTS AND REVENUES OF HEALTH CARE SERVICES PROVIDER UNDER THE NEW HEALTH CARE LEGISLATION AND PRICE POLICY

Malovecká I.1, Minaříková D.1, Folan V.1

BCMA system was compared. We also collected the numbers of phone calls for tracking purposes from Oct 3rd to Nov 15th in 2012. The implementation of the BCMA system, the medication error rate was significantly reduced from 0.18% to 0.12% (p < 0.05). Pharmacists agreed that the BCMA system provides assistance in tracking prescriptions (90%), identifying medications (60%), and resolving medication errors (53%). However, they did not believe that the system has increased their routine workload (57%). Nurses agreed that the BCMA system can improve patient identification (73%), administration of right medication (57%), and access to correct prescription/medication information (42%). Both pharmacists and nurses were dissatisfied with the stability of the system (53%, 69%) and poor barcode sensitivity (47%, 64%). From Oct 2nd to Nov 15th in 2012, we received 469 phone calls. The average of one phone call for a drug is 1.5 times every hour. CONCLUSIONS: BCMA system significantly decreases medication error rate in the hospital. It is recognized to be able to improve medication safety by both pharmacists and nurses. Improving the quality of associated computer equipment is the next important step.

HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector

PHP261

PHARMACO ECONOMICAL EVALUATION FOR REIMBURSEMENT PURPOSES IN BULGARIA: RECENT UPDATES

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OBJECTIVES: Our study evaluates the preferred methods which the pharmacoeconomical evaluations submitted for reimbursement purposes in Bulgaria are using.

METHODS: This is a retrospective, descriptive study. We have reviewed all applications submitted to National Council on Pricing and Reimbursement in 2013 on which positive opinion was issued. Quantitatively and qualitatively described findings were converted to model frameworks of the submitted pharmacoeconomical evaluations. RESULTS: 22 new INNs were submitted and approved for reimbursement during the studied period (average time for approval: 194.55 days). Only 18.18% (n=4) were orphan drugs. The most common types of methods used in pharmacoeconomic evaluations were cost-effectiveness analysis (n=10), followed by cost-minimization analysis (n=4). Only one cost-utility analysis was provided. In all other cases only budget impact analyses (BIA) was submitted that correspond with national regulatory requirements. Only one analysis included hospitalization costs calculation. The chosen perspective was the payer’s perspective for all analyses. The time horizon varies between 10 days and 5 years. 68.18% (n=15) of the pharmacoeconomic evaluations were adjusted to 1 year calculations. 72.73% of the INNs were approved for 100% reimbursement rate, 3 INNs – for 75% and 75% for 50% reimbursement rate. 45.45% of the submitted evaluations contained local epidemiological data. Only one analysis did not include the relevant comparator and only two hans’t been discussed any additional benefits of the treatment. Pharmacoeconomic evaluations of new medicinal products was only inadequately validated by incorrect type of pharmacoeconomic analysis chosen, lack of Bulgarian epidemiological data, costs and effects were not correctly analyzed which led to prolongation of the time horizon from 10 days to 5 years. CONCLUSIONS: More detailed guidelines are obvious in the light of increasing importance of pharmacoeconomic evaluations for reimbursement purposes.

PHP263

THE EFFECT OF PROCUREMENT DESIGN ON ENTRY AND SUCCESS OF GENERIC DRUG Firms

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OBJECTIVES: Competitive tendering of active ingredient-specific contracts for generic drugs has emerged in Germany due to regulatory changes in 2009. The central goal of these changes is to accomplish that small and medium sized firms have better chances to succeed. Another goal is more participation of manufacturers, including outright market entry. We study how different designs of the competitive tendering affect participation and the outcome of generic drug manufacturers.

METHODS: We use a newly collected data set on almost all of the around 4000 public competitive awardings of procurement contracts by purchase groups in Germany from the first one in 2008 to the end of 2012. An important source of cross-sectional variation is caused by the nine purchasing groups, which differ in the number of possible contracting firms and whether a drug is of a specific active pharmaceutical ingredient is auctioned in one or different lots. We use OLS regressions with fixed effects for unobserved active pharmaceutical ingredient (API) market characteristics, as well as count data and discrete choice models. RESULTS: Our econometric analysis reveals that there are more bidders in tenders where contracts with more than one supplier are possible, when the drugs for one API are auctioned in a single lot and when the lot size is smaller. We find that the design of awarding procedures influences participation in tenders and, furthermore, the chance of new suppliers to win the contract. This is relevant for both purchasing groups and policy makers as low bids and thus drug expenses of the statutory health insurance can only be achieved with a competitive industry structure.

PHP264

10 YEARS EVALUATION OF COSTS AND REVENUES OF HEALTH CARE SERVICES PROVIDER UNDER THE NEW HEALTH CARE LEGISLATION AND PRICE POLICY

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OBJECTIVES: The economical crisis and the requirements for structural changes in all aspects of public health brought a new era of reforms in the country as well as the health care system itself. The Pharmaceutical Legislation, both European and national, was supposed to be more purposeful and effective. The introduction of new legislation influenced provider of health care services in different areas. Therefore it is important to evaluate the impact and performance on costs and revenues of health care seen. METHODS: We considered a monitoring of the indicator of the implementation of new legislation and assessment of costs and revenues with the help of financial analysis indicators for years 2003-2012, using financial statements was conducted, with respect to profitability, debt, liquidity, working capital and efficiency ratios. These ratios constituted significant information of implementing new health care legislation and price policies. RESULTS: In case of profitability, parameter gross profit ranged from $-15.000 to $1.500,000 (x mean=-19.2, X(min)=-19.8, e=-0.4), but in 2012 decreased on $23.000. Net profit ranged X(mean)=1.18% (X(min)=-16.6, X(max)=-16.6, e=0.45%), while in 2012 reached only 7%. Debt parameters varied from x 2003-2012, 2 33.4-48 % (X(min)=3.44, X(max)=3.06, e=0.82), liquidity parameters current ratio x 2003-2012, 4 1-1.7 (X(mean)=1.43, X(min)=1.45, e=0.15) and quick ratio x 2003-2012, 4 1-1.3 (X(mean)=0.49, X(min)=0.19, e=0.15), working capital x 2003-2012, 4 1.1-1.7 (X(mean)=1.1, e=3.1) and efficiency ratios were measured either. CONCLUSIONS: Implementation of new health care legislation and price policy that were intended to increase system efficiency and cost savings had a significant impact on health care services providers by worsening profitability and liquidity parameters as key indicators of provider stability. Despite the improvement of profitability ratio, working capital and efficiency ratios, stability may be threatened and may affect the amount of health care services providers.
Children and other (N = 28) of the identified CED schemes, study outcomes and funding decisions were reported. In 74% (N = 17) of reported cases, the technology evaluated was successfully funded. One technology (lung volume reduction surgery) was considered a major breakthrough, and one technology, was decided to be on hold. On many accounts CED has proven challenging to implement. CONCLUSIONS: Although a large number of CED activities were identified, detailed information especially on study outcomes and final reimbursement decision, only limited information of final decisions was publicly available. CED is a promising mechanism to reduce uncertainty and aid timely patient access, but with emerging implementation challenges.

**PHP257**

**COVERING WITH EVIDENCE DEVELOPMENT ACTIVITIES AROUND THE WORLD: AN ENVIRONMENT SCAN**

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**OBJECTIVES:** To analyze the risk-sharing agreements that are currently being negotiated in Europe between health care authorities and pharmaceutical makers to enable them to make evidence-based decisions on immunisation. The study identified multiple problems in risk-sharing agreements such as insufficient terminology and methodology, the absence of adequate infrastructure for implementation and a lack of trust and dialogue between the establishing parties: health care authorities and pharmaceutical industry. These issues question the crucial concept of sharing the risks equally and disgrace the agreements, even though it would be of great value to overcome current challenges. Such agreements could help the health care authorities to keep within their budget while still providing innovative pharmaceutical treatments to the patients. Currently, there is no consistent guidance within the pharmaceutical industry and stakeholders need to be aware of these issues to achieve a better agreement. This study examined the possible changes to cost-effectiveness models that manufacturers may need to consider when assessing new vaccines.

**RESULTS:** The assessment revealed that there is a high variability in the degree of NITAG Alignment between countries and regions. There are currently being negotiated on the importance of the WHO-recommended and additional vaccines in their vaccination programmes. The governments and health care authorities need to employ the WHO's indicators as the country's national immunization programme indicators. The final recommendation should be based on the ICERs, the ICERs must be re-analyzed if the cost per QALY exceeded £50 000/QALY. The assessment revealed that there is a high variability in the degree of NITAG Alignment between countries which could not be explained by differences in GDP per capita, health expenditure per capita, or geographic location. Countries with a reasonably well-aligned NITAG have a higher proportion of the WHO-recommended and additional vaccines in their national immunisation programmes. This study examined the possible changes to cost-effectiveness models that manufacturers may need to consider when assessing new vaccines.

**PHP271**

**RISK-SHARING SCHEMES IN POLAND - ANALYSIS AND CLASSIFICATION OF RSS PROPOSED IN REIMBURSEMENT APPLICATIONS RECEIVED BY AHTAPol IN 2013**

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**OBJECTIVES:** To analyze and classify the Risk-Sharing Schemes (RSSs) proposed in reimbursement applications received by Agency for Health Technology Assessment in Poland (AHTAPol) in 2013. METHODS: Risk-Sharing Schemes proposed in reimbursement applications received by AHTAPol in 2013 were quantitatively and qualitatively analyzed. The classification of the RSSs was conducted based on both the manufacturer's approach and the Polish Act on the reimbursement of medicinal products. RSSs included drug reimbursement schemes, special purpose dietary supplements or medical devices were received by AHTAPol. Among them, there were 52 RSSs for 51, medical technologies. They were classified into 5 categories according to the Act on the reimbursement. The most common objective was to achieve cost-effectiveness 

- Table:**

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**DISCUSSION:** The analysis and classification of the Risk-Sharing Schemes (RSSs) proposed in reimbursement applications received by Agency for Health Technology Assessment in Poland (AHTAPol) in 2013 were quantitatively and qualitatively analyzed. The classification of the RSSs was conducted based on both the manufacturer's approach and the Polish Act on the reimbursement of medicinal products. RSSs included drug reimbursement schemes, special purpose dietary supplements or medical devices were received by AHTAPol. Among them, there were 52 RSSs for 51, medical technologies. They were classified into 5 categories according to the Act on the reimbursement. The most common objectives were to achieve cost-effectiveness, equivalence, and to improve the affordability of the included medicinal technologies.

**HEALTH CARE USE & POLICY STUDIES – Conceptual Papers**

**PHP272**

**WHATEVER HAPPENED TO NICE VALUE-BASED PRICING? WELCOME, VALUE-BASED ASSESSMENT**

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**OBJECTIVES:** To evaluate the current state of the UK’s NICE value-based pricing framework. To assess what has happened to the methodological groundwork laid down by NICE and how the approach might be adapted to other countries. The aims of this paper are to: (1) to review the NICE value-based assessment framework and policy context; (2) to identify the key elements of NICE value-based pricing; (3) to assess the impact of NICE value-based pricing on the pharmaceutical industry; (4) to evaluate the potential benefits and limitations of NICE value-based pricing; and (5) to consider the implications of NICE value-based pricing for international pharmaceutical pricing agreements.

**RESULTS:** This paper provides a critical review of NICE’s value-based pricing framework and its implementation in the UK. The framework has been evolving over recent years, and it has been influenced by the international landscape. The impact of NICE value-based pricing on the pharmaceutical industry has been significant, with many pharmaceutical companies adapting their pricing strategies to align with the framework. The potential benefits of NICE value-based pricing include increased transparency, improved access to new technologies, and increased patient safety. However, the limitations of the framework include the complexity of the methodology, the potential for international differences in pricing, and the need for further research to support the framework.

**PHP273**

**NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUPS - A FRAMEWORK FOR ASSESSMENT AND INSIGHTS FROM RESEARCH**

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**OBJECTIVES:** A National immunization Technical Advisory Group (NITAG) is a body of national experts that empowers and provides guidance to national health policy makers to enable them to make evidence-based decisions on immunisation. The aim of this study was 1) To develop a framework for the assessment of NITAGs that will aid the public and open-source practice, 2) to develop a framework for the assessment of NITAGs for use in the open-source practice, 3) to develop a framework for the assessment of NITAGs for the open-source practice. The study identified multiple problems in NITAGs such as insufficient terminology and methodology, the absence of adequate infrastructure for implementation and a lack of trust and dialogue between the establishing parties: health care authorities and pharmaceutical industry. These issues question the crucial concept of sharing the risks equally and disgrace the agreements, even though it would be of great value to overcome current challenges. Such agreements could help the health care authorities to keep within their budget while still providing innovative pharmaceutical treatments to the patients. Currently, there is no consistent guidance within the pharmaceutical industry and stakeholders need to be aware of these issues to achieve a better agreement. This study examined the possible changes to cost-effectiveness models that manufacturers may need to consider when assessing new vaccines.
national immunization programme. Some lower and middle income countries with facultative immunization programmes for recently established NITAGs have basic immunization programmes. This study also found that NITAGs are usually developed following a stepwise maturing process. CONCLUSIONS: Our detailed analysis of data from 35 countries suggests that, with the right support, all countries – regardless of their GDP/capita – can adopt expert and geographical geopolitical factors to achieve high performing NITAGs that are well-aligned with international recommendations. Well-aligned NITAGs are generally instrumental for having strong immunization programmes. Through awareness of its position in this maturation process, a NITAG can focus on the appropriate next step for development and strengthening.

PHP274
DISCONTINUITIES BETWEEN HEALTH TECHNOLOGY ASSESSMENT (HTA) AND HEALTH CARE SERVICE OBJECTIVES OF THE NHS

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OBJECTIVE: To identify the cost-effectiveness threshold for orphan designations, that would be different (higher) than the generally accepted cost-effectiveness threshold (due to high price of orphan drugs to provide value for money is unlikely), is particularly important from the point of view, because of substantial therapeutic meaning of these drugs and/or absence of other treatment options of proven benefit for the disease.

PHP275
THE ECONOMIC VALUE OF VACCINATION: WHY PREVENTION IS WEALTH

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CONCLUSION: Prevention is a major driver of economic growth. The European economic crisis has resulted in health care budget cuts conferring consequences for health systems. Preventative programmes, and particularly vaccination, are most vulnerable to short-term cuts because the effects are not always immediately identifiable. Despite public health benefits are recognised, only a minor fraction of the health care budget is allocated to vaccination. It has been suggested that cost-effectiveness analyses, as part of cost-effectiveness or cost-benefit appraisals, may render a too narrow perspective of the overall economic benefits of vaccination. OBJECTIVES: The aim of this project is to demonstrate that, in addition to contributing to health care system sustainability, vaccines have importance for wider health and social policy. The study aimed to demonstrate: 1) to demonstrate the full economic value of vaccination with real life examples; 2) to inform policy-makers on how immunisation contributes to health care systems sustainability and efficiency; 3) to launch a call for action for the consideration of the full economic value of vaccination. DISCUSSION: Immunisation programmes require adequate value recognition to ensure quick population acceptance and wide accessibility. Policy-makers should acknowledge that prevention through vaccination involves long-term and often intangible effects. In five-year-olds, affordable and effective vaccination programmes can be significantly reduced by health care costs associated with managing patients for longer. This study highlights discontinuities between HTA for treatments that extend patients’ lives and the NHS’s objective to improve patients’ survival rates. METHODS AND RESULTS: Economic comparison of two treatments with an equivalent QALY gain, one that extends life while the other enhances the quality of life, indicates that to achieve a common cost per QALY outcome the life-extending treatment must be valued lower than the life-enhancing therapy. This anomaly arises primarily because the value assessment for life-extending treatments includes NHS costs of patient management during their extended life in addition to the new treatment costs. For long-term chronic conditions these additional costs may be easily offset; however, for severe, debilitating, or terminal diseases the impact can be significant. Furthermore, for new treatments added in combination to standard care, the greater the cost of existing care the lower the value that may be placed on the new life-extending treatment, to the point that new therapies may be deemed uneconomical even if available at no cost to the NHS. These findings challenge the equitable use of ICERs for HTA including the accounting for health services and the context of the extended lifetimes of a patient act decision with a new treatment. CONCLUSION: Value-based metrics used to appraise new treatments can inadvertently discriminate against life-extending therapies. Use of the ICER as HTA can result in inconsistency with health service objectives e.g. the UK Government’s goal to improve 1-year and 5-year survival rates for cancer patients.

PHP277
THE COST-EFFECTIVENESS THRESHOLD FOR ORPHAN DESIGNATIONS IN POLAND BASED ON REIMBURSEMENT DECISIONS

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The aim of this study was to identify the cost-effectiveness threshold for an orphan designation in Poland. According to criteria introducted by the European Medicines Agency (EMA) a medical treatment must meet strict criteria to qualify for orphan designation, such as: treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; disease prevalence level in the European Union (EU) of no more than 5 cases in 10,000 patients is necessary, no satisfactory method of disease diagnosis, prevention, treatment or if such method exists, the drug must deliver significant benefits to patients. In Poland, orphan drugs undergo full pharmacoeconomic evaluation and coverage decision process similar to any other innovative medicines. One of the important element of reimbursement recommen-
and governmental authorities, case studies and the latest publications in value-based assessment (VBA) way to determine the current perception of RWD, and to identify the advantages and challenges of using RWD to support market access and reimbursement. Only 10 guidelines were found from 73 European HTA agencies or governmental authorities which cited RWD as a source for evidence. NICE acknowledged the need for generalising RCT results to clinical practice, and supports the capture and analysis of observational data. In addition, recent developments in VBA anticipate a greater scrutiny of attempts to model natural history in economic evaluations. RWD is increasingly addressed by using longitudinal observational data. Case studies have shown economic evaluations based on RCT data may lack external validity, and may consequently produce inaccurate estimates of economic endpoints. There is a consensus that RWD are valuable in providing clinical practice evidence on treatment pathways, resource use, long-term natural history and true effectiveness. However, there are methodological challenges (such as lack of randomisation) to be addressed before RWD are widely accepted as a complement to RCTs to support decision-making. RWD is increasingly recognised as a valuable source of evidence for market access and reimbursement, and as a complement to clinical trial evidence. Nevertheless, there are challenges that need to be addressed to ensure real-world data provide valid evidence to the decision process.

PHP281
REIMBURSEMENT HURDLES FOR HIGH-COST BRAND-ON-BRAND COMBINATIONS AND IMPACT ON PATIENT ACCESS
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Combinations of high-cost branded drugs are becoming a reality. The synergistic value of combining two poten drugs is expected to considerably benefit the patient in terms of efficacy and, in some cases, even safety. However, the synergistic cost of using branded combinations increases exponentially due to longer treatment duration, creating a market access and reimbursement for branded combinations is therefore a challenge for health systems. This poster aims to explore the pricing and reimbursement issues that health systems will encounter during the evaluation of branded combination therapies. The primary objective is to make the right decisions for the best health care systems and ensure patient access to innovative drugs. To meet these objectives, an in-depth review of published sources was conducted, including a thorough analogue assessment. Moreover, targeted interviews with twenty payers involved in the selection and approval of pricing and market access decision-making in the EU were also conducted to support analysis. Research revealed that synergistic costs of already expensive monotherapies, further exacerbated by longer duration of treatment, exceed payers’ cost thresholds. Therefore, on one hand payers will struggle to award a value-based price for the individual drugs as well as for the combination and will look to discount and/or restrict access. On the other hand, as this approach will not reflect the combination’s synergistic value and could threaten the life of individual therapies, or each compound, manufacturers may not launch in some markets, thus, limiting patient access. Consequently, it is important to find a balance in setting a value-based price for individual indications and for the combinations to ensure broad patient access. Aligning payer, patient and manufacturer needs is paramount to find a win-win-win solution. In the context of brand-on-brand combinations, traditional pricing models are not the solution and alternative approaches need to be adopted.

PHP282
THE CASE FOR EARLY PAYER ENGAGEMENT
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BACKGROUND: Knowledge of payer evidence requirements is vital to manufacturers who are facing increasing development costs for uncertain market access outcomes. Failure to engage payers early in asset development could result in delay of approval and/or coverage. OBJECTIVES: Build the case for early payer engagement as a means of reconciling the needs of payers and manufacturers. METHODS: A literature search was performed and primary research with key opinion leaders in the US and EU was conducted to characterize 5 early engagement strategies (informal consultation, formal consultation, outcomes-based risk sharing, financial-based risk sharing, and formal partnerships). 7 major markets (Canada, France, Italy, Germany, Spain, UK, and US) were also assessed for their historic use of early engagement models. RESULTS: Payors want more manufacturer involvement in evidence development, including input into clinical trial design and RWE development in phases II and III through formal and informal consultations. Articulation of an asset’s value story in the peri-launch phase and negotiations with regional and local payers through direct consultations allows manufacturers to position the asset for optimal pricing and reimbursement. When agreement cannot be reached on price or reimbursement terms, risk-sharing agreements allow broader access in exchange for the manufacturers bearing incrementally greater financial risk. Manufacturers have also built partnerships to uncover the real-world value of therapies and gain insight into usage and adherence patterns. Each market has its own challenges for promoting collaboration, requiring manufacturers to tailor their approach to the various national and local payers. CONCLUSION: Early planning is imperative in value-focused health care. When early payer engagement succeeds, it provides manufacturers time to design informed strategies to meet payer valuation needs. Evidence development activities that is closely aligned with payer requirements results in therapies that are more cost-effective and gain quicker market access, benefitting manufacturers, payers, and patients alike.

PHP283
EARLY NICE DECISION PROBLEM MEETINGS: IMPLICATIONS FOR CROSS-FUNCTIONAL INDUSTRY TEAMS
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The National Institute for Health and Care Excellence (NICE) in England and Wales has developed a decision problem meeting process several months before starting a technology appraisal, rather than approximately 10 weeks after formal invitation for the manufacturer to submit evidence, per current protocol. In general, the purpose and outcomes of the meeting, involving the NICE team, payer evidence representatives from NICE and payers, is to determine the evidence that will be considered before the technology appraisal is launched, rather than happening earlier. However, the meeting does allow manufacturers and sponsors to signal potential regulatory developments during the appraisal, ahead of the submission. It can incorporate potential inclusion and handling of patient access scheme proposals. For the meeting, an outline is required to demonstrate how the manufacturer/sponsor intends to approach the decision problem. This outline is to include, but is not limited to: evidence sources to be used, evidence likely to be needed while during the appraisal and how this may be managed; the planned approach to disease and economic modelling, potential challenges in interpreting the evidence; proposed approach to handling of uncertainty. If adopted, there are several implications for this process, with considerable time savings for manufacturers. This strategy will need to be considered earlier than currently, with implications for data availability and analyses, value story development, positioning and indications, etc; cost-effectiveness models and their base cases will need earlier definition and communication; and intentions regarding patient access schemes must be made before submission. PRMs may be reviewing limited published evidence in fast-moving therapy areas, manufacturer market access groups will require more information from clinical, regulatory, medical affairs, modellers, epidemiologists much earlier than currently do. Therefore, this seemingly simple change of meeting date relative to time of submission has important implications for manufacturers beyond their market access teams that require careful consideration in terms of planning and communication.

PHP284
THE IRISH COST-EFFECTIVENESS THRESHOLD: DOES IT SUPPORT RATIONAL RATIONING OR MIGHT IT LEAD TO SYSTEMATIC DAMAGE OF IRELAND’S HEALTH SYSTEM?
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Irish legislation recognises the need to consider the cost-effectiveness of health services, both for new interventions and their opportunity cost. Ireland did not have an explicit cost-effectiveness threshold until a 2012 agreement between the pharmaceutical industry and government established a €45,000/QALY threshold. It was agreed as part of a deal that provided cost savings on existing medications and only applies to pharmaceuticals; there is no official threshold for non-drug interventions. Drugs with cost-effectiveness ratios within the threshold are guaranteed reimbursement, whereas those exceeding the threshold may be approved following further negotiation. A number of drugs far exceeding the threshold have been relisted in recent years. There are four reasons for concern regarding Ireland’s threshold. Firstly, as a price floor not a ceiling it offers only a weak constraint on the introduction of cost-ineffective interventions, which leaves patients exposed to non-therapeutic treatments creating potential for inconsistencies whereby relatively cost-effective non-drug interventions may not necessarily be approved, leading to sub-optimal resource allocation. Secondly, the current threshold has no apparent empirical or clinical basis. Finally, recent efforts to refine the appropriate cost-effectiveness threshold in the UK have estimated a threshold of approximately £13,000/QALY. Assuming Ireland’s threshold should be broadly comparable, the current Irish threshold is probably too high. Consequently, reimbursing new interventions at and above the €45,000/QALY threshold is likely to result in net harm, as new drugs produce less health than the interventions they displace. The failure of the €45,000/QALY threshold to empirically determine an appropriate cost-effectiveness threshold for services foregone means the requirements of current legislation are no longer met and reimbursement decisions cannot be considered fully evidenced-based. It is likely the current threshold is excessive and will lead to systematic damage of the health system.

PHP285
AN ETHIC SYSTEM OVERVIEW: BRAZILIAN PERSPECTIVES FOR OBSERVATIONAL STUDIES
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BACKGROUND: Observational studies have been one of the hallmarks for the development of public health and health economics fields. It includes epidemiologic studies, evaluation of patterns of care, use of resources, cost of illness, analysis of safety and effectiveness of interventions from real world. However, there are different patterns of requirements for ethics reviews concerning observational studies, including vastly available models of ethics systems among different countries. Therefore, the objective of this study is to evaluate the ethics systems, regulations and guidelines governing observational studies in Brazil. METHODOLOGY: Researches were performed in the database Medline and SciELO using the terms “ethics”, “observational study” and “multicenter study” among other similar terms. RESULTS: In Brazil, same ethics regulation is applied for both interventional and observational projects, plus there is a minimum ethical review timelines and duplicated reviews when considering multicenter studies. Specific pathways for multicenter studies are available only in New Zealand, Australia, USA and UK. For the exception of Brazil, other evaluated countries have specific guidelines, recommendations or regulations for observational studies. CONCLUSIONS: Brazil and Argentina still have a lot of
challenges to overcome regarding the overall ethics system. Applying same ethics regulations or guidelines from interventional studies may not be the most adequate choice for observational studies.

**PHP286**

**STATE OF THE ART RESEARCH IN AUSTRIA: DEXHELPP - DECISION SUPPORT FOR HEALTH POLICY PLANNING: METHODS, MODELS AND TECHNOLOGIES BASED ON EXISTING HEALTH CARE DATA**

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The Austrian health care system incurs costs of 30 billion/year, the bulk of the costs (77%) are publicly financed. Health policy and decision planning based on research evidence helps to tackle increasing costs. The urgent need for the evaluation of new health technologies, services, infrastructure, as well as for the development of improved technologies for the analysis, planning and control of health systems is growing. Today, decision support in health care is usually based on evidence from studies of limited size, but not yet on the analysis of large volumes of routinely collected health care data. DEXHELPP is dedicated to filling the gap by combining academic excellence by research partners with professionalism in implementation including knowledge of commercial partner institutions. By doing so, special methods for statistical analysis, simulation and visualisation will be implemented as well as new methods for documentation and providing of k-anonymity for used individual data. For this task, existing cooperation schemes provide a firm substantial and conceptual knowledge base. All relevant fundamental technological competencies from academic and applied research are provided by the consortium, coming from universities, competence centres, and research and development (R&D) institutes. Developed methods (1) making based on higher and lower price, (2) estimating the consequences of interventions. A scientific research server with routine data in order to test developed methods will be run. The project covers all relevant areas within this complex process, from data management via analysis and modelling through to user friendly presentation of results and quality assurance. Some of the most important actual decision making can be completed the construction with application-specific expertise. CONCLUSIONS: DEXHELPP focuses on the development on high innovative technological methods. Future focus will lay on building up a network with more stakeholders to integrate those methods in national and international processes.
patient's involvement and better health outcomes. Improving service development and access to health advice with care experience are other adjuvant interventions. So patient's participation is a key better care plan.

PHP297

TURKISH PUBLIC PROCUREMENT SYSTEM FOR MEDICAL DEVICES: A GUIDE FOR REIMBURSEMENT POLICY?

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In 2008, Public Procurement Law (PPL) was amended to implement and regulate e-Procurement in Turkey. Non-private, public purchaser hospitals are obliged to enter tender results of their medical device purchases into an e-procurement system (EPS) to be eligible for a reimbursement by the Social Security Institution (SSI) in Turkey. Objectives of this research are to examine the impact of the EPS that is currently being used for medical device purchases in Turkey since 2011, and to investigate how the system is being used to define ceiling prices for reimbursement, concurrently assessing the quality and quantity of data uploaded by hospitals. EPS data is downloaded on a GMDB basis from Turkish National Database for Medical Devices, (TITUBB) which is an e-catalogue system that was launched to provide barcode level product registration, search and the e-procurement result. In accordance with the objectives, assessment is conducted on more than ten GMDBs and results are utilized to see the effect of EPS on pricing, comparing the prices on officially published SSI positive lists. Our study shows that a lowest price detected on EPS could be set as the reimbursement price, as was the case for the product; aortic stent graft, contralateral limb, where a defined SSI positive list price was reduced after determination of a lower price on EPS, on account of a mispriced tender record. An EPS evaluation while searching out the reimbursement prices is needed instead of SSI's calculations based on merely a retrospective and detection of lowest price practice. Effectiveness of this policy depends on resolving the weaknesses of EPS data, quality of data and the tender or a mispriced product could be a ground for an erroneous price setting and tenders that are not recorded at all or deferred might lead to incomplete EPS data to define reimbursement prices.

DISEASE-SPECIFIC STUDIES

MENTAL HEALTH – Clinical Outcomes Studies

PMH1

THE RISK OF METABOLIC DISORDERS IN PATIENTS TREATED WITH ASENAPIE OR OLANZAPINE: A REAL WORLD DATA STUDY CONDUCTED IN ITALY AND SPAIN

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OBJECTIVES: Second-generation antipsychotic drugs, known as Atypical Antipsychotics, have a better tolerability than conventional antipsychotics but it has reported that its usage to a substantial weight gain, an increase risk of dyslipidemia and type 2 diabetes mellitus. In this article authors assessed the risk of metabolic adverse events associated with Asenapine in comparison with those associated with Olanzapine by studying real world data. METHODS: The study was a retrospective analysis based on data extracted from Italian and Spanish Cegedim Strategic Data Longitudinal Patient Data databases. Patients were divided in two cohorts (Asenapine and Olanzapine) according to the inclusion criteria and data from these patients were analyzed starting from 2009 up to 2013. Diabetes and dyslipidemia registries have been referenced in each first year of development or any metabolic adverse events. RESULTS: The retrospective analysis showed a lower risk of developing type 2 diabetes and dyslipidemia associated with Asenapine in comparison with Olanzapine. Asenapine was associated with a lower risk of metabolic adverse events than Olanzapine, demonstrating a better safety profile with regard to metabolic effects.

PMH2

EFFICACY OF THE PHOSPHORYLATED TAU P181 FOR THE ALZHEIMER’S DISEASE DEMENTIA - A SYSTEMATIC REVIEW AND META ANALYSIS

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OBJECTIVE: The purpose of this study was to apply a systematic review of the literature to evaluate the diagnostic effectiveness of the Phosphorylated tau p181 for the Alzheimer’s disease dementia. METHODS: A systematic literature review was used to evaluate the effectiveness of the Phosphorylated tau p181 for the Alzheimer’s disease dementia. The Scottish Intercollegiate Guidelines Network (SIGN) tool was used by two evaluators to independently evaluate the quality of the ten studies. The literature review covered from October 27, 1946 to July 22, 2012, and included data from all databases, including Ovid MEDLINE, EMBASE, and Cochrane Library were used. RESULTS: A total of 9 studies (9 diagnostic evaluation studies) were identified to evaluate Phosphorylated tau p181. Using a fixed or random effect model, the effectiveness of this test was evaluated based on diagnostic accuracy. The diagnostic effectiveness for identifying AD of ELISA was high (pooled sensitivity, 0.943 [95% CI 0.781-0.967], pooled specificity, 0.799 [95% CI 0.768-0.828]), summary receiver operating characteristic under the curve the 0.908±0.0236. Primary criteria for inclusion were: study participants with dementia, measurement with confirmed or suspected AD and non-AD dementia, and (ii) assessment of tau levels using appropriate comparative tests. CONCLUSIONS: Asenapine is associated with a lower risk of metabolic adverse events than Olanzapine, demonstrating a better safety profile with regard to metabolic effects.
A systematic review was conducted, according to National Institute for Health and Care Excellence guidelines, to identify randomized controlled trials (RCTs) of guanfacine (GXR), atomoxetine (ATX), lisdexa-metamfetamine (LMDX), and methylphenidate (MPH) extended release (ER) and immediate release (IR) in children and adolescents with ADHD. A Bayesian mixed treatment comparison was conducted to compare baseline-to-endpoint change in ADHD-RS-IV score, response (defined as a clinician global impressions – improvement [CGI-I] score ≤2), with meta-regression adjustments permitted by data availability (age and percent female). 95% credible intervals (CIs) for treatment effects and the percentage of participants treated for each SSD were estimated. RESULTS: Of 5,619 records retrieved, 29 RCTs met the inclusion criteria. Five trials included GXR, 4 included LDX, 16 included ATX, 7 included MPH-ER, and 5 included MPH-IR. Meta-analysis of GXR showed a greater effect than each comparator. Mean change in ADHD-RS-IV score change from baseline and 95% CI (active minus placebo) were -8.68 (-10.63, -6.72) for GXR, -14.98 (-17.14, -12.80) for LDX, -6.88 (-8.22, -5.49) for ATX, and -9.33 (-11.63, -7.04) for MPH-ER. The relative risk and 95% CI for CGI-I response (defined as very much improved) were 3.42 (2.59, 4.64) for MPH-ER, 2.81 (1.79, 2.81) for MPH-IR, 1.97 (1.43, 2.58) for ATX, and 1.66 (1.02, 2.32) for MPH-IR. Among non-stimulants, GXR was more effective than ATX when comparing ADHD-RS-IV change (posterior probability of 99.91% and CGI-I response (posterior probability of 71.01%). Conclusions: When analyzing data, the presented review found that GXR had a higher efficacy compared with GXR, ATX, and MPH in the treatment of children and adolescents with ADHD with no overlap in CIs. Among non-stimulants, although GXR had a higher probability of being more efficacious than ATX, their CIs overlapped.
from a common Normal distribution of treatment effects with an overall SSRi class effect, and the treatment within class heterogeneity. RESULTS: There were 55 eligible studies identified in the systematic review. The treatment with the greatest decrease in YBOCS was behavioural therapy (“exposure and response prevention”) showing a decrease of 13.86 (95% CI 3.4 to 24.31). The second and third greatest effects were cognitive therapy (12.75, 95% CI 8.5 to 16.98) and social skills training (12.20, 95% CI 2.0 to 22.4) respectively.

CONCLUSIONS: This analysis showed a combination of behavioural therapy plus clomipramine has the greatest decrease in YBOCS. There is little evidence to show a difference between SSRIs.

PMH9
SYSTEMATIC REVIEW AND MIXED-TREATMENT COMPARISON OF LITHIUM OR ATYPICAL ANTI-PSYCHOTIC (AAP) AS AN ADDITIVE SEROTONIN REUPTAKE INHIBITOR (SSRI) IN TREATMENT RESISTANT DEPRESSION (TRD)

OBJECTIVES: To estimate the clinical effectiveness of augmentation with either lithium or an AAP in TRD, defined as failure to respond to two or more antidepressants in the current episode of depression. METHODS: Systematic review of CENTRAL, EMBase, MEDLINE, and PsycNFO was completed in August 2011. Additional data were obtained from manufacturers. Studies were assessed for quality using the Cochrane Risk of Bias Tool. Pairwise meta-analysis and network meta-analysis (NMA) were undertaken based on intention-to-treat data. RESULTS: Of the 3,721 papers found in the literature search, 12 randomised controlled trials (RCTs) were identified; 10 (SSRI + AAP vs SSRI + placebo) and two (SSRI + lithium vs SSRI + placebo). The RCTs included in the primary analyses used fluoxetine as the SSRI and olanzapine as the AAP. Results of the NMA showed a non-significant trend in favour of lithium over olanzapine for response (OR = 1.32; 95% CI 0.88 to 1.96). NMA of the individual SSRI trials showed a decrease in core YBOCS from 0.38 to 0.48, p < 0.05. No significant differences were found between SSRi and olanzapine on global improvement, social function, or clinician’s global assessment of improvement at the end of the trial. Predictive factors of PIP.

CONCLUSIONS: There is little evidence to show a difference between SSRIs. Combination of behavioural therapy plus clomipramine has the greatest decrease in YBOCS. There is little evidence to show a difference between SSRIs.
OBJECTIVES: Major depressive disorder affects approximately 10-15% of the population and is associated with significant morbidity and mortality. It is one of the leading causes of disability in young adults. A large proportion of the burden can be attributed to treatment-resistant depression (TRD). To understand the prevalence and disease burden of TRD in Western European countries, the US and Canada, a systematic literature review was performed. OVID, the Cochrane Library and the CRD database were used to retrieve TRD publications in English language from January 2003-October 2013. In total, 6306 abstracts were identified. Predefined selection criteria regarding study design, patient population (age >12 years, US, Canada, Germany, Italy, France, Spain or UK), TRD definition as one treatment failure and high symptom severity (e.g., MADRS ≥31, or an inadequate response to ≥2 antidepressants) and outcomes of interest were applied. RESULTS: Only seven studies included prevalence and/or disease burden data. Five studies provided prevalence estimates which adhered to the strict TRD definition used for this review. Study design and definition of the patient population were critical in determining the prevalence rates. The higher treatment failure rates observed in US clinical trials (11%-15%), higher rates in commercial health insurance databases (29%-31%) and the highest rates in a European multicenter study (51%-56%). The database studies mainly included employed patients thereby likely underestimating the prevalence, whereas the clinic-based studies likely overestimated the prevalence due to a less stringent TRD definition. Inconsistent data were reported regarding treatment outcomes, comorbidities, hospitalization and work productivity. There was no information on other outcomes such as health-related quality of life or functioning. CONCLUSIONS: No consistent data were found in the literature from January 2003-October 2013 regarding the epidemiology and disease burden of TRD. To determine the prevalence and disease burden for TRD, further studies are needed.

PMH15

PREVALENCE OF METABOLIC SYMPTOMS IN PATIENTS WITH SCHIZOPHRENIA ACCORDING TO THE PRESENCE OR ABSENCE OF NEGATIVE SYMPTOMS

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OBJECTIVES: The aim of this study was to estimate the prevalence of metabolic syndrome (MS) in patients with schizophrenia according to the presence or absence of negative symptoms. METHODS: A retrospective, cohort study was conducted using electronic health records from the health authorities. Only patients with a diagnosis of schizophrenia were followed for 12 months. Two study groups were defined by the presence or absence of negative symptoms based on the NCEP ATP III criteria. Descriptive statistics and logistic regression models were applied. RESULTS: We studied 1,120 patients (mean age: 46.8 ± 13.8 years; male: 58.4%). One or more negative symptoms were present in 52.5% of patients in the MS group (35.7%) compared to 17.5% in the non-MS group. Patients with negative symptoms showed a greater mean number of comorbid conditions than patients without this symptomatology (8.5 and 7.0, respectively; p < 0.001). Prevalence of MS was 38.6% (CI: 35.4-41.5%), higher among patients with one or more negative symptoms (43.9% vs. 34.9%, respectively; p<0.002). MS was associated with the presence of negative symptoms (OR: 1.4, 95% CI: 1.2, 1.6; p < 0.05). CONCLUSIONS: Further studies are necessary to elucidate the association between the presence of negative symptoms and MS among patients with schizophrenia as well as the underlying mechanisms involved.

MENTAL HEALTH – Cost Studies

PMH16

THE POTENTIAL BENEFITS OF LONG-ACTING ATYPICAL ANTI PSYCHOTICS THROUGH PREVENTING RELAPSE IN BIPOLAR DISORDER IN BRAZIL

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OBJECTIVES: To quantify the economic burden of schizophrenia relapse in Brazil, and to estimate the impact of atypical Long Acting Injektibles (LAIs) on relapse. METHODS: Administrative health service data from a Brazilian public system database (DATASUS) were used to estimate the number of relapse patients and related resource utilisation. Corresponding data for private system patients were estimated based on published literature and by extrapolating DATASUS data. A prevalence-based costing with a mixed bottom-up and top-down approach was used to quantify direct and indirect costs, disability adjusted life years (DALYS) and their associated monetary value. A decision-analytic model was constructed to evaluate the cost effectiveness of potentially transferring non-compliant patients from oral antipsychotics to atypical LAIs. All costs are presented in 2013 Brazilian real. RESULTS: In 2011-12, 88,721 patients with schizophrenia in Brazil experienced 263,037 episodes of relapse that resulted in hospital or outpatient care. The potential avoidable health care cost of relapse was $9,184,000,000 (3.1%) were avoided if transferred to atypical LAIs. Only 1,214 patients were non-compliant and $5,595 if non-compliant patients could be transferred to atypical LAIs to achieve 5% overall utilisation. Reducing relapses would give Brazil potential avoidance of $233,000,000,000. This corresponds to a saving of $482.8 million in the stock of health capital. CONCLUSIONS: The economic burden of schizophrenia relapse in Brazil is significant. Brazilian policymakers should provide greater access to LAIs.

PMH17

ANALYSIS OF ‘REVOLVING DOOR’ PATIENTS IN OPIOID DEPENDENT PATIENTS: THE IMPACT OF TREATMENT DISCONTINUATION ON RELAPSE RATES AND HEALTH CARE COSTS IN US PUBLIC HEALTH INSURANCE CLAIMS

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OBJECTIVES: Buprenorphine/naloxone (BUP/NAL) combination is a well-known treatment for opioid dependence. As a chronic relapsing disorder, some patients alternate between periods of on treatment and off treatment. The aim of this study was to investigate the resource utilisation of these patients and patients treated continuously. METHODS: Statistical analyses were conducted on a Medicaid insurance claims database (TruvenHealth MarketScan® Medicare Supplemental 2012). Patients with at least two treatment episodes in the first year after the initial filled prescription were identified. The end of a treatment episode was defined as a period of 60 days with no filled prescription. An ordered logistic regression model was used to analyze the impact of initial treatment episode duration on the number of new episodes in the year following the end of the first episode. Health care resource utilization and related costs during the period between treatment episodes for public and private payers were estimated. RESULTS: 2,223 patients were included in the analysis. During the first year, 86% of patients had only one treatment episode, 13% had two and 1% had three. Compared to patients who remained in treatment continuously over 12 months, the multiple treatment episode group had lower medication costs ($2,877) but higher psychiatric inpatient costs ($720), non-psychiatric inpatient costs ($2001) and emergency room costs ($430) over 12 months. Total health care costs over 12 months were higher among patients with multiple treatment episodes compared to patients treated continuously.

PMH18

TREATMENT COST COMPARISON: PALIPERIDONE PALMITATE Versus RISPERIDONE LONG ACTING IN BRAZIL

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OBJECTIVES: To compare the treatment cost of paliperidone palmitate (PP) versus risperdone long acting (R-LA), both indicated for the treatment of schizophrenia in Brazil. METHODS: In Brazil, both (PP and R-LA) long acting 2nd generation antipsychotics are approved for the treatment of schizophrenia. Published literature shows that PP is currently preferred over them, but no studies have been conducted on a Brazilian database. The treatment analysis was performed. Yearly treatment costs were calculated for an average dose of 37.5 mg per patient in the case of R-LA and 75 mg in the case of PP. The two initial treatment doses were considered; for PP, 150 mg on the 1st day and 100 mg on the 2nd day, and for R-LA 21 days oral supplementation with 3 mg of risperidone, according to dosing intervals defined in the product label. Prices were gathered from the official price list (CMED – Apr’14). RESULTS: PP has the lowest cost of treatment, at R$16,165 in the 1st year - against R-LA R$18,165 – and R$11,595 in the 2nd year (R-LA has R$17,971). Treatment with PP compared to R-LA may bring important savings to the payers (RHos or Government), with potential to reduce the cost of treatment by 30% in the 1st year, and 37% in the 2nd year, allowing a higher number of patients to be treated at the same budget level. CONCLUSIONS: Although both molecules, PP and R-LA, have demonstrated similar efficacy, PP offers treatment at a reduced cost (enhanced cost-saving therapeutic option for schizophrenia compared to R-LA).
PMH20
THE SOCIOECONOMIC COSTS OF SCHIZOPHRENIA IN SWITZERLAND
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OBJECTIVES: The objectives of this study are to estimate the prevalence of schizophrenia in Switzerland and to assess its burden on patients, caregivers and society as a whole. We compared the burden of schizophrenia with that of other common morbid conditions. We used health insurance claims data to capture all patients living in the northern part of the canton of Zurich. Total costs included direct medical and non-medical costs and lost production. All costs were calculated for the year 2012 from a societal perspective using a prevalence-based bottom-up approach. Independent of the type of treatment, costs were expressed as quality adjusted life years (QALY) lost and were calculated from Swiss life tables, standardized mortality ratios and utility weights from the literature. Uncertainty and its sources were addressed in univariate and probabilistic sensitivity analysis. RESULTS: The point prevalence of schizophrenia in 2012 was estimated at 0.39% of the Swiss population. The average annual costs of schizophrenia amounted to EUR 39,408 per patient and consisted of direct medical costs of EUR 9,507 per patient, and non-medical costs of EUR 8,793 (12%) and lost production of EUR 25,108 (64%). Inpatient hospital care accounted for EUR 6,242 per year or 66% of direct medical costs. The estimated reduction in life expectancy of 10.46 years and the utility decrement of 22.05 percentage points lead to intangible costs of 19.02 QALY per incident chronic case. CONCLUSIONS: The results of this study show the high burden of schizophrenia on patients, caregivers and society as a whole. The high costs of inpatient hospital care demonstrate the need for urgent and more effective prevention of schizophrenia. Programs for the reintegration of schizophrenic patients into the labor market have a high potential to reduce the costs of schizophrenia considering the high burden of lost production and the early onset of the disease.

PMH21
A MODEL TO ESTIMATE THE SCHIZOPHRENIA SUBSTRATE OF PRESCRIPTION OPIOID ABUSE IN EUROPE
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OBJECTIVES: Prescription opioid (“RxO”) abuse has not been regarded as a major problem in Europe so far, but a lack of reliable data hinders the assessment of this problem. This study aimed to derive estimates of the prevalence and excess costs of RxO abuse in the five largest European countries (France, Germany, Italy, Spain, and UK; “EUS”). METHODS: Data from the European Monitoring Centre for Drugs and Drug Addiction and the UN Office on Drugs and Crime, on the prevalence of prescription opioid abuse and the share of opioid abuse patients who report using non-licensed heroin and cocaine, were used to estimate the prevalence of RxO abuse in the EUS. The costs of RxO abuse were calculated by applying published estimates of the excess health care costs of RxO abuse to country-specific estimates on the costs of chronic pain. Sensitivity analyses varied assumptions surrounding the prevalence of opioid abuse patients in the general population and the estimates of the excess costs of RxO abuse in the EUS. RESULTS: The prevalence of RxO abuse, in the general population, varied between the EUS countries, ranging from 0.7 per 10,000 in Italy to 4.5 per 10,000 in Spain. In the base case scenario, the annual total health system burden of RxO abuse across all EUS countries was estimated to be €323 million; results of sensitivity analyses ranged from €98 million to €730 million. These cost estimates included medical costs only, excluding indirect costs. CONCLUSIONS: RxO abuse imposes a burden on EUS health systems. Future research should examine trends in the prevalence and total economic burden of RxO abuse in Europe over time, and assess the potential benefits of abuse-deterrent formulations, which publications have reported to be associated with a significant relative reduction in rates of diagnosed opioid abuse.

PMH22
PRODUCTIVITY LOSS AND RESOURCE UTILIZATION IN INDIVIDUALS PROVIDING CARE FOR ADULTS WITH SCHIZOPHRENIA IN THE EU
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OBJECTIVES: This study aimed to understand the impact of providing care for adults with schizophrenia on productivity, daily activities and resource utilization in the EU. METHODS: Data from the 2010-2011 and 2013 EU5 (France, Germany, Italy, Spain, UK) National Health and Wellness Survey, an online CONCLUSIONs of a nationwide sample of adults (18+ years) was analyzed. Schizophrenia caregivers (n=398) were matched to non-caregivers (n=158,989) and other caregivers (n=14,341) on baseline characteristics (sociodemographics, BMI, comorbid status) via propensity scores [1-2]. Outcome measures included health care utilization (type/number of resources used within the past 6 months) and Work Productivity and Activity Impairment questionnaire-based scores. Chi-square tests and Wilcoxon-Mann-Whitney tests were used to determine significant differences between schizophrenia caregivers vs. non-caregivers and other caregivers (e.g., cancer, Alzheimer’s). RESULTS: The average age of schizophrenia caregivers was 45.3 (SD=12.8, 69% were female, and 52% were currently employed). After matching, schizophrenia caregivers reported greater activity impairment (38.4% vs. 26.1%), more health care provider visits (8.0 vs. 0.2) and hospitalizations (8.0 vs. 0.1) than non-caregivers, all p<0.01. Among month-end-based schizophrenia caregivers, schizophrenia caregivers reported less absenteeism (12.4% vs. 5.6%), presenteeism (29.9% vs. 17.5%), and overall work impairment (35.0% vs. 20.7%) than non-caregivers, all p<0.01. Comparing schizophrenia caregivers and other caregivers, schizophrenia caregivers reported more activity impairment (38.4% vs. 32.3%) and health care provider visits (8.0 vs. 6.6), both p<0.05. A greater proportion of schizophrenia caregivers reported at least one emergency room visit (26.1% vs. 20.2%) and hospitalization (20.4% vs. 14.3%) than other caregivers, both p<0.05. No significant difference was found on work-related impairment, probably due to the small sample of employed respondents. CONCLUSIONS: Schizophrenia caregivers reported greater activity impairment vs. non-caregivers and other caregivers, with less absenteeism, and more health care provider visits. Better family and social support systems may help reduce the burden for schizophrenia caregivers.

PMH23
MEDICATION USAGE PATTERN, HEALTH RESOURCE UTILIZATION AND ECONOMIC BURDEN FOR PATIENTS WITH MDD IN BEIJING, CHINA
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OBJECTIVES: To investigate medication usage patterns, health care resource utilization and direct medical costs of patients with Major Depressive Disorder (MDD) in Beijing, China. METHODS: Data were randomly extracted from Beijing Urban Employee Basic Medical Insurance Database. Patients who were aged ≥18 years, with at least 1 primary diagnosis of MDD and 12-month continuous enrollment after their first observed MDD diagnosis between 2012 and 2013 were identified. Those with a diagnosis of schizophrenia, bipolar disorder or cancer within the study period were excluded. Descriptive statistics were used to describe patient profiles, medication usage, health care resource utilization and costs. RESULTS: A total of 4484 patients were included with mean (±SD) age of 57.15 (±15.34) years. Female and co-morbid disorders were more prevalent among patients who were treated with antidepressant medications, including 60.53% of patients with SSRIs, followed by NaSSA (8.96%) and SNRIs (8.26%). Concomitant medications were prescribed to 37.76% of patients. Only 0.42% of patients experienced ≥1 hospital-related hospitalizations during the 1-year follow up and the average annual number of hospitalization was 1.22 (±0.64) for those hospitalized patients. The length of stay was 1.58 days (±0.6) per hospitalization and 46.24 days (±6.4) per patient-year. All patients had ≥1 MDD-related outpatient visits. The mean annual number of outpatient visits was 3.06 (±2.99). The mean annual direct medical cost for all MDD patients was 1694.05 (±2513.71) RMB with 48.54% for antidepressant medications and 41.46% for non-pharmacological costs. CONCLUSIONS: In Beijing, China, most MDD patients also had co-morbid conditions and were mainly treated in the outpatient setting. SSRIs were the most commonly used antidepressants. The economic burden of MDD was considerable.

PMH24
ATOMoxetine FOR THE TREATMENT OF NEWLY DIAGNOSED ADULTS WITH ADHD - A COST EFFECTIVENESS ANALYSIS IN SPAIN
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OBJECTIVES: The first aim of this research was to receive marketing authorization for Spain for the treatment of newly diagnosed adults with Attention-Deficit/Hyperactivity Disorder (ADHD) associated with comorbidities. The second aim of this treatment is to measure the economic burden of ADHD. METHODS: A Markov state transition model was developed. Patients were treated with atomoxetine in adults with ADHD was cost-effective vs. placebo from the Spanish Healthcare System perspective. RESULTS: In Spain, the most commonly used antidepressants. The economic burden of MDD was considerable.

PMH25
ARIPIPrazOLE ONCE-MONTHLY IS A COST-EFFECTIVE THERAPEUTIC OPTION IN THE MAINTENANCE TREATMENT OF SCHIZOPHRENIA: RESULTS FROM A MARKOV MODEL
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OBJECTIVES: Aripiprazole is a second-generation antipsychotic with a unique pharmacological profile with numerous clinical advantages in many respects compared with traditional antipsychotics. RESULTS: Aripiprazole is a second-generation antipsychotic with a unique pharmacological profile. Conclusions: Aripiprazole 30 mg once-monthly is a cost-effective therapeutic option in the maintenance treatment of schizophrenia.
nance treatment of schizophrenia. METHODS: The schizophrenia Markov model developed by the National Institute for Health and Care Excellence (NICE) was adapted to the context of LAI antipsychotics. Effectiveness was measured through Quality-Adjusted Life Years (QALYs) and number of relapses. The economic analy-

sis was conducted over a ten-year time horizon, including cost of managing stable schizophrenia, relapse and treatment-emergent adverse events (TEAEs). Probabilities of relapse, discontinuation due to adverse events, and due to other reasons came from a mixed treatment comparison of pivotal clinical trials; disu-
tility was applied to otherwise non-treatment effects from various epidemiological sources. RESULTS: AOM was associated with higher number of QALYs (7.26 vs 7.17, 7.18 & 7.19 for PP, RLAI and OP respectively) over a 10-year time horizon. Assuming a theoretical parity price between AOM and PP, the base case analysis showed that AOM was the dominant strategy compared to RLAI, PP and OP. Deterministic sensitivity analyses confirmed these overall Conclusions, the main drivers of cost-effectiveness were both probability and cost of relapse. In the probabilistic sensitivity analysis, AOM dominated PP-LAI in cost-effectiveness than RLAI, PP and OP at a willingness to pay of €20,000 (52%, 88% and 90%, respectively). CONCLUSIONS: Although model outcome may vary according to local data and settings, and assuming a theoretical parity price between PP-LAI and RLAI, AOM is associated with lower total costs compared to other atypical LAI antipsychotics, showing its value in the maintenance treat-

men t of schizophrenia.

PMH26

PRESCRIBING ANTI-DEPRESSANTS BY BASELINE SEVERITY: EVIDENCE SYNTHESIS, ECONOMIC MODEL AND VALUE OF INFORMATION ANALYSIS

Aim to determine the most cost-effective threshold of depression severity in patients who will prescribe anti-depressants compared to AOM in the United Kingdom. Objectives: Aim to determine the most cost-effective threshold of depression severity in patients who will prescribe anti-depressants compared to AOM in the United Kingdom. METHODS: Meta-regression of existing studies resulted in estimating a propor-
tional trend effect on depression severity, which is then extrapolated to a wider range of severity than included trials. An economic model which con-
sists of a Markov model for the initial 12 weeks of treatment, followed by a Markov model with states for depression category and treatment. Treatment effects on Hamilton Depression Rating Scale (HAM-D) were mapped to EQ5D. Expected value of partial perfect information (EVPPI) was used to determine an effects on Hamilton Depression Rating Scale (HAMD) were mapped to EQ5D. A cost-effectiveness Markov model with states for depression category and treatment. Treatment effects on Hamilton Depression Rating Scale (HAM-D) were mapped to EQ5D. The analysis showed that AOM was the dominant strategy compared to RLAI, OP and OP. Deterministic sensitivity analyses confirmed these overall Conclusions, the main drivers of cost-effectiveness were both probability and cost of relapse. In the probabilistic sensitivity analysis, AOM dominated PP-LAI in cost-effectiveness than RLAI, PP and OP at a willingness to pay of €20,000 (52%, 88% and 90%, respectively). CONCLUSIONS: Although model outcome may vary according to local data and settings, and assuming a theoretical parity price between PP-LAI and RLAI, AOM is associated with lower total costs compared to other atypical LAI antipsychotics, showing its value in the maintenance treat-

men t of schizophrenia.

PMH27

ECONOMIC EVALUATION OF NALMEFENE FOR THE TREATMENT OF ALCOHOL DEPENDENCE

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OBJECTIVES: To determine the cost-effectiveness of atypical long-acting injectable LALs (RIE, AOM, RIS-LAI, OLZ-LAI) for the treatment of alcohol dependence in the Finnish National Health Service. METHODS: A 1-year decision tree was adapted for use with patients in relapse, guided by an expert panel. Drugs included available atypical long-acting antipsychotics: paliperidone (PP-LAI), risperidone (RIS-LAI), olanzapine (OLZ-LAI) and aripiprazole (ARI-LAI). Rates of adherence, success, relapse and hospitalization were taken from the literature. Prices were obtained from standard lists and expressed in 2014 euros: drugs, psychiatric/ psychological and psychiatric nurse and inpatient and outpatient hospital care. Outcomes included expected cost/patient treated, QALYs, rates of re-hospitalization, emergency room (ER) visits and days in relapse. The primary analysis was the incre-

men
t per QALY. RESULTS: These provide confidence in the cost-effectiveness of antipsychotics on important inputs. RESULTS: Over the 1-year time horizon, PP-LAI had the lowest total cost of €34,461 per patient, RIS-LAI cost €37,338, ARI-LAI cost €41,578 and OLZ-LAI cost €49,706. The relative costs were: RIS-LAI (41%) followed by OLZ-LAI with 36%, RIS-LAI with 34% and ARI-LAI with 30%. PP-LAI also had the lowest rates of all negative outcomes. Re-hospitalization rates were 10.1%, 12.5%, 14.2% and 12.2% for PP-LAI, RIS-LAI, ARI-LAI and OLZ-LAI, respec-
tively. PP-LAI had 24.0% (95% CI 22.0%-26.0%) of being cost-effective at €20,000 willingness-to-pay threshold. CONCLUSIONS: PP-LAI was shown to have the lowest cost and best clinical outcomes, and hence should be the atypical LAI of choice.

PMH30

THE COST EFFECTIVENESS OF GROUP ART THERAPY FOR PATIENTS WITH NON-PSYCHOTIC MENTAL HEALTH DISORDERS IN ENGLAND AND WALES

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OBJECTIVES: Art therapy provides an alternative to standard forms of psychological therapy. We estimated the cost-effectiveness of group art therapy for people with non-psychotic mental health disorders in England and Wales. METHODS: The economic model was constructed with the following assumptions that: the maximum treatment effect would be associated with the time at which treatment ended; there would be a discount rate for other non-treatment years, and the model did not consider the costs of treatment at 52 weeks after treatment ended; there would be a residual effect of treatment with a linear decline in benefit until there was zero benefit at 52 weeks; given the short assumed duration of treatment, discounting was not necessary. Two RCTs identified in an accompanying clinical review provided data from which EQ-5D values could be estimated via map-
ing allowing comparisons to be made of group art therapy with wait-list control and with group verbal therapy. Scenario analyses altering the cost per patient and the threshold for discounting residual benefit were conducted. RESULTS: Art therapy compared with wait-list control had a mean cost per quality adjusted life year (QALY) below €16,000 per QALY gained (equal to the GDP per capita of Greece).
£500 for all scenarios and a 100% probability of being cost-effective at a willingness-to-pay £30,000 per QALY. Verbal therapy compared more cost-effective than art therapy with a cost per QALY below £1000 but there was considerable uncertainty in the decision and a sizeable probability (20%) that art therapy was dominant. In neither comparison was the art therapy intervention similar to that employed in England and the model assumed that the health state was not explicitly diagnosed with non-psychotic mental disorders. As such, the generalisability of the results to practice in England and Wales is uncertain. CONCLUSIONS: Art therapy was more cost-effective versus wait-list but uncertain value compared with verbal therapy. Consensus statements are required to allow more definitive statements to be made.

PMH31 COST-EFFECTIVENESS OF LITHIUM VERSUS AN ATYPICAL ANTI-PSYCHOTIC (AAP) USED TO AUGMENT TREATMENT WITH A SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRI) IN TREATMENT RESISTANT DEPRESSION (TRD)

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OBJECTIVES: To estimate the cost-effectiveness of augmentation of SSRI antidepressants with AAP (i.e. lithium) versus a selective serotonin reuptake inhibitor (SSRI) in patients with treatment-resistant depression (TRD). METHODS: A de novo probabilistic economic model was developed to synthesise the available data on costs and clinical effectiveness of lithium versus AAP and SSRI treatment in TRD, based on systematic reviews and international guidelines. Model outputs were an incremental cost-effectiveness ratio (ICER) and uncertainty was characterised using cost-effectiveness acceptability curves. RESULTS: The model is highly sensitive to changes in the effect of lithium versus the SSRI on clinical outcomes. Lithium was associated with lower remission rates and more relapses compared to all atypical LAIs. Oral therapies were less expensive but associated with lower levels of QALYs and oral risperidone was associated with the highest number of QALYs (ICER of £23,675/QALY compared to oral risperidone, £15,258/QALY to oral paliperidone and £35/QALY to long-acting risperidone). The robustness of the model was supported by one-way deterministic analysis and probabilistic sensitivity analysis, which gave stable results. The cost-effectiveness of lithium compared to oral risperidone was more uncertain than oral paliperidone and long-acting risperidone. Conclusions: The treatment of schizophrenia using long-acting paliperidone was more cost-effective than lithium. The cost-effectiveness of the simulations compared to oral risperidone, long-acting paliperidone treatment gained incremental 0.903 QALYs on average compared to oral risperidone. CONCLUSIONS: The treatment of schizophrenia using long-acting paliperidone was more cost-effective than lithium. The cost-effectiveness of the simulations compared to oral risperidone, long-acting paliperidone was more uncertain than oral paliperidone and long-acting risperidone.

PMH34 COST-UTILITY OF VORTIOXETINE IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER: COMPARISON WITH AGOMELATINE, BUPROPION, SERTRALINE AND VENLAFAXINE IN THE FINNISH SETTING

To estimate the cost-effectiveness of augmentation of SSRI antidepressants with AAP (i.e. lithium) versus a selective serotonin reuptake inhibitor (SSRI) in patients with treatment-resistant depression (TRD). METHODS: A de novo probabilistic economic model was developed to synthesise the available data on costs and clinical effectiveness of lithium versus AAP and SSRI treatment in TRD, based on systematic reviews and international guidelines. Model outputs were an incremental cost-effectiveness ratio (ICER) and uncertainty was characterised using cost-effectiveness acceptability curves. RESULTS: The model is highly sensitive to changes in the effect of lithium versus the SSRI on clinical outcomes. Lithium was associated with lower remission rates and more relapses compared to all atypical LAIs. Oral therapies were less expensive but associated with lower levels of QALYs and oral risperidone was associated with the highest number of QALYs (ICER of £23,675/QALY compared to oral risperidone, £15,258/QALY to oral paliperidone and £35/QALY to long-acting risperidone). The robustness of the model was supported by one-way deterministic analysis and probabilistic sensitivity analysis, which gave stable results. The cost-effectiveness of lithium compared to oral risperidone was more uncertain than oral paliperidone and long-acting paliperidone was more uncertain than oral paliperidone and long-acting risperidone. Conclusions: The treatment of schizophrenia using long-acting paliperidone was more cost-effective than lithium. The cost-effectiveness of the simulations compared to oral risperidone, long-acting paliperidone was more uncertain than oral paliperidone and long-acting risperidone.

PMH35 COST-UTILITY OF VORTIOXETINE IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER

Vortioxetine was dominant from the payer's and societal perspective versus all comparators. It was projected to result in QALY gain of 0.013, 0.017, 0.025 and 0.028, and £223 (£1074), £128 (£957), £110 (£720) and £238 (£1390) direct (total) annual cost saving compared to agomelatine, bupropion, venlafaxine and sertraline respectively. These results were confirmed to be robust in several sensitivity analyses. CONCLUSIONS: Vortioxetine dominated agomelatine, bupropion, venlafaxine and sertraline in Finland and appears to be a relevant treatment option for MDD patients who need a therapy switch.
PMH36
ECONOMIC EVALUATION OF AGOMELATINE FOR MAJOR DEPRESSIVE
DISORDERS RELATIVE TO OTHER ANTIDEPRESSANTS IN THE ITALIAN
SETTING
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OBJECTIVES: The purpose of the present study is to conduct an economic evaluation of Agomelatine vs the current alternatives in daily clinical practice for treating patients with major depression disorders (MDD) in Italy (Venlafaxine, Fluoxetine, Sertraline, Escitalopram and Duloxetine). METHODS: Using a Markov model-based cost-effectiveness analysis, Agomelatine was compared with other therapies used for the treatment of MDD commonly prescribed (Venlafaxine, Fluoxetine, Sertraline, Escitalopram and Duloxetine), chosen on the basis of market share, and compared with placebo. The population considered in the model consists of patients suffering from MDD and with an average age of 45 years. The perspective of the third party payer (Italian National Health Service) and the societal perspective were considered. RESULTS: The study shows that Agomelatine administration is linked with higher direct and indirect costs only when compared with Duloxetine (respectively €4,365 vs. €4,253 and €5,535 vs. €5,498). Nevertheless, Agomelatine has the higher efficacy in terms of the outcomes considered in the analysis. The societal perspective, Agomelatine is dominant against Venlafaxine, Escitalopram, Fluoxetine and Sertraline, since it is less expensive and more effective and cost-effective compared to Duloxetine since the incremental cost per QALY gained is €12,461. According to the perspective of the Italian NHS, Agomelatine is dominant versus Venlafaxine, Fluoxetine and Sertraline and is cost-effective in comparison to Duloxetine (€6,101 per QALY) and Escitalopram (€3,356 per QALY). CONCLUSIONS: The economic evaluation indicates that, with two-thresholds for health benefits, the cost effectiveness in terms of QALY is in Agomelatine’s favor and is less costly compared to generic Venlafaxine, generic Escitalopram, generic Fluoxetine and generic Sertraline and that Agomelatine is cost-effective compared to Duloxetine. In conclusion, according to its favorable tolerability profile and its proven efficacy, Agomelatine represents a powerful tool for many patients suffering from MDD, which may lead to both clinical and economic advantages.

PMH37
RETROSPECTIVE DATABASE STUDY ON HEALTH CARE RESOURCE UTILIZATION
OF PATIENTS INITIATING LONG-ACTING OLANZAPINE IN SWEDEN
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OBJECTIVES: Nowadays selective serotonin reuptake inhibitors (SSRIs) are the most frequent antidepressant drugs due to their better efficacy, tolerability, and safety, when compared to tricyclic antidepressants or monoamine oxidase inhibitors. However, despite this, especially at the beginning of treatment SSRIs are associated with side effects, which may lead to premature treatment discontinuation, in some cases. Assessment of these factors was the aim of the present study. METHODS: This retrospective database analysis used data from 50,824 patients first time treated with SSRIs for major depressive disorder selected from a Electronic Medical Records (EMR) database (IMS Disease Analyzer) in Germany, providing information on SSRI side effects and their influence on premature treatment discontinuation calculated by regression analysis. In addition to this, to assess the cost of SSRIs, we needed to study the cost of continued treatment to medication. RESULTS: Mean age was 54 ± 18 years, mean duration of treatment was 13.6 months and 54.5 ± 19 years with two-thirds of study population being female. The most common SNRI and SSRI were Duloxetine (respectively 33.9% and 28.7%) and Escitalopram (3,336 /QALY) and Escitalopram (3,356 €/QALY). In conclusion, according to its favorable tolerability profile and its proven efficacy, Agomelatine represents a powerful tool for many patients suffering from MDD, which may lead to both clinical and economic advantages.

PMH38
USE OF SERVICES AND COST OF AGITATION AND CONTAINMENT IN
PSYCHIATRIC HOSPITALS A SYSTEMATIC REVIEW
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OBJECTIVES: The aim of this study was to evaluate the use of services and costs related to agitation and containment of adult patients admitted to a psychiatric hospital. METHODS: Systematic review through searches of Pulbmed, CINAHL, and Web of Knowledge (using a wide variety of terms related to agitation, inpatient care and use of services/costs), bibliographic references in retrieved studies and expert consultation. Studies published since 1998 were selected in duplicate by reviewing abstracts and full-text papers. RESULTS: After removing duplicates, 372 papers were reviewed and 11 included in the review. Four studies were of high quality, 4 of moderate-high to moderate-low quality and three of low quality. Eight of the studies evaluated the effect of agitation and containment of patients in comparison with non-agitated patients. Two studies evaluated medication, one showed that the mean medication dose was higher in agitated patients and the other found higher costs of treatment compared to non-agitated patients in the unadjusted analysis. Another estimated the cost of containment of alcohol, medication side effects, existing denial of illness and use of traditional medicine. CONCLUSIONS: The level of agitation to antidepressant this finding will help psychiatric to improve adherence and clinical outcome by addressing medications taking behavior using a systematic approach based in this finding.

PMH41
ADHERENCE TO PSYCHOTROPIC MEDICATIONS BY OUTPATIENTS IN
PSYCHIATRIC HOSPITAL, USELU BENIN CITY, NIGERIA
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OBJECTIVES: Patients adherence therapies are essential for evaluating the quality of care delivery of a health facility and patients’ role in improving their conditions. The objective of this study is to determine the level of adherence of outpatients to psychotropic drugs and evaluate the impacting factors. METHODS: The study was a cross-sectional study done at the psychiatric hospital, Useelu, Benin city, Nigeria from April to September, 2013. Convenient sampling method was used in population size determination for data collection. The participants were adult patients (18 years and above) attending the outpatients psychiatric clinic of the hospital with diagnosis of various psychiatric illnesses. A total of 250 patients participated in the study and a well-structured self-report 10-item questionnaire using the medication adherence rating scale (MARS) was used. Additioanl information was patients’ socio-demographic profile and clinical variables that affect patients’ adherence to medications. RESULTS: The study adherence rating scale (MARS) was used. Additional information was patients’ socio-demographic profile and clinical variables that affect patients’ adherence to medications. The level of adherence to psychotropic medications was 63.6% and factors found to significantly affect include medication side effects per clinic visit, perception of social support, interaction of alcohol, medication side effects, existing denial of illness and use of traditional medicine. CONCLUSIONS: The level of adherence to psychotropic medications was fairly high and factors that were significantly related to adherence status were amount spent per clinic visit, perception of social support, intake of alcohol, medication side effects, existing denial of illness and use of traditional medicine.
PMH42 TREATMENT CONTINUATION AND TREATMENT CHARACTERISTICS OF 3 LONG-ACTING ATYPICAL抗性 drugs: paliperidone palmitate, risperidone microspheres and haloperidol decanoate were evaluated in the Belgian outpatient setting using panel data from public pharmacies. Drug dosage, age distribution and frequency of co-prescribed antidepressant medications were investigated. METHODS: IMS LifelineTM Treatment Dynamics database was used, selecting appropriate prescription criteria. Three patient cohorts that started paliperidone palmitate, risperidone microspheres or haloperidol decanoate treatment respectively, between 1 December 2011 and 31 August 2012, were analyzed. All cohorts included at least 13 months of follow up. Treatment continuation was investigated. RESULTS: After 90 and 180 days, more patients continued treatment with paliperidone palmitate (60.71% and 42.41%, respectively) than with risperidone microspheres (39.07% and 26.49%) or haloperidol decanoate (34.23% and 17.57%). Within 3 months after discontinuation, more patients restarted their treatment when using paliperidone palmitate (41.0%) compared to risperidone microspheres (27.6%) or haloperidol decanoate (17.4%). For all therapies, dosing was comparable between treatment initiation and discontinuation. Patients treated with paliperidone palmitate were generally older and more likely to have comorbidities than patients treated with the other two therapies. Overall, 18% of patients discontinued treatment with atypical antipsychotics due to adverse effects. CONCLUSIONS: Results of the database research indicate that more patients treated with paliperidone palmitate continued their therapy, restarted therapy and were of younger age than patients receiving risperidone microspheres or haloperidol decanoate. Monitoring and managing treatment is needed for all three therapies, but especially for paliperidone palmitate, where more patients withdrew treatment due to adverse effects compared to the other therapies.

PMH43 DESCRIBING THE HEALTH STATUS OF SCHIZOPHRENIA CAREGIVERS IN THE UK

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OBJECTIVES: Research indicates schizophrenia is a cause of burden for patients and caregivers. This study examined health-related quality of life (HRQoL) and comorbidities experienced by schizophrenia caregivers compared to non-caregivers and caregivers of other conditions. METHODS: The caregiver burden subscale of the CarerQoL12 was used to evaluate the ability of existing patient-reported outcome (PRO) measures to assess anxiety among patients with obstructive pulmonary disease (COPD). In addition, the estimated mean utility of the cohort was significantly lower than 0.81, the value that would be predicted in the general population given the age and gender characteristics of the cohort. CONCLUSIONS: Informal caregivers have significantly lower HRQoL than age-matched controls. While it is not possible to draw firm conclusions around the estimated mean utility of the cohort, the lack of control arm, the evaluation of a carer breaks service indicates a potentially modest benefit.

PMH45 THE IMPACT ON WORK AND SOCIAL ACTIVITIES AMONG CAREGIVERS OF CHILDREN WITH ADHD IN SWEDEN RELATIVE TO OTHER NORDIC COUNTRIES

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OBJECTIVES: To understand social and work impacts of caring for children/adolescents with attention-deficit/hyperactivity disorder (ADHD) in Sweden relative to a combined cohort of other Nordic countries (Denmark, Finland and Norway). METHODS: Carers in Sweden and other Nordic countries completed the Caregiver Perspective of Pediatric ADHD (CAPPA) online survey capturing carer impacts, providing data on work, social activity and health-related quality of life for the child's ADHD. Impacts were explored when the child was “on” and “off” medication (e.g. days medication not taken). Comparisons of “on” and “off” medication were examined using the Wilcoxon Signed-Rank test. No statistical comparisons of impacts were made between countries.

RESULTS: 215 Swedians and 249 other Nordic caregivers of ADHD children aged 6-17 years completed the survey. 37% of Swedish carers reported being late for work (18% vs 6%), compared to their child's ADHD; 52% of these changes occurred when the child was “on” medication. In the past 4 weeks, 60% of Swedish carers reported missing work and 45% reported being late for work. After excluding outliers (n=15), mean number of hours missed was 4.32 (n=51, SD 3.53) and mean number of times late was 2.91 (n=59, SD 3.15). Swedish carers reported fewer “moderate” to “tremendous” impacts on social life when their child was “on” versus “off” medication (partner relationship strain 7% vs 67%, relationship strain with work 3% vs 57%, personal activity interference 40% vs 55%). Relative to other Nordic countries, more Swedish carers reported being late for work (36% vs 45%) and more “moderate” to “tremendous” interference with social activities while the child was medicated (3% vs 45%). All other impacts described were lower in Sweden compared to other Nordic countries. CONCLUSIONS: While medication helped, it did not completely alleviate child ADHD-related impacts on work and social activities among carers from Sweden and other Nordic countries.

PMH46 CONCEPTUAL COMPREHENSIVENESS OF ANXIETY INSTRUMENTS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: EXPLORING THE POTENTIAL FOR CONCLUDING SOMATIC INSTRUMENTS

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OBJECTIVES: The Anxiety Inventory for Respiratory disease (AIR) is a novel, non-proprietary PRO measure of anxiety among patients with chronic obstructive pulmonary disease (COPD), affecting up to 74% of patients. However, despite its prevalence, co-morbid anxiety remains under-recognised and under-managed. Furthermore, its identification and measurement can be confounded by the overlap of somatic symptoms with COPD. This study aimed to evaluate the ability of existing patient-reported outcome (PRO) measures to assess anxiety in COPD through conceptual mapping, with particular attention on the coverage of non-somatic anxiety symptoms. METHODS: To determine conceptual comprehensiveness, the content of 12 extant anxiety PROs was mapped to a conceptual model of anxiety in COPD, developed through a qualitative literature review and in-depth qualitative interviews (n=15) of COPD patients with anxiety. RESULTS: The conceptual model contained 29 concepts within five domains (somatic [15 concepts]; psychic tension [5 concepts]; apprehension [5 concepts]; panic [3 concepts]; behavioural [1 concept]). The most comprehensive conceptual coverage was found in the Mind Over Mood Anxiety Inventory which assesses 18/29 (62%) concepts across all five domains. Concept mapping revealed the majority of PROs were biased toward assessing somatic symptoms of anxiety, with no measure comprehensively assessing non-somatic concepts. Indeed, the two most widely used anxiety PROs in COPD research and clinical practice (Beck Anxiety Inventory [BAI] and Hospital Anxiety and Depression Scale) provide sub-optimal coverage of anxiety concepts. In particular, the BAI is heavily weighted toward assessing somatic concepts, with little focus on psychic, apprehensive, panic and behavioural concepts of anxiety. CONCLUSIONS: In light of the sub-optimal content validity of extant instruments, including those commonly used in research and practice, there is a clear need for a comprehensive and disease specific PRO for COPD. Such an instrument can be utilised in clinical trials for evaluating new products and enhancing the accuracy of anxiety screening and measurement in clinical practice.

PMH47 THE ANXIETY INVENTORY FOR RESPIRATORY DISEASE (AIR): AN EXPLORATION OF THE AIR’S PSYCHOMETRIC PROPERTIES THROUGH RASCH ANALYSIS

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OBJECTIVES: The Anxiety Inventory for Respiratory disease (AIR) is a novel, non-somatic patient-reported outcome (PRO) measure of anxiety among patients with chronic obstructive pulmonary disease (COPD). Traditional psychometric meth-
ods have demonstrated promising properties of the tool. However, traditional psychometric methods have clinically relevant limitations, including scaling and interpreting the data. The objective of this study was to evaluate the AIR’s strengths and weaknesses using more sophisticated Rasch Measurement Theory (RMT) methods.

**Methods:** Previously collected data from an observational study of 56 patients with current or remitted AUD (20 current AUD, 18 remitted AUD; 26 male, 12 female; age range 23-69 years) were analysed using RMT (conducted using RUMM2030 software) to evaluate scale-to-sample targeting, measurement adequacy and person reliability. **Results:** Person severity was well spread (<4.7% of variance accounted for at the lower end of the anxiety severity spectrum. Monotonic ordering of response categories for all 10 items suggested that the response options work as expected. Monotonic ordering of response categories for all 10 items indicated local dependency (range -0.6 to 2.04 logits) and suggested that the sample was well separated by the instrument. **Conclusions:** RMT analysis demonstrated that the AIR has promising measurement properties. Mis-targeting at the lower end of the severity spectrum is of minimal concern given the mild severity of the sample in this study. Further modifications to the instrument and appropriate to the target culture.

**PMH50**

**THE PATIENT EXPERIENCE OF ALCOHOL USE DISORDER**

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**Objectives:** Alcohol consumption carries a risk of adverse personal, social, and health effects. Alcohol use disorder (AUD) is a problematic pattern of alcohol use leading to clinically significant impairment or distress. The aim of this study was to describe the patient-perceived impact of AUD in the UK and France to identify key areas of impact from the patient perspective. The AIR was used to describe the patient’s experience. The aim of the analysis of the data was undertaken. **Results:** Ten focus groups were conducted with a total of 38 patients (20 current AUD, 18 remitted AUD; 26 male, 12 female; age range 23-69 years). All patients met the diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition). Demographic analysis of the data was undertaken. **Conclusions:** AUD and other alcohol-related problems have a significant impact on the patient’s life, their relationships, and their work. The AIR is appropriate to measure the impact of AUD on the patient’s life and has shown good construct validity.
Burden felt by the entourage was positively correlated with the physical and affective proximity between the interviewee and the drinker, particularly when the interviewee lives with him, and with the presence of social, behavioral and medical consequences of alcohol consumption (on average the number of medical comorbidities was 2.1 for ‘severe’ burdens vs 1.4 for ‘minimal’ burdens, p < 0.05). Disproportionate drinking had harmful effects on drinkers and his entourage. Our results demand greater recognition of caregivers’ burden in the management of patients with alcohol dependence and further support the need for improving alcohol dependence management and prevention of its development to reduce the global burden of alcoholism.

PMH53
QUALITY OF LIFE IN HOSPITALIZED SENIORS WITH PSYCHIATRIC DISORDERS
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OBJECTIVES: The number of these patients in Europe is increasing. The aim of our research study was to determine quality of life in the long term hospitalized seniors with psychiatric diseases and to determine to what extent the age and education affects the quality of life. METHODS: Two standardized questionnaires - WHOQOL-BREF (World Health Organization Quality of Life Assessment-Brief) and WHOQOL-OLD (World Health Organization Quality of Life Assessment-Old) were used in the study. The research sample consisted of 100 patients hospitalized in geriatric psychiatric department of a Woman’s Psychiatric Hospital in KromsBre. Patients were from 65 to 95 years old. Duration of hospitalization was from 2 to 12 months. Data were collected was in October 2012 - February 2013. RESULTS: Average score WHOQOL-BREF was lower than of the population norms. Satisfaction with health was lower than the assessment of quality of life. Assessment of the quality of life by older patients was lower than the assessment of quality of life by the younger patients. The physical and mental health of social relations were worst for patients with lower level of education. Other domains were worse evaluated by patients with higher level of education. Assessment domains WHOQOL. OLD values were lower than of population norms. Very low score, regardless of age and education, indicated greater impairments among undiagnosed vs. diagnosed respondents (n = 17,820) of an internet-based cross-sectional survey (the 2011 National Health and Wellness Survey fielded in Japan) were categorized according to depression diagnosis (diagnosed or undiagnosed) and severity (Patient Health Questionnaire-9 score ≥10 or <10). Work Productivity and Activity Impact questionnaire-based measures were predicted by diagnosis, severity and treatment.

PMH54
A POTENTIAL GENDER BIAS IN THE QUALITY OF LIFE - AN EXPLORATORY STANDARD GAMBLE EXPERIMENT AMONG ECONOMICS STUDENTS
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OBJECTIVES: To estimate determinants of quality of life of undergraduate Economics Students at the University of Vienna. METHODS: Quality of life values were elicited by means of the standard gamble approach. The impact of several variables such as gender, site, job, length of study and living arrangements on the quality of life were identified using different types of regression techniques (OLS, GLM, Betafit). RESULTS: The observed gender differences in quality of life can be attributed to a higher level of stress and risk aversion among women. A higher risk aversion leads to a higher valuation of health states and a potential gender bias in health economic evaluations.

PMH55
ECONOMIC EVALUATION OF DIALECTICAL BEHAVIOR THERAPY (DBT) AMONGST THOSE WITH BORDERLINE PERSONALITY DISORDER (BPD) WHO ENGAGE IN SELF-HARM IN IRELAND
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OBJECTIVES: This study examines the cost effectiveness of Dialectical behavior therapy (DBT) amongst those with borderline personality disorder (BPD) who engage in self-harm compared to treatment as usual (TAU) in Ireland. DBT is a comprehensive cognitive-behaviour treatment, which has been demonstrated to be effective in reducing suicidal behavior, hospitalizations, etc. The programme consists of group therapy and individual therapy, running for 24 weeks in total. METHODS: A decision analytical model is developed to conduct the economic evaluation. The perspective taken is that of the health care provider/professional (HSE). Costs of the treatments were identified, measured and valued. This included direct costs of DBT and TAU, as well as additional resources consumed (emergency department, outpatient and inpatient attendances). Relevant health effects of the treatments were measured using a variety of condition specific and generic measures including the Beck Depression Inventory, Borderline Symptom Checklist and EQ-5D. These measures were collected at baseline, six months and 18-month intervals. RESULTS: Sensitivity analyses were performed to assess the robustness of the analysis, employing a Monte Carlo simulation, is performed. RESULTS: Preliminary results indicate there are additional costs associated with DBT compared to TAU. With regard to effectiveness, there were no significant differences in treatment success rates with the two interventions. However, patients treated with DBT had a significantly lower number of emergency department, out-patient and in-patient stays, higher utilisation and better scores on all health condition specific measures. The reduction in health service utilizations represents cost savings to the health care provider and payer. CONCLUSIONS: This is first economic evaluation of DBT in Ireland. The results suggest that the intervention is cost effective when compared to no pharmacological treatment. METHODS: A retrospective cohort analysis was performed using insurance claims extracted from the US Truven Health MarketScan® Medicaid database from January 2007 to December 2012. Two groups were compared: 1) patients with opioid prescription drug (OPD) dependence treated with buprenorphine/naloxone and 2) patients with opioid prescription drug (OPD) dependence and no pharmacological treatment. Final study groups were selected with one-to-one matching on demographic characteristics, comorbidities at baseline and cost of outpatient and inpatient care over six months before index date.
Resource use (pharmacy claims, outpatient claims, emergency room admission and hospital admission) and corresponding costs over twelve months after index date were compared between groups. RESULTS: Each group included 362 patients. Patient characteristics at baseline, resource use, and health care costs before index date were comparable between the two groups. At twelve months after the index date, 91% of patients with schizophrenia were in the LAI group and 6% in the oral group, respectively. The treatment cost for LAI was higher (p < 0.001). The unadjusted difference-in-difference analysis showed a relative reduction in total health care costs of $4,997 in the LAI cohort compared to the oral cohort. CONCLUSIONS: Initiating treatment with an LAI resulted in greater reductions in hospitalizations and ER visits compared to oral second generation antipsychotic medications in patients with schizophrenia or bipolar disease.

PMH63

ANTIDEPRESSANT USE AND SUICIDE RATE IN ENGLAND: THE GEOGRAPHIC DIVIDE

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OBJECTIVES: Mental illness is widespread, with 1 in 3 people worldwide reporting symptoms indicative of a psychiatric disorder at some point in their lives. The use of antidepressants and with it, serious and potentially lethal side effects, is associated with a suicide rate, and the correlation between these two measures was found to be significant. The aim of this research is to analyse the use of antidepressants in England and identify any trends.

METHODS: Antidepressant prescribing was obtained from the Electronic Prescription Service (EPS) in England for all patients on antidepressants in 2011. The number of antidepressants prescribed per 1,000 population was calculated for each of the four NHS regional area teams (North, Midlands & East, London, and South) and analysed against population size and suicide rate. RESULTS: Antidepressant use in England has increased dramatically in recent years and coincides with a year-on-year drop in ingredient costs, with 27.7 million prescriptions in 2003 and a net ingredient cost of £211.1 million. From 2010 to 2014, almost £1 billion has been saved. The average number of prescriptions per 1,000 population was 1,140.7, 987.4, 888.2 and 540.5 in the North, Midlands & East, South and London, respectively. These figures were correlated with a suicide rate of 9.87 and 7.05 per 100,000 people in the North and London, respectively. CONCLUSIONS: There is a clear divide within regions of England regarding antidepressant use and suicide rate, and the correlation between these two measures was found to be opposite to that reported for Europe generally. These findings highlight the importance of understanding mental illness and the underlying reasons for the wide disparity in England.
linkage between the pharmaceutical database and the SANAR database, using anonymous patient data. Based on the drug database of the first on the market, the following prescribing patterns have been defined: continuous (subjects with a gap <30 days between two prescriptions on-going), intermittent (subjects with a gap >30 days but that receive another prescription at index date), switchers (discontinuation of one drug and prescription of a new antidepressant), add-on (addition of a new antidepressic), as-needed (addition of a new antidepressic for a limited period).

RESULTS: We identified 2,768 patients (44.5% females) with at least one prescription of a typical antidepressic and with a diagnosis coded in the study period. Schizophrenia is the most frequent indication (31.1%) the most prescribed drug is olanzapine (29.1%), followed by risperidone (17.7%), quetiapine (13.4%), aripiprazole (22.5%), clozapine (10.3%) and asenapine (3.1%). About 70% of schizophrenic patients is treated with the same drug and 20% switch 2-3 times during the study period.

CONCLUSIONS: The use of SANAR, web-platform to allow the systematic monitoring of prescribing patterns of drugs, is of primary importance for better health planning.

PMH65 MAINTENANCE DAILY DOSE OF VENLAFAXINE AND DULOXETINE IN THE MONOTHERAPY OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER RESISTANT TO SELECTIVE-SEROTONIN-REUPTAKE-INHIBITORS IN ROUTINE CLINICAL PRACTICE IN SPAIN

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OBJECTIVES: Major Depressive Disorders (MDD) guidelines recommend using antidepressants with dual mechanism-of-action (venlafaxine, duloxetine) when resistance to a prior new treatment of Selective-SEROTONIN-REUPTAKE-INHIBITORS is observed. These guidelines do not indicate to use should be close to the RDD recommended by WHO. Routine clinical practice may be frequently far from this guideline. The aim was to ascertain the average maintenance daily dose of venlafaxine and duloxetine in the monotherapy of patients with MDD who showed resistance to a previous SSRI in routine medical practice in Spain.

METHODS: Retrospective analysis extracting consecutively electronic medical records (EMR) of the BSA, a provider which health plan coverage includes near 120,000 inhabitants in Badalona (Spain). EMR of male/female patients >18 years, included in the chronic prescription follow up program, with a MDD ICD-9-CM code (296.2x/296.3x), and who were resistant to a previous SSRI course, were extracted for analysis. Resistance was defined as persistence of symptoms (score >7 in the Hamilton-Depression scale and/or reduction lower than 30% of the baseline score). Maintenance DD was considered the dose repeated (refills) at least two times consecutively during the study period (years 2012-2015). RESULTS: Three-sixty-one EMR (Gender: 60.3% (15-25 years) were women). Very few were venlafaxine and 208 of venlafaxine. Average maintenance DD were 65mg/day and 117 mg/day for duloxetine and venlafaxine, respectively. Demographics, number of comorbidities or previous SSRI were not related with average dose. 86% of duloxetine EMR were prescribed the WHO RDD for this drug (60mg), while only 42% of venlafaxine received its WHO RDD (100mg), p<0.001. Number of DD per day were significantly higher with venlafaxine, 1.7 (1.0-10.3) vs. 1.9 (1.0-11.9), p=0.004. CONCLUSIONS: Routine clinical practice may be frequently far from guidelines. Studies are needed in order to ascertain the relationship between gender and age specific suicide rates and unemployment, economic evaluations. RU data should reflect how patients are actually treated. In Spanish patients, countries and subgroups and assess their transferability to other countries.

PMH69 THE IMPACT OF ECONOMIC CRISIS ON SUICIDE RATES IN GREECE

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BACKGROUND AND OBJECTIVES: Economic crisis in Greece has several social implications, as unemployment and poverty have largely increased during the past years. Suicide rates in the Greek general population and among the elderly have also increased in the last two decades, showing a 22% increase in the period 2001-2012. Therefore, aim of this study is to investigate the relationship between suicides and the economic crisis and certain macroeconomic indices. METHODS: Annual suicide rates were obtained from the Hellenic Statistical Authority. Multiple linear regression models were constructed to examine the relationship between gender and age specific suicide rates and unemployment, GDP per capita and economic crisis (binary variable). Additionally, several statistical tests were conducted in order to examine the properties and the robustness of the model. RESULTS: Unemployment appears as the major factor affecting suicides of men and women above the age of 15. However, gender and age-related differences are being observed. Unemployment is positively associated with the suicides of men aged 15-24 (p=0.018), while 55-64 age group (p=0.021). Besides, unemployment rates (p=0.002) were significantly higher among women aged 45-54 years old. Interestingly, suicides of women aged between 45-54 and 55-64 were negatively associated with economic crisis. In the total population, unemployment has an inverse impact on suicides. However, economic crisis affects suicide rate in the age group of 25-34. In addition, GDP per capita is negatively associated with suicide rates for young men (aged under 24).

The current economic turmoil in Greece affects suicides deaths. According to this analysis, unemployment is the major factor that determines age-specific rates and essentially point to the direction where measures should be taken in order to control suicides incidence and lessen the effect of economic crisis on health.
identifying Veterans at risk for poor mental health may be working to provide health care benefit coverage but the persistence of symptoms, amongst those enrolled, may suggest a need for improved treatment or surveillance.

PMH71

HISTORY OF ANTIPSYCHOTIC USE AMONG PRIMARY CARE DEPRESSED PATIENTS SWITCHING TREATMENTS IN THE UNITED KINGDOM

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OBJECTIVES: Major depressive disorder is characterised by the presence of one or more major depressive episodes. Up to one-third of patients do not adequately respond to first-line therapies. In case of treatment failure, the most common strategy is to switch to another antipsychotic drug (AD). However, patients may have been exposed in prior episodes to one or more other ADs, which could impact the efficacy of subsequent treatments. This study describes historical AD use in depressed patients initiating treatment switching. This retrospective longitudinal cohort study used a database of medical records from general practitioners located throughout the UK (CPRD). Adult patients with a depression diagnosis undergoing an AD switch between 01/01/2012 and 30/06/2013 and with no diagnosis of another AD after 6 months were included. Patients using VPA, a new anticonvulsant which may have anti-depressant properties, were excluded. The prevalence of AD use at 6 months was compared between patients taking VPA at baseline and those not. RESULTS: 1,555 patients were included. The use of ADs at 6 months was significantly more common in patients initiating a switch to VPA than in those not initiating a switch (27% vs. 18%, p<0.0001). Conclusions: In depressed patients with prior AD use, initiation of treatment with VPA was associated with a higher rate of AD use at 6 months. Initiation of VPA, which can switch from a depression adverse effect, may allow the use of VPA as a disease modifying AD switch treatment in some patients.
OBJECTIVES: Automated periorenal dialysis (APD) has been increasingly used since pyramidal scheme was extended to cover APD machine in addition to the continuous ambulatory periorenal dialysis (CAPD) in the benefit package of National Health Insurance Program in May of 2008. This study aims to compare the health outcome between patients who used APD and CAPD. METHODS: The including criteria were patients treated by APD or CAPD identified in National Health Insurance Research Database (NHIRD) during 2001-2010. The excluding criteria were patients who were treated by hemodialysis for more than 3 months before PD, or younger than 18 years, or patients who died or were kidney transplant before the PD. The APD patients and APD patients were identified and matched according to their propensity score predicted by age, gender, comorbid conditions, Charlson Comorbid Index, medication history, and premiums wages in the year of treatment initiation. There were 2,267 APD and 2,267 CAPD patients entered the final analysis. The Kaplan-Meier curves and Cox proportional hazard regression were performed to examine the differences in mortality rate, technique failure rate and incident rate of peritonitis between APD and CAPD patients. RESULTS: CONCLUSIONS: The APD patients seemed to have higher mortality rate and technique failure rate compared with the CAPD patients, however, APD patients had lower incidence rate of peritonitis than CAPD patients in Taiwan.

PUC1 A STUDY TO ASSESS DISEASE PROGRESSION TO ESRD WITHIN A YEAR IN PATIENTS WITH ADVANCED CKD

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OBJECTIVES: Aimed at determining the period time for the progression to ESRD and also to identify the risk factors for significantly progression to ESRD. METHODS: A retrospective cohort study was conducted in a tertiary care teaching hospital. The data was collected from medical record dept. for the last two years (2012 and 2013) in hospital. Demographic details and clinical parameters of ESRD patients with major risk factors determined by the study population were collected using the descriptive statistics feature of SPSS v20.0. RESULTS: A total of 240 patients were included in the study. The mean age of the population was found to be 54.6±14.2 years. Majority of the population were males (72.5%). Hypertension 67.1%, Diabetes 47.1% and CKD 72.5% took more than a year to progress to ESRD. CONCLUSIONS: The study revealed that males are at a higher risk of ESRD with than females. This study consisted of a small number of patients and more studies are required to generalize this findings. The study results confirmed that hypertension is the most common risk factor for ESRD followed by diabetes and anemia. Most of the CKD patients took more than one year to progress to ESRD (72.5%). This information helps physicians and patients inform decisions regarding preparation for renal replacement therapy in patients with advanced CKD.

PUC4 BE CAUTIOUS OF TRIPLE WHAMMY!!!

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OBJECTIVES: This study was aimed to identify the occurrence of concomitant pre-prescribing of NSAIDs, ACE Inhibitors (ACEI) and diuretics known as triple whammy recorded in patients at a Malaysian teaching hospital. It also aimed to identify the relationship between the prescriptions of triple whammy with specific age. METHODS: A retrospective, observational study was performed in a general teaching hospital. The patients’ prescriptions (January-March 2012) from the outpatient pharmacy department that were prescribed with NSAIDs, ACE inhibitors (ACEI) and diuretics were reviewed and recorded. The association between the prescriptions with age was investigated. Statistical analysis was done using SPSS with significance difference determined by p value of < 0.05. RESULTS: Four hundred and twenty four patients (56.1% male) were included. Four hundred and twenty two patients were taking one or more of NSAIDs, ACEI and diuretic and only 2 patients were taking all three. Majority of our patients (60.1%) received the combination of ACEI and diuretics. Combination of ACEI and diuretics were mainly (21.7%) prescribed to patients above 65 years old (p=0.362). CONCLUSIONS: The occurrence of triple whammy at a teaching hospital during the period of data collection is low. This is indeed a good predictor of safe prescribing in clinical practice.

URINARY/KIDNEY DISORDERS – Cost Studies

PUC5 A BUDGET IMPACT ANALYSIS (BIA) OF THE USE OF PARICALCITOL FOR THE TREATMENT OF SECONDARY HYPERPARATHYROIDISM (SHPT) IN END STAGE RENAL DISEASE PATIENTS

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OBJECTIVES: Budget impact analysis (BIA) of the use of paricalcitol versus alternative treatment for the management of secondary hyperparathyroidism (SHPT) in end stage renal disease patients. METHODS: A Markov model was used to simulate the evolution of end stage renal disease patients through transplant and death and to estimate associated direct health costs comparing the use of paricalcitol and different low dose vitamin D over a 5-years horizon and using the Italian National Health System perspective. The model was developed using parameters from literature and assumption discussed with clinicians. National tariffs and costs from literature were used to value drug use, dialytic treatment, hospitalizations and transplant. One-way sensitivity analyses for model inputs were conducted. Costs and effects were discounted at 3% annum. RESULTS: Considering 13,311 candidate subjects for each treatment strategy, results from the model showed a decrease in 5-years total cost savings from 1.762.921.351 Euros to 1.657.209.653 Euros in favor of paricalcitol over 5 years. Particularly, paricalcitol produced an overall saving in drug costs for more than 51 millions Euros while the other direct health costs related to dialysis, hospitalization and transplant were reduced by approximately 109 millions Euros. CONCLUSIONS: The high economic burden of end stage renal disease mainly associated with dialysis and transplant the use of paricalcitol for the treatment of IPTS in these patients represents a valid alternative not only from a clinical point of view but also from an economic point of view.

PUC6 ANALYSIS OF BUDGET IMPACT OF ANEMIA CORRECTION IN RUSSIAN PATIENTS WITH CHRONIC KIDNEY DISEASE

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OBJECTIVES: To analyze budget impact of strategies of anemia correction with different stimulators of erythropoiesis in patients with chronic kidney disease (CKD). METHODS: Pharmacoeconomic analysis included cost modelling for a new strategy for patients with CKD and anemia that includes the use of continuous erythropoietin receptor activator (CERA) compared with tradional darbepoetin alfa (as described in ARCTOS study). The model included two stages: 1. Estimation of costs in 18 week correction period (phase 1 study) and 2. Estimation of costs and effects in 12 month period (phase 2 study). Patients treated in 10 groups of 100 people, the first with CERA and the second with darbeopetin alfa. According to ARCTOS study, fewer patients treated with continuous erythropoietin receptor activator (CERA) reached the target Hb < 12 g/dl. The costs in darbeopetin alfa group were 2.7 times higher compared with CERA in respect of blood transfusion and 2 times higher in respect of drug administration. The cost of chemotherapy in CERA group was significantly lower in group of darbeopetin alfa. Total costs in CERA group were 1.7, 1 times lower than those for darbeopetin alfa. CONCLUSIONS: The study demonstrates that administration of CERA is the most economically effective strategy for the treatment of patients with chronic kidney disease (CKD) in Russia. It is associated with considerably lower costs compared to darbeopetin alfa.

PUC7 BUDGET IMPACT EVALUATION OF TREATMENT WITH A LOW PROTEIN DIET AND KETOANALOGUES OF ESSENTIAL AMINOACIDS FOR PREDIALYSIS PATIENTS IN RUSSIAN FEDERATION

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OBJECTIVES: To evaluate budget impact of low protein diet (LFD) and ketoanalogues of essential aminoacids for predialysis patients in Russian Federation. METHODS: A prevalence-based, deterministic budget impact model with a five-year time horizon was developed from the perspective of the Spanish health care system. The effectiveness of LFD and ketoanalogues in controlling proteinuria, delaying start of dialysis at least for one year. The following prices were used: rates of hemodialysis, hospitalization and transplant were reduced by approximately 109 millions Euros. CONCLUSIONS: The high economic burden of end stage renal disease mainly associated with dialysis and transplant the use of paricalcitol for the treatment of IPTS in these patients represents a valid alternative not only from a clinical point of view but also from an economic point of view.

PUC8 A MATHHEMATIC MODEL TO INVESTIGATE THE BUDGET IMPACT IN SPAIN OF ONABOTULINOUMTOXIN A TO MANAGE URINARY INCONTINENCE IN PATIENTS WITH IDIOPATHIC OVERACTIVE BLADDER

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OBJECTIVES: Treatment options for patients for whom urinary incontinence (UI) due to idiopathic overactive bladder (OAB) is inadequately managed by anticholinergic therapy are limited, and can be expensive, invasive and inefficacious. This can lead to a significant economic burden to hospitals and health care systems. OnabotulinumtoxinA may provide an effective and minimally-invasive treatment option. An economic model developed to explore the potential cost savings associated with the use of OnabotulinumtoxinA – as an adjunct to best-supportive care (BSC) – to manage OAB rather than other treatment options in Spain. METHODS: A prevalence-based, deterministic budget impact model with a five-year time horizon was developed from the perspective of the Spanish health care system.
system. The model took into account the cost of drugs, disposables (e.g. incontinence pads), and devices, procedures, monitoring costs, and the cost of managing adverse events. Model input data were derived from the Spanish Ministry of Health, published and unpublished clinical studies, clinical guidelines, and expert opinion. RESULTS: In the Spanish population, an estimated 96,360 individuals were eligible for treatment with intermittent catheterization. The main cost component was the cost of catheters and the overall estimated additional cost compared to the current treatment in which 5% of patients received OnabotulinumtoxinA, increasing OnabotulinumtoxinA usage annually from 10% in year 1 to 30% in year 5 resulted in an estimated cost saving of €24.6 million in 5 years. This saving represented a 4.7% decrease in overall spending compared to the current treatment pattern. Increased drug acquisition costs were entirely offset by savings due to decreased use of incontinence pads and anticholinergic therapy. CONCLUSIONS: Costs associated with inadequate management of UI due to CVD and T2DM are significant and avoidable. Our model estimated that OnabotulinumtoxinA may reduce the economic burden to the Spanish health care system, with increased acquisition costs of OnabotulinumtoxinA completely offset by savings due to decreased resource use.

PUK10
THE IMPACT OF CARDIOVASCULAR DISEASE AND TYPE 2 DIABETES MELLITUS ON SOCIAL COST IN CHRONIC RENAL DISEASE PATIENTS IN ITALY
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OBJECTIVES: Chronic kidney disease (CKD) is leading condition of several comorbidities with additional social economic burden. The study aims to estimate the economic impact of cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM) on social cost of a patient with CKD (stage IV and V pre-dialyses) in Italy. METHODS: All adults aged ≥18 years, enrolled in 14 main Hospitals in Tuscany region, were included. The annual total costs were estimated by multivariate Generalized Linear Models (log link, Gamma family) adjusting for gender, age and stage of CKD. Costs are expressed in Euro 2012. RESULTS: Among 484 CKD patients enrolled, CVD and T2DM were found respectively in 214 (44%) and 171 (35%) patients. The raw estimated mean annual social costs were €11,375 (€7,480) per patient with CVD and €11,627 (€7,657) per patient with CVD-T2DM. Direct medical costs and indirect costs accounted respectively for 31% and 69% of social cost for CVD and 30% and 22% for CVD-T2DM. The incremental mental effects of having comorbidities on the overall social cost of CKD were €2,928 (95% CI: -1,660-14,176, p=0.000) for CVD and €2,640 (95% CI: €1,301-3,979, p=0.000) for T2DM. CONCLUSIONS: CVD and T2DM significantly increase the social cost of CKD and are important factors in the management of these patients.

PUK11
THE ECONOMIC COST OF URINARY TRACT INFECTIONS IN THE COMMUNITY: RESULTS FROM IRELAND
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OBJECTIVES: Urinary tract infections (UTIs) are the second most common bacterial infection in primary care and are often treated empirically with antibiotics. However, outside of the United States, there has been a lack of systematic cost-of-illness studies in UTIs. METHODS: The study was performed in the practices of 22 general practitioners (GPs) across the 22 practices was approximately one month. Total primary care costs (including antibiotics) to treat suspected UTIs were obtained from the University Hospital Galway laboratory. Health care costs were extracted included objectives, costing methodology, sources of data, disaggregated costs, and conclusions. Extracted included objectives, costing methodology, sources of data, disaggregated costs, and conclusions. RESULTS: Of 2,850 GP consultations, 57% reported having a UTI. Among 484 CKD patients enrolled, CVD and T2DM have been found respectively in 214 (44%) and 171 (35%) patients. The raw estimated mean annual social costs were €11,375 (€7,480) per patient with CVD and €11,627 (€7,657) per patient with CVD-T2DM. Direct medical costs and indirect costs accounted respectively for 31% and 69% of social cost for CVD and 30% and 22% for CVD-T2DM. The incremental mental effects of having comorbidities on the overall social cost of CKD were €2,928 (95% CI: -1,660-14,176, p=0.000) for CVD and €2,640 (95% CI: €1,301-3,979, p=0.000) for T2DM. CONCLUSIONS: CVD and T2DM significantly increase the social cost of CKD and are important factors in the management of these patients.

PUK12
A REVIEW OF COST OF ILLNESS STUDIES IN PATIENTS WITH END STAGE RENAL DISEASE
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OBJECTIVES: End-stage renal disease (ESRD) is a debilitating medical condition of chronic kidney failure. In ESRD, the kidneys are permanently impaired and patients require regular renal replacement therapy (RRT). In order to understand the economic burden of ESRD, this scoping literature review was undertaken to identify published cost of illness (COI) studies in ESRD. METHODS: The search strategy identified studies quantifying the economic burden of ESRD in USA, Canada, Japan, UK, France, Germany, Spain, and Italy. We searched electronic databases (MEDLINE, EMBASE, SCIENCE CITATION INDEX, NHSEED, HEED, CEAC REGISTRY, FAME-ITAY database) for manuscripts published between January 2003 and November 2013. Results were assessed for relevance by two reviewers. For eligible studies, data extracted included objectives, costing methodology, sources of data, disaggregated and aggregated costs, and conclusions. RESULTS: OF 2094 de-duplicated references identified, only 24 were manuscripts retained after review of titles/abstracts and 40 after full-text review. The majority of the studies used retrospective data; the most common country studied was the US (n=16); most studies (n=35) reported primary care costs only. The costs of ESRD patients with diabetes mellitus in the US and €184 million in the UK in 2013. Annual per-patient ESRD health care costs ranged from $US 35,917 (PF) in 2006 in Australia, to $US 96,014 (2002) in US patients with diabetes. Studies also reported national and patient level costs in transplant and dialysis. CONCLUSIONS: A number of manuscripts have quantified the cost of ESRD and demonstrate the substantial economic burden associated with the management of this patients.

PUK13
COST-UTILITY AND VALUE OF INFORMATION (VOI) ANALYSES ON THE FEASIBILITY OF A FUTURE RANDOMISED CONTROLLED TRIAL (RCT) OF INVASIVE URODYNAMIC TESTING PRIOR TO SURGERY FOR STRESS URINARY INCONTINENCE IN WOMEN
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OBJECTIVES: To assess the feasibility and VOI of conducting a definitive RCT to determine whether invasive urodynamic testing (IUT) is cost-effective compared with clinical assessment and cystoscopy for stress urinary incontinence (SUI). Methods: VOI analyses of ISUI and mixed urinary incontinence (MUI) to reframe the economic evaluation for a definitive RCT. METHODS: Cost-utility analysis was performed alongside a pilot RCT to estimate the cost and outcomes of the ‘IUT’ arm and the ‘no IUT’ arm after surgery. Health service resource use costs, utility values (from EQ-5D-3L and SF-12) and quality-adjusted life years (QALYs) were calculated. Expected value of sampling information (EVSII) analysis was used to determine the expected net benefit (cost utility) and the optimal sample size to maximise QALY in a future trial. RESULTS: At 6 months the average cost incurred in the ‘IUT’ arm was €154 less than the ‘no IUT’ arm (95% bootstrapped CI -315 to 24) and there was no evidence of a difference in effects (0.019 QALYs, 0.95% bootstrapped CI -0.028 to 0.013). IUT generated an incremental cost per QALY of £890. A sto-
OBJECTIVES: Conduct an economic evaluation of darbeoetin alfa for the treatment of anemia in patients with chronic kidney disease (CKD) on dialysis to obtain premarketing approval. The model is a Markov model developed to simulate patients on dialysis with CKD, and the effects of darbeoetin alfa on the anemia control was defined as the number of patients being alive, not hospitalised, nor transfused during the analysis period. Clinical inputs depend on dialysis target and on CKD as extracted from published studies. Cost inputs are drug acquisition, administration, hospital and clinical event costs, laboratory and hospitalisation and blood transfusion costs (2014). Analysis was conducted from a public, third-party-payer perspective.

RESULTS: For both dialysis target strategies in patients on HD and PD, darbeoetin alfa demonstrated the lowest overall costs per patient in control. As clinical time-cycles are identical across all scenarios, the overall costs per patient in control are mainly affected by drug acquisition costs and by ESAs doses. Treatment with darbeoetin alfa at target level (11±1) g/dL is associated with the lowest overall costs per patient in control at 18,210 and 16,689, for patients on HD or PD, respectively. CONCLUSIONS: Darbeoetin alfa may be the most cost-effective treatment compared to other ESAs for the management of anemia (CKD) in patients on HD or PD in Greece.

P1K6

COST EFFECTIVENESS OF SOLIFENACIN COMPARED WITH ORAL ANTIMUSCARINIC AGENTS FOR THE TREATMENT OF PATIENTS WITH OVERACTIVE BLadder IN THE UK

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OBJECTIVES: To evaluate the cost effectiveness of solifenacin 5mg compared with other oral antimuscarinic agents in adults with an OAB and a UK NHS payer perspective. The object of this study was to compare the cost effectiveness of solifenacin 5mg in the management of OAB and the efficacy and tolerability of antimuscarinics. A 5-year time horizon with monthly cycles was used in the base case. Five levels of symptom severity were used for transition into the appropriate (intolerance) (25 health states). Treatment with at least two antimuscarinic agents was assumed before patients received botulinum toxin. For each antimuscarinic, there was a probability of continuing or discontinuing medication, or switching to an alternative antimuscarinic with or without adverse drug effects. Resource utilisation inputs were based on a phase 3 study of solifenacin (Chapple et al. BJU Int 2004; 93: 303–10) and a mixed treatment comparison (results reported separately). Other model inputs were obtained from the literature or expert opinion. All costs were based on 2012/2013. Utilities were based on EuroQol-5D. Incremental cost-effectiveness ratios (ICER) were expressed as cost per quality-adjusted life year (QALY). Deterministic (DSA) and probabilistic (PSA) sensitivity analyses were performed. RESULTS: Solifenacin 5mg was dominant versus tolterodine extended-release 4mg, darifenacin 7.5mg, fesoterodine 4mg and solifenacin 10mg, and cost-effective versus darifenacin 15mg (ICER = £1117.32/QALY), fesoterodine 8mg (ICER = £2325.32/QALY), oxybutynin extended-release 10mg (ICER = £3117.92/QALY) and trospium 60mg (ICER = £3767.24/QALY). Both DSA and PSA showed that results were robust at a willingness-to-pay threshold of £20,000/QALY. At a cost-effectiveness threshold of £20,000/QALY, the probabilities that solifenacin 5mg was cost-effective versus compared with TRUS-Bx was USD 3,871.58. Strategy 2 (TRUS-Bx) would be more cost-effective if the cost of percent free PSA increased to USD 36.78 or if prostate cancer prevalence increased to 42%. CONCLUSIONS: The use of percent free PSA prior to TRUS-Bx may be a cost-effective diagnostic strategy and will become more cost-effective as prostate cancer prevalence increases in the ageing population and the free PSA test costs down.

P1K9

COST EFFECTIVENESS OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY AGAINST URETEROSCOPIC LASER LITHOTRIPSY FOR TREATMENT OF URETERAL CALCULI

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OBJECTIVES: To evaluate the cost-effectiveness of extracorporeal shock wave lithotripsy against ureteroscopic laser in the treatment of ureteral stones in the La Fe Hospital in Valencia. METHODS: A decision tree was performed to evaluate the costs and effectiveness of two treatment strategies (starting after diagnostic evaluation: ureteroscopy (URS), versus directly start with US). It was considered as a parameter of effectiveness, the ratio of patient with stone-free status or the presence of insignificant residual fragment (TR), ±1 mm. Subsequently, it was determined if the true cost-effectiveness ratio was dominant. Results of the decision tree, a sensitivity analysis of Monte Carlo with 1000 iterations was developed. Were available from a database of 162 patients treated for ureteral stones at the Hospital La Fe de Valencia. Of these, 77 were treated in lithotripsy sessions (27 % of whom had upper stones 1 cm), while 85 were referred directly to URS (the percentage of these patients with upper stones centimeter was 32.4 %). The unit cost of each treatment was calculated from data provided by the economic management of the Hospital La Fe and were 285.06 for each session in the case of ESWL and 1409.89 for URS. RESULTS: The overall effectiveness after four sessions of lithotripsy plus second line URS was 99.76%, while in the case of URS was 98.81%. The average cost of ESWL plus URS alternative was 881.59 euros, while in the case of the strategy of starting with URS was 1,496 euros. Therefore, the ESWL plus URS showed dominant versus first line URS. For both group upper and less than 1 cm also ESWL plus URS was dominant. CONCLUSIONS: Thus, the combination of first line lithotripsy plus second line ureteroscopic laser for treatment of ureteral calculi in terms of cost effectiveness.
performed using Monte Carlo technique. RESULTS: Annual patient costs of MMF were: $7,746.75, $7,993.03, $7,694.19 and $7,599.14 USD. For MPS the WTP was $7,673.35, $7,989.92, $7,605.80 and $7,920.64 USD with an incremental efficacy of 0.07 less graft rejection in AFD, IPMED, IMPAD and hemodialysis respectively in one year horizon. PSA shows consistency on model results. CONCLUSIONS: MPS was a dominant alternative having lower costs and more effectiveness than MMF. The results show possibilities to achieve cost-savings and a potential clinical benefit in renal transplants, from the perspective of the Mexican public health system, in specific from IMSS. *IMSS (Mexican Institute of Social Security)

PUK21

A COST-EFFECTIVENESS ANALYSIS OF ONABOTULINUMTOXINA VERSUS BEST SUPPORTIVE CARE (BSC) FOR THE TREATMENT OF ANTICHOLINERGIC TREATMENT-REFRACTORY NEUROGENIC DETRUSOR OVERACTIVITY (NDO) Hamid R.1, Loveman C.2, Milner C.2, Colaco J.1, Stanisic S.3, Gulyaev D.2

1Capsule Trust, 2Royal National Orthopaedic Hospital, London, UK, 3Allergan Holdings Ltd., Marlow, UK, 4Allergan, Inc., Irvine, CA, USA, 5The LASER Group, Milano, Italy, 6The LASER Group, Lorch, Germany.

OBJECTIVES: Uncontrolled NDO may lead to medical sequelae, such as upper urinary tract injury, incontinence, catheter failure. Treatment choices include BSC (compromised of behavioural therapy and pads, alone or in combination with clean intermittent catheterisation, and possibly with anticholinergics), onabotulinumtoxina, and surgery. The study’s objective was to determine the cost-effectiveness of onabotulinumtoxina 200 U vs. BSC among patients inadequately managed with anticholinergics in a UK setting. METHODS: A Markov model was developed to compare onabotulinumtoxina + BSC to BSC alone, with surgery as a downstream option. The inputs were based on published values derived from a UK preference elicitation study. Costs were obtained from various NHS sources. Model uncertainty was examined through deterministic and probabilistic sensitivity analysis. RESULTS: The base case incremental cost-effectiveness ratio (ICER) was £3,856, with an incremental cost of £1,692 and incremental benefits of 0.4387 quality-adjusted life-years (QALYs) for onabotulinumtoxina + BSC vs. BSC alone. Sensitivity analysis indicated that the main cost drivers are mean monthly use of catheters and treatment administration costs. Probabilistic sensitivity analysis suggested there would be 100% probability for patients with NDO who are inadequately managed with anticholinergics in a UK setting.

PUK22

COST-EFFECTIVENESS COMPARISON OF BOTULINUM TOXIN TYPE A PLUS BEST SUPPORTIVE CARE VERSUS BEST SUPPORTIVE CARE ALONE IN THE TREATMENT OF IDIOPATHIC OVERACTIVE BLADDER WITH URINARY INCONTINENCE AMONG PATIENTS NOT ADEQUATELY MANAGED BY ANTICHOLINERGIC THERAPY AND FAIL Safe

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OBJECTIVES: To assess the cost-effectiveness of botulinum toxin type A (BOTOX®) 100 U in the treatment of idiopathic overactive bladder (OAB) with urinary incontinence (UI) among patients inadequately managed by anticholinergics in France. METHODS: A 10 year Markov model divided into 3-month cycles was developed to predict the long-term costs and health outcomes of BOTOX + BSC vs. BSC alone. Incremental costs and QALYs were calculated for the transition from BSC alone to a societal perspective (excluding productivity loss) in France. Health states were determined by daily number of UI episodes. Patients discontinuing BOTOX and BSC due to lack of efficacy and patients inadequate managed with anticholinergics in France. RESULTS: The estimated treatment cost per patient per year with SC and LC was 1441,75€ and 1569,50€ respectively at the low dose regime (4000 mg of SC vs. 2000 mg of LC), while within the high dose regime (6400 mg of SC vs. 3000 mg of LC) it was 2306,80€ and 2354,26€ respectively. Expected cost savings (discounted) for the BOTOX+SC group in the 5 years period was €267.56. The model market shares were: 1 348 794 and 2 696 431 at the low dose regime, while at the high dose regime the estimated cost savings was between 501 59€ and 1 001 52€ respectively. The results of SA (discounted) showed that the major cost drivers in the treatment of hypertension were the unit costs of SC and LC.

CONCLUSIONS: The equal efficacy and lower cost of sevelamer carbonate than lanthanum carbonate when used for treatment of hyperphosphatemia in patients with CKD-ND in Bulgaria should be the decision-makers' alternative preference.

PUK23

A COST-EFFECTIVENESS ANALYSIS OF SEVELAMER CARBONATE IN NONDIALYSIS-DEPENDENT CHRONIC KIDNEY DISEASE (CKD) PATIENTS

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OBJECTIVES: In a 36-month, open label RCT that involved 213 patients in stage 3 nondialysis-dependent chronic kidney disease (CKD-ND), sevelamer carbonate showed lower rates of all-cause mortality and dialysis inception vs. calcium carbonate. The aim of this study was to assess the cost-effectiveness of sevelamer vs. calcium carbonate in NDD-CKD patients with hyperphosphatemia in Spain. METHODS: A Spanish National Health System perspective and lifetime horizon was chosen for the analysis. A Markov model was developed considering health states of “alive with NDD-CKD”, “alive with dialysis-dependent CKD”, and “dead”. All-cause mortality, dialysis inception, hospitalization (frequency and length of stay (LOS)), and drug dosage data were taken from the INDEPENDENT study. All-cause mortality and dialysis inception were extrapolated beyond 36 months using Weibull regression analysis. Local costs (euros, 2014) were applied to pharmaceutical, hospitalization and dialysis utilization. Health utility data was taken from the published literature. Costs and effects were discounted at a rate of 3%. RESULTS: In the base case analysis sevelamer was associated with increased survival, delay in dialysis inception, fewer hospitalizations, shorter LOS, 2.13 times life years gained (LYG) and 1.61 quality-adjusted life years gained (QALYs) vs. calcium carbonate. Increased survival translated into more treatment time and dialysis sessions vs. calcium carbonate, resulting in an incremental cost of 33.687 €. The incremental cost per LYG for sevelamer was £1,761 ($2,361) and the incremental cost per QALY gained was £29,857 ($38,907). Sensitivity analysis showed that sevelamer was more effective and less costly (i.e., dominant) vs. calcium carbonate in time horizons >1 year.

CONCLUSIONS: The analysis showed that sevelamer was a cost-effective strategy vs. calcium carbonate for the treatment of hyperphosphatemia in patients with NDD-CKD, with cost-effectiveness ratios well below the accepted thresholds of 30,000-40,000 i/QALY gained.

PUK24

BENEFIT-COST MINIMIZATION ANALYSIS USING THE DIRECT COSTS OF SEVELAMER CARBONATE AND LANTHAMNUM CARBONATE IN THE TREATMENT OF CKD-ND PATIENTS

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OBJECTIVES: Hyperphos­phatemia or elevated phosphorus in the blood is prevalent in patients with chronic kidney disease - mineral and bone disorder (CKD-MBD) and it contributes to morbidity and mortality. The objective of this study is to perform cost-minimization analysis of the newly available medicines sevelamer carbonate (SC) and lanthanum carbonate (LC), for the treatment of hypophosphatemia in patients with non-dialysis-dependent CKD (NDD-CKD) in Bulgaria. METHODS: The results of the head-to-head clinical trial conducted by Spraque (2009) demonstrated equivalent efficacy and safety profiles between the two treatment options. To differentiate the cost in high dose and low dose therapy, we performed minimization analysis. The expected cost saving was forecasted the expected cost savings for four years period. Discounting rate of 3.5% was applied. The robustness of the Results was tested through sensitivity analysis (SA) using tornado diagram. RESULTS: The estimated treatment cost per patient per year with SC and LC was €7,748.92, €7,993.03, €7,694.19 and €7,599.14 USD. For MPS were: €7,673.35, €7,989.92, €7,605.80 and €7,920.64 USD with an incremental efficacy of 0.07 less graft rejection in AFD, IPMED, IMPAD and hemodialysis respectively in one year horizon. PSA shows early KA initiation with LPD at eGFR 15-29 mL/min/1.73m2 would remain cost-effective if the reduction of eGFR decline associated with LPD plus KA was 13.5% or above. 10,000 Monte Carlo simulations showed early KA initiation with LPD at eGFR 15-29 mL/min/1.73m2. The robustness of the Results was tested through sensitivity analysis (SA) using tornado diagram. RESULTS: The estimated treatment cost per patient per year with SC and LC was 1441,75€ and 1569,50€ respectively at the low dose regime (4000 mg of SC vs. 2000 mg of LC), while within the high dose regime (6400 mg of SC vs. 3000 mg of LC) it was 2306,80€ and 2354,26€ respectively. Expected cost savings (discounted) for the BOTOX+SC group in the 5 years period was €267.56. The model market shares were: 1 348 794 and 2 696 431 at the low dose regime, while at the high dose regime the estimated cost savings was between 501 59€ and 1 001 52€ respectively. The results of SA (discounted) showed that the major cost drivers in the treatment of hypertension were the unit costs of SC and LC.

CONCLUSIONS: The equal efficacy and lower cost of sevelamer carbonate than lanthanum carbonate when used for treatment of hyperphosphatemia in patients with CKD-ND in Bulgaria should be the decision-makers' alternative preference.
OBJECTIVES: Anticholinergic drugs (ACHD) are an established first-line pharmacological therapy for overactive bladder (OAB). Despite the fact that many patients cycle through multiple antimuscarinics, there is limited evidence on the relationship between secondary care and patients whose OAB is inadequately managed with ACHD. The objective of this study was to analyze the variation in health care burden among patients who cycle through multiple ACHD. METHODS: A retrospective observational study was conducted to examine the relationship between health care burden and number of prior ACHD with each ACHD switch. Data was extracted from the Hospital Episode Statistics (HES) database and 3,059 GP practices for patients with a diagnosis for OAB, or any of the symptoms of OAB (frequency, urgency, incontinence, or nocturia) and with at least one prescription for an ACHD between April 2007 and March 2013. Treatment activity and cost burden (including bupenturine) were calculated using the health service (NHS) tariff prices to treatment activity. RESULTS: Overall, the number of patients identified was 13,117. Our analysis showed that there were increases of 70%, 40% and 10% in inpatient, outpatient and emergency settings respectively from the initial ACHD prescription to 3+ ACHD. This led to an increase in overall health care costs of 3% from the first 3+ to 6+ during each investigation period. CONCLUSIONS: OAB patients who are inadequately managed with ACHD place an increased burden on hospital resources. These findings emphasize the importance of identifying alternative ways to treat these patients to address the cumulative burden they place on health care systems.

**URINARY/KIDNEY DISORDERS – Patient-Reported Outcomes and Patient Preference Studies**

PUK27 ACCEPT® QUESTIONNAIRE: RELATION BETWEEN ACCEPTANCE AND COMPLIANCE IN LIVER- AND KIDNEY-TRANSPLANTED PATIENTS CONVERTED TO ONCE-DAILY TACROLIMUS

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OBJECTIVES: ACCEPT® is a 32-items self-administered questionnaire recently validated to measure patient acceptance to treatment. The objective of this study was to examine the relationship between treatment advantages and disadvantages as rated by the patient and may help predict adherence. The objective was to evaluate the relation between Acceptance and Compliance in liver- and kidney-transplanted patients converted to once-daily tacrolimus (TAC-OD). METHODS: 12-month observational, prospective, longitudinal, multicenter study conducted by 23 hepatologists and 56 nephrologists in France. 1106 adult patients with kidney and/or liver transplant, initiating TAC-OD during post-transplant follow-up were included. Acceptance and compliance were assessed 3 and 6 months after TAC-OD initiation using ACCEPT® and Compliance Evaluation Test questionnaires. RESULTS: Data from 271 liver-, 824 kidney- and 11 liver+kidney-transplanted patients were analyzed. Mean age was 52.4 ± 13.2 years, 61.5% of patients were male. Mean time between graft and TAC-OD initiation was 5.0 (4.9) years. Mean general acceptance score (range: 0-100) at 3 months was 75.4 ± 26.5. At month 6, 25.5% of patients had good treatment compliance, 68.0% non-compliant and 6.4% with treatment discontinuation. Total general acceptance score at month 3 was significantly associated with better compliance at month 6 (good compliance: 75 ± 25.7 vs. poor compliance: 68 ± 29.6), even after controlling for month 3 general acceptance score was particularly low in patients who specified at month 6 having 'omitted to take their treatment this morning' (N=44, mean: 41.7 ± 4.1) or ‘ever forgotten to take their treatment because their memory was failing’ (N=53, mean: 69.5 ± 29.7). Although not significant, the 17 patients who discontinued between April 2007 and March 2013 had less acceptance (N=44 ± 64 ± 36.5 vs. 75 ± 72 ± 59.5 in patients still treated with TAC-OD). CONCLUSIONS: This study highlighted a strong association between early Acceptance and late Compliance to TAC-OD. Further investigations are needed to explore how early detection of low acceptance can help patient management and improve long-term outcomes.

**PUK28 PERSISTENCE AND ADHERENCE WITH MIRABEGRON, A NEW BETA-3 RECEPTOR AGONIST, VERSUS ANTIMUSCARINICS IN OVERACTIVE BLADDER: EARLY EXPERIENCE IN CANADA**

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OBJECTIVES: To compare persistence and adherence with mirabegron versus antimuscarinic treatment for overactive bladder (OAB). METHODS: This was an exploratory analysis of retrospective claims data from the largest Private Drug Plan database in Canada. Patients aged ≥18 who had a first prescription claim for a target medication during the 4-month assessment period identified. A six-month evaluation period was used to categorize patients as ‘treatment-naive’ (no claims for OAB medication) or ‘treatment-experienced’ (≥1 prior medication) during this time. Time to end of persistence defined as the first gap in the treatment of ≥90 days or switching to another medicine (new medication) and adherence (calculated by medication possession ratio) were analyzed after six months. Hazard ratios (HR) with 95% confidence intervals (CI) were calculated for mirabegron versus each antimuscarinic, using Cox proportional hazards modeling. RESULTS: Data were analyzed for 13,391 patients (mirabegron, n=993). In the treatment-experienced cohort, six-month persistence was highest with mirabegron (51%), followed by solifenacin (39%) (HR 1.383, CI 1.109–1.726, p=0.004), ranging to 18% with oxybutynin (HR 2.848, CI 1.961–3.157, p<0.001). In the treatment-naive cohort, persistence was also highest with mirabegron (40%), followed by fesoterodine (24%) (HR 1.512; CI 1.333–1.716, p<0.001), ranging to 13% with oxybutynin (HR 2.315; CI 0.953–5.661, p=0.061). Median time to discontinuation was 183 (treatment-experienced) and 129 (treatment-naive), compared with 67–120 and 34–90 days with antimuscarinics, respectively. Mean adherence overall was 68% with mirabegron vs 39–55% with antimuscarinics (each p<0.05 vs mirabegron). CONCLUSIONS: Patients treated with mirabegron showed improved persistence and adherence compared with antimuscarinics. While differences in patient characteristics among the OAB drugs were accounted for within the model, these findings should be viewed in the light of the likely predominance of patients already on any new medication to the market; hence this sample may not be reflective of more mature usage.

**PUK29 TREATMENT DISCONTINUATION IN PATIENTS WITH URINARY INCONTINENCE SUFFERING FROM GLAUCOMA**

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OBJECTIVES: The frequency of side effects in the treatment with anticholinergic drugs is well described in a number of previous studies. However, little is known about the impact of side effects on therapy discontinuation. The aim of the present study was to estimate the frequency of glaucoma in association with urinary incontinence therapy begin and the impact of glaucoma diagnosis on the therapy discontinuation based on real life data. METHODS: Data from Disease Analyzer database including 988 general, 95 urologist and 203 gynecologist practices were used. 26,834 patients (17,125 female and 9,709 male) were identified to have received a first-time anticholinergic prescription of UI, namely darifenacin, fesoterodine, oxybutynin, tolterodine or trospium. Co-variates studied included demographic data, comorbidities and potential drug-induced side-effects. Glaucoma (H40) was defined as strict indication for the use of anticholinergic drugs. A Cox proportional hazards regression model was used to test the relationship between non-persistence and the diagnosis of glaucoma for up to 36 months. RESULTS: The proportion of patients that were diagnosed with glaucoma during the follow-up was very similar in the treated and placebo arms. 32 ± 8% of patients received a referral to an ophthalmologist and 0.3 ± 1.2% of patients were first time diagnosed with glaucoma. Not surprisingly, there was a highly increased risk for treatment discontinuation in patients having glaucoma (HR: 1.860, 95% CI: 1.002–3.441). CONCLUSION: Overall, the potential side effects including the aggravation of diagnosed glaucoma that were registered in the database were rarer than in clinical trials; most likely they were under-reported due to the nature of the registries to test, there was a significant impact of glaucoma on therapy discontinuation. This finding should be taken into account in clinical practice for the use of anticholinergic drugs in patients suffering from glaucoma.

**PUK30 HEALTH-RELATED QUALITY OF LIFE (HRQOL) OF ASIAN PATIENTS WITH END-STAGE RENAL DISEASE (ESRD) IN SINGAPORE**

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OBJECTIVES: This study aimed to assess the health-related quality of life (HRQOL) of ESRD patients in Singapore. METHODS: The Kidney Disease Quality of Life (KDQOL) instrument and questions assessing socio-demographic characteristics. Clinical data including co-morbidities, albumin level, haemoglobin level, treatment modality, and dialysis vintage (dialysis and dialysis adequacy) were retrieved from medical records. The 36-item KDQOL (KDQOL-36) were used to generate three summary scores (physical component summary [PCS], mental component summary [ MCS], kidney disease component summary [KDCS]) and two health utility scores (Short Form 6- Dimension [SF-6D] and EuroQol 5-Dimension [EQ-5D]). Multivariate analysis was performed to examine the association of demographic, social and clinical variables with each of the HRQOL scores. RESULTS: Five hundred and two patients were included in the study (HD: 236, PD: 266, mean age: 57.1 years, female: 47.6%). The mean (standard deviation [SD]) were PCS 37.9 (9.7), MCS 46.4 (10.8) and KDCS 5.7 (18.1); the mean (SD) of the health utility were 0.66 (0.12) for SF-6D and 0.60 (0.23) for EQ-5D. In multivariate regression analysis, factors found to be significantly associated with better HRQOL included: fewer co-morbidities, higher albumin level, and higher haemoglobin level with PCS and EQ-5D, higher albumin level with SF-6D; longer dialysis vintage with MCS, and Malay ethnicity, PD modality, and longer dialysis vintage with KDCS. CONCLUSIONS: Socio-demographic and clinical factors are both associated with HRQOL in ESRD patients on dialysis in Singapore. Dialysis modality has no impact on the health utility of these patients.
ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA (BPH)

METHODS: In 2014 a multicenter cross-sectional questionnaire survey was conducted in Hungary. Inclusion criteria were diagnosis of BPH/LUTS at least 12 months before the study and patient had never been undergone any prostate surgery. Men were recruited indirectly by the ODG and visual analog scale (VAS) and directly by matching indifference time trade-off (TTO) where patients’ subjective life expectancy was applied as time frame. Subjective happiness was measured on a visual analog scale (VAS) and using TTO. In total 64 men completed the questionnaire, mean age and disease duration were 70.8±8.8 years and 6.9±6.5 years, respectively. At the time of the survey, 75% of the patients received alpha-blockers (AB), 11% were treated by 5-alpha-reductase inhibitors (SARI), and 11% by combination therapy (AB+SARI). Median EQ-5D VAS, TTO, and IPSS were 0.85, 0.70, 0.73 and 6.5, respectively. Utilities assessed by EQ-5D were found significantly higher compared to those elicited by TTO (p<0.001). Mean utilities decreased with clinical severity measured with EQ-5D (mild: 0.86±0.3, moderate to severe: 0.73±0.2), whereas increased when assessed with TTO (mild: 0.64±0.3, moderate to severe: 0.63±0.3, p=0.336). Patients with moderate to severe disease reported significantly lower happiness scores than those with mild disease (5.6±2.2 and 7.0±2.3, respectively). Dependence on treatment and its impact on quality of life (QoL) was assessed using a mixed methods approach (MMA).

RESULTS: A mixed methods approach combined qualitative and quantitative methods (discrete choice experiment [DCE]). ODGs and a self-administered online DCE survey were conducted with men in the UK aged ≥45 years (Ikenwilo, et al). Median EQ-5D, EQ VAS, TTO and happiness scores were 0.85, 0.70, 0.73 and 6.5, respectively. Utilities assessed by EQ-5D were found significantly higher compared to those elicited by TTO (p<0.001). Mean utilities decreased with clinical severity measured with EQ-5D (mild: 0.86±0.3, moderate to severe: 0.73±0.2), whereas increased when assessed with TTO (mild: 0.64±0.3, moderate to severe: 0.63±0.3, p=0.336). Patients with moderate to severe disease reported significantly lower happiness scores than those with mild disease (5.6±2.2 and 7.0±2.3, respectively). Dependence on treatment and its impact on quality of life (QoL) was assessed using a mixed methods approach (MMA).

CONCLUSIONS: In 2014 a multicenter cross-sectional questionnaire survey was conducted in Hungary. Inclusion criteria were diagnosis of BPH/LUTS at least 12 months before the study and patient had never been undergone any prostate surgery. Men were recruited indirectly by the ODG and visual analog scale (VAS) and directly by matching indifference time trade-off (TTO) where patients’ subjective life expectancy was applied as time frame. Subjective happiness was measured on a visual analog scale (VAS) and using TTO. In total 64 men completed the questionnaire, mean age and disease duration were 70.8±8.8 years and 6.9±6.5 years, respectively. At the time of the survey, 75% of the patients received alpha-blockers (AB), 11% were treated by 5-alpha-reductase inhibitors (SARI), and 11% by combination therapy (AB+SARI). Median EQ-5D VAS, TTO, and IPSS were 0.85, 0.70, 0.73 and 6.5, respectively. Utilities assessed by EQ-5D were found significantly higher compared to those elicited by TTO (p<0.001). Mean utilities decreased with clinical severity measured with EQ-5D (mild: 0.86±0.3, moderate to severe: 0.73±0.2), whereas increased when assessed with TTO (mild: 0.64±0.3, moderate to severe: 0.63±0.3, p=0.336). Patients with moderate to severe disease reported significantly lower happiness scores than those with mild disease (5.6±2.2 and 7.0±2.3, respectively). Dependence on treatment and its impact on quality of life (QoL) was assessed using a mixed methods approach (MMA).

CANCERS THERAPY IN TURKEY: ASSESSMENT OF LEGISLATIVE AND REGULATORY POLICY

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OBJECTIVES: This study assessed the prevalence of symptoms, and symptom clusters in a sample of dialysis patients in Uruguay. METHODS: A longitudinal study aimed to assess HRQOL in hemodialysis (HD) and peritoneal dialysis patients (PD) was conducted in thirteen centers in Uruguay. Data of the first assessment was included here. The 12 items of the KDQOL-36 Symptom Subscale were analyzed for symptom prevalence. For cluster analyses the ECLUST procedure was followed, using an algorithm to hierarchically cluster items to form composite scales. Alpha, the mean split halves correlation, and beta, the worst split half correlation, are estimates of the reliability and general factor saturation of the test. Clusters are formed if coefficients increase in the new cluster. RESULTS: Of a total of 751 patients, 486 accepted to participate and completed the forms (64.7%), with mean age 60.5 years, SD: 15.5), 441 (58.2%) were women; 407 (83.7%) were HD, and 79 (16.3%) were PD patients. Most common symptoms were muscle sores (59.0%), cramps (57.5%), “washed out” (50.9%), dry skin (48.5%), and itchy skin (43.8%). Five clusters of symptoms were identified, “cutaneous” (itchy and dry skin, α = 0.6), “cardiac” (chest pain and shortness of breath, α = 0.5), “digestive” (nausea and lack of appetite, α = 0.62), “neuropathic, digestive and lack of energy” (numbness and cramps, α = 0.5), “energy” (“washed out”, faintness, α = 0.59). A second block called “lumotropic” included neuropathic plus muscle sores (α = 0.64), and a third of “neurological symptoms” included locomotive plus energy (α = 0.59). A second cluster was composed of “neurological symptoms” included locomotive plus energy (α = 0.59). A second cluster was composed of “neurological symptoms” included locomotive plus energy (α = 0.59). A second cluster was composed of “neurological symptoms” included locomotive plus energy (α = 0.59). A second cluster was composed of “neurological symptoms” included locomotive plus energy (α = 0.59).

CONCLUSIONS: Dialysis patients experience a high number of symptoms. The study of clusters identified five groups of symptoms; cutaneous, cardiac, neuropathic, digestive and lack of energy. More complex associations included neurologic, digestive and cardiac complaints. The identification of symptom clusters can help to understand common underlying pathways, and the use of drugs targeted to associated symptoms.
OBJECTIVES: Data are limited on the course of patients after an acute venous thromboembolism (VTE) event under clinical practice conditions. METHODS: We present current results on the outcome of hospitalization of patients in a cohort with deep venous thrombosis (DVT) or pulmonary embolism (PE) from the PREFER in VTE registry in 7 Western European countries (France, Italy, Spain, Germany, UK, Austria and Switzerland).

The current interim analysis includes data of 2863 patients. 1689 patients had DVT alone and 1174 had PE (±DVT) as qualifying event for inclusion. The study included 40,348 patients from 31 sites in 7 countries. Patients were followed for 1 year (FU) and results reported within the seven most important hospitalization reasons for VTE patients were analyzed. RESULTS: At baseline, 72.2% of the patients received heparin, 11.9% fondaparinux, 48.8% vitamin K antagonists, 25.4% non-VKA oral anticoagulants, 7.0% acetylsalicylic acid, 2.1% other anticoagulants and 1.0% unfractionated heparin. With the first 6 months of follow-up, 13.4% of VTE patients were hospitalized for any reason (DVT: 12.9%, PE: 17.5%). Hospitalization rates varied between countries (Spain 10.7%, Germany 10.8%, France 12.5%, Italy 19.3%, UK at 3 months: 7.5%). The mean number of hospitalizations was 1.3 ± 0.85 (1.1 to 1.5 in the various countries; median 1, range 1-6). The documented reasons for hospitalization, among others, were VTE (15.3%), surgery/truma (13.5%), bleeding (7.4%), or stroke/TIA (3.7%). Mean duration of all combined hospital stays was 9.8 ± 6.1 days (4.0 days at AF, 4.7 in France, 9.0 in Spain, 14.0 in Italy). The overall median duration of hospitalization was 6 days (interquartile range 2-12, for DVT cases it was 6 days (IQR 3-13), for PE cases it was 5 days (IQR 2-13). CONCLUSIONS: Under real-life conditions, one in seven patients had to be readmitted to hospital in the first 6 months after the DVT or PE event. However, the majority of hospitalizations were not due to the thromboembolic disease or bleeding. The duration of hospital stays showed a wide range across Western European countries.

PCV2

DISCONTINUATION AND HOSPITALISATION RATES IN PATIENTS WITH ATRIAL FIBRILLATION (AF) FROM THE PREFER IN VTE REGISTRY (PREFER / PCV2) RESULTS OF A PROSPECTIVE INTERIM ANALYSIS


OBJECTIVES: The great majority of patients with atrial fibrillation (AF) require lifelong anticoagulation therapy for prevention of stroke. For optimal treatment, it is important to check if treatment discontinuation is associated with increased hospitalization rates. As potential indicator for unstable anticoagulation efforts we assessed hospitalization rates for non-vitamin K antagonist oral anticoagulants (NOAC) and for warfarin under real-life practice conditions.

METHODS: PREFER in AF (The PREvention of thromboembolic events – European Registry in Atrial Fibrillation) is a prospective non-interventional disease registry of patients with AF in 7 countries in Western Europe. Discontinuation rates were assessed looking at all patients (n=6420), whereas hospitalization rates reported at Baseline (BL) and 1 year Follow-Up (FU) focused on two groups: patients treated with warfarin (BL=1379, FU=1571) and patients treated with NOAC (BL=194, FU=424). Descriptive statistics were used to report hospitalization rates (HR) and the atrial fibrillation (AF) is an independent risk factor to control for potential confounders and identify recipient risk factors. CONCLUSIONS: The study shows an increased risk of same-day TE rates for patients without congenital CF deficiency, 70.2 (0.2 of 1.45), as compared to those with congenital CF deficiency (4.6 (1.4-8.4)). Further investigations are needed to explore the reasons for hospitalizations. In addition, study findings suggest elevated same-day TE rates for CF patients with additional multivariable investigation ongoing.

PCV5

THE EFFECT OF ATRIAL FIBRILLATION IN ACUTE MYOCARDIAL INFARCTION PATIENTS IN TAIWAN

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OBJECTIVES: Acute myocardial infarction (AMI) is a major cause of mortality and morbidity worldwide. AMI with atrial fibrillation (AMIF) patients are at high risk and thus heart muscle is injured due to insufficient constant oxygen received. It will cause severe complications or co-morbidities if the condition is lasting. Hence, we aim to investigate the clinical characteristics of AMI patients and risk factors for the major severe cardiovascular events (MACE) that occurred in AMI patients. METHODS: The AMI patient is defined by the patient treated in the emergency room at the beginning of the illness. Frequencies and costs of AMI data were extracted from the National Health Insurance Research Database for this observational retrospective cohort study between 2007 and 2012 in Taiwan. ICD-9-CM 410 was used to extract the AMI patients. Fisher’s exact test and categorical data analytic method were utilized to assess the AF as a risk factor to MACE in the AMI patients. RESULTS: We mainly focused on the AMI adults without any prior MACE occurred. As a result, there were 3,452 AMI who can be divided into 2 groups: 2,939 AMI patients and 513 non-AF patients. The average medical cost was USD$3142.8 and the mean LoS was 10.4 days at d with ≥90.0 days. There were 1,791 MACE identified among the AF patients (60.9%), while there were 251 MACE among the non-AF patients (48.9%). In consequence, the AMI with AF resulted more MACE than those in non-AF (RR = 1.35, 1.97, p < 0.0001). The difference of cost was not significant between both groups. The mean LoS in AF was 16.6 days, which was significantly longer than that in non-AF (19.1 days). The difference was probably due to higher fatalities in AF. CONCLUSIONS: This study demonstrated that AF risk is associated with MACE in patients after AMI occurred.

PCV6

DEVELOPMENT OF A COLLABORATIVE EUROPEAN PHARMACOEPIEMIOLOGICAL POST-AUTHORIZATION SAFETY STUDY (PASS) PROGRAM EXAMINING RIVAROXABAN USE IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: There has been an increase in the number of clotting factor (CF) products available in the U. S. in recent years. Thrombotic events (TEs) are serious adverse events that can occur following administration of CFs. The objective of this study is to assess the same-day TE risk following exposure to CF products. METHODS: A retrospective cohort study of individuals exposed to CF products during January 2008 through June 2013 was conducted using HealthCore Integrated Research Database (HCIRDb). CF products were identified by Health care Common Procedure Coding System (HCPCS) codes, and TEs were ascertained via ICD-9-CM diagnosis codes. Crude same-day TE rates (per 1,000 persons exposed) were estimated overall, by congenital clotting factor deficiency status and by specific CF products, age, and gender. RESULTS: Of 3,801 individuals exposed to CFs, 117 (3.1%) had one or more same-day TE events during the same-day TE event (per 1,000) were estimated overall, by congenital clotting factor deficiency status and by specific CF products, age, and gender. CONCLUSIONS: Further analyses are underway to control for potential confounders and identify recipient risk factors. CONCLUSIONS: This study demonstrated that same-day TE rates for CF products with additional multivariable investigation ongoing.
of athertothrombotic events (when combined with antiplatelet therapy) following an acute coronary event. Use, safety, and effectiveness of rivaroxaban use settings need to be monitored to understand its value and comply with regulatory requirements. OBJECTIVES: To develop a pharmacoeconomic logic PASS programme to characterize post-authorization rivaroxaban use and relevant outcomes related to safety and economic logic. RESULTS: 35% of endpoints were rinaleds and 30% were percutaneous transluminal coronary angiography (myocardial infarction, ischaemic stroke and thromboembolic events). METHODS: European sources of longitudinal observational health care data were identified that contained population-based data on demographics, comorbidities and co-medications. Additional studies were designed to capture drug utilization, safety and effectiveness data in primary and secondary care via physician questionnaire completed based on medical chart review. With an emphasis on the consistent definition of endpoints, protocols were developed and tailored to the drug’s logic. Data were submitted to regulatory authorities and relevant ethics committees. RESULTS: A PASS programme of 7 studies was designed. Rivaroxaban drug utilization, and safety and effectiveness data in primary and secondary care were collected at the patient level. Safety and effectiveness data were collected using The Health Improvement Network (UK), the PHARMO Database Network (The Netherlands), the German Pharmacoepidemiological Research Database and the National Swedish Registries. The programme also included 2 Specialist Cohort Event Monitoring studies to collect data on the initial treatment period in secondary care settings, and a complementary Modified Prescription-Event Monitoring study that evaluates long-term use in primary care. CONCLUSIONS: This pharmacoeconomic logic PASS programme, with its unique and complementary approach, will monitor and characterize the real-life benefit-risk profile of rivaroxaban. A flexible design allows the accommodation of any new indications for rivaroxaban approved during the study.

PCV7
CORONARY AND CARDIOVASCULAR DISEASE RISKS IN MIGRAINE PATIENTS: EVIDENCE FROM NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY - 1999-2004
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OBJECTIVES: (1) To assess the prevalence of migraine using the National Health and Nutrition Examination Survey (NHANES) conducted in the general United States population; (2) To calculate the 10-year Framingham cardiovascular disease (CVD) risk and compare it to the percentage of individuals with cardiovascular disease (CVD) risk; and (3) To determine if migraineurs had a higher prevalence of CVD risk factors. METHODS: Migraine prevalence was assessed in NHANES data. Multivariable ordinal logistic regressions were used to examine the odds ratios of low, moderate, and high CVD risk factors in migraineurs compared to non-migraineurs. RESULTS: There was a significant increase in migraine prevalence with increasing CVD risk factors. There was a higher percentage of females with migraine compared to non-migraineurs. The average age of migraineurs was 42 years, compared to 47 years in non-migraineurs. CONCLUSIONS: Migraineurs had a higher prevalence of CVD risk factors compared to non-migraineurs.

PCV8
EFFECTIVENESS AND COSTS OF DIFFERENT STRATEGIES FOR THE DIAGNOSIS OF STABLE CORONARY ARTERY DISEASE RESULTS FROM THE 45 STUDIES
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OBJECTIVES: The analysis of different non-invasive imaging strategies in a European population of patients with stable angina could help the identification of the best approach for the diagnosis of CAD. METHODS: In 475 pts (291 males, 60±9 yrs) with stable angina enrolled in the EVINCI multicenter study, CT coronary angiography (CTCA) and stress imaging were performed before invasive coronary angiography (ICA). Significant CAD was defined as >50% stenosis in the left main or >70% stenosis in a major coronary vessel or 30-70% stenosis with fractional flow reserve ≤0.8. Nine non-invasive imaging strategies including CTCA or stress imaging (ECHO, CMR, SPECT or PET) alone or in combination with ICA were performed as first line examinations were evaluated. Combinations were positive if both CTCA and the stress test were positive and their performance was evaluated in terms of accuracy (AUC). Centres specific reclassifications were collected. RESULTS: 24 centers participated using the EVINCI protocol. Key with different strategies were obtained at individual patient level by summing the feature and comparison with results obtained using The Health Improvement Network (UK), the PHARMO Database Network (The Netherlands), the German Pharmacoepidemiological Research Database and the National Swedish Registries. The programme also included 2 Specialist Cohort Event Monitoring studies to collect data on the initial treatment period in secondary care settings, and a complementary Modified Prescription-Event Monitoring study that evaluates long-term use in primary care. CONCLUSIONS: This pharmacoeconomic logic PASS programme, with its unique and complementary approach, will monitor and characterize the real-life benefit-risk profile of rivaroxaban. A flexible design allows the accommodation of any new indications for rivaroxaban approved during the study.

PCV9
AN ASSESSMENT OF THE CURRENT LITERATURE ON APHRESIUS USE IN THE TREATMENT OF FAMILIAL HYPERCHOLESTEROLEMIA
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OBJECTIVES: Although apheresis is an important treatment for reducing LDL-C in familial hypercholesterolemia (FH) patients, little is known about its treatment patterns. We conducted a systematic review to assess the efficacy/effectiveness, practices, costs, and clinical guidelines for apheresis in FH patients. METHODS: Electronic databases were searched for publications of apheresis in FH patients. Inclusion criteria included: articles in English published 2000-2013, description of practice patterns, efficacy/effectiveness, and costs. Data were stratified by country and apheresis type: Three-strategies comparisons between significant VH and non-significant VH (≤0.909 – 1.582, p-value < 0.001) for moderate CHD risk, and ≤0.818 – 1.683, p-value < 0.001) for high CHD risk. RESULTS: Thirty-two studies were included in the review. Cost-effectiveness analyses were conducted at the population level in the Netherlands, Germany, and the USA. Calculated annual costs may reach $88,400-$225,000 per patient for FH treatment. CONCLUSIONS: LDL-C apheresis treatment is necessary for FH patients when drug therapy is inadequate. While apheresis reduces LDL-C, high per-session costs and the frequency of guideline-recommended treatment result in substantial annual costs. The diagnostic and the inconvenience of apheresis sessions are barriers in optimal treatment of FH.

PCV10
DETERMINED ADDED BENEFIT OF CATHETER-BASED RENAL DENERVATION FOR MODERATE TREATMENT-RESISTANT HYPERTENSION: IMPACT OF AGE AND CARDIOVASCULAR RISK FACTORS
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OBJECTIVES: Our objective was to estimate the impact of catheter-based renal denervation plus standard plus care (RDN) versus standard care alone (SoC) on European stage-1 hypertension patients with different cardiovascular risk factor profiles. METHODS: We simulated resistant hypertension cohorts with different cardiovascular risk factor profiles (CVRFs) who had stage-1 hypertension despite adequate treatment with SoC. Six different cohorts with permutations of starting ages of 40, 55, or 70 years; and low and high CVRFs based on JNC7 guidelines were modeled. Interventions were RDN plus SoC with three or more anti-hypertensives including a diuretic at full doses or SoC alone. As observed in a recent prospective, uncontrolled pilot study, the impact of a 13 mmHg reduction in systolic blood pressure (SBP) – from a baseline SBP of 151 mmHg – was evaluated. Undiscounted life year (LY) and quality-adjusted life year (QALY) gains were computed using a published life-time Markov simulation model based on multivariate risk equations. RESULTS: Across the studied age groups and cardiovascular risk profiles, catheter-based renal denervation was associated with gains in unadjusted (0.51-1.48 QALYs) and quality-adjusted life expectancy (0.39-1.20 QALYs). Younger age and higher cardiovascular risk profile led to numerically higher increments. The cohort-specific LY and QALY gains were projected as follows: i) 40 year old cohorts: low CV risk profile: 0.84 LYs/0.78 QALYs; high CV risk profile: 1.48 LYs/1.20 QALYs; ii) 55 year old cohorts: low CV risk profile: 0.69 LYs/0.60 QALYs; high CV risk profile: 1.29 LYs/0.95 QALYs; iii) 70 year old cohorts: low CV risk profile: 0.51 LYs/0.39 QALYs; high CV risk profile: 0.93 LYs/0.68 QALYs. CONCLUSIONS: RDN, when used to treat moderate treatment-resistant hypertension, is associated with clinically significant increases in life expectancy. These model-based findings need to be confirmed in clinical trials.

PCV11
THE USE OF MINIMALLY INVASIVE SURGERY (MIS) AND INTRAOPERATIVE IMAGING MODALITIES IN THE TREATMENT OF INTRACEREBRAL HEMORRHAGE (ICH): A SYSTEMATIC REVIEW OF THE LITERATURE
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OBJECTIVES: The objective of this review was to investigate the use of MIS and intraoperative imaging technologies in the treatment and management of persons with ICH. METHODS: A systematic search of the published literature was undertaken in PubMed, EMBASE, the Cochrane Library Database and The Cochrane Library Database. Key with different strategies were obtained at individual patient level by summing the feature and comparison with results obtained using The Health Improvement Network (UK), the PHARMO Database Network (The Netherlands), the German Pharmacoepidemiological Research Database and the National Swedish Registries. The programme also included 2 Specialist Cohort Event Monitoring studies to collect data on the initial treatment period in secondary care settings, and a complementary Modified Prescription-Event Monitoring study that evaluates long-term use in primary care. CONCLUSIONS: This pharmacoeconomic logic PASS programme, with its unique and complementary approach, will monitor and characterize the real-life benefit-risk profile of rivaroxaban. A flexible design allows the accommodation of any new indications for rivaroxaban approved during the study.
RESULTS: The clinical research AVALON found, that the use of IFP amloidipine-atorvastatin provides significant clinical benefit: the largest absolute reduction in the number of events reached in all outcomes, including- low-density lipoprotein cholesterol (LDL-C) (45.5%), versus amloidipine (3.8%), atorvastatin (28.6%), placebo (3.5%). The scheme using amloidipine is the most expensive (cost of treatment course of treatment (CCT) € 200/96), the regimen of atorvastatin 10 mg (CCT € 10.46) and the IFP amloidipine-atorvastatin (CCT € 17.72) is less costly. This PP is more cost effective versus IFP monotherapy (CER = € 38.95 versus € 244.34 per patient with target levels of BP and LDL-C). The cost of an additional unit of effectiveness (ICER) showed that the use of IFP amloidipine-atorvastatin instead amloidipine provides for the treatment of each 100 patients 3.8 additional years of life expectancy, 2 patients achieved target levels of BP and LDL-C and saving € 6.88 per patient. CONCLUSIONS: Pharmacotherapy of patients with hypertension and dyslipidemia based on IFP amloidipine-atorvastatin provides significant clinical benefit versus monodrugs and pharmacoeconomic advantages versus amloidipine.

OBJECTIVES: To assess the impact of switch decisions, with individuals randomized to receive various doses of either available doses of the two drugs. Comparison B assessed the impact of initial treatment using the Archimedes model, a validated, individual-based simulation of human system. Thus, Proteus can identify specific individual needs for progressing through the recommended treatment pathway and for advancing toward treatment goals.

RESULTS: In this example using the well-validated Archimedes system. Thus, Proteus can identify specific individual needs for progressing through the recommended treatment pathway and for advancing toward treatment goals.

CONCLUSIONS: In comparison A, rosuvastatin was estimated to result in greater reductions than atorvastatin in major adverse cardiac events (MACEs) at 5 and 20 years at all doses examined (relative risk [RR] 0.970; 0.892 and 0.931 at 20 years, respectively). Comparison A assessed the impact of initial treatment decisions, with individuals randomized to receive various doses of either rosvastatin or atorvastatin and eligible for treatment intensification for at least 5 years if target lipid levels were not met. Comparison A assessed the effect of switching patients’ treatment from rosvastatin to atorvastatin. RESULTS: In comparison A, rosuvastatin was estimated to result in greater reductions than atorvastatin in major adverse cardiac events (MACEs) at 5 and 20 years at all doses examined (relative risk [RR] 0.970; 0.892 and 0.931 at 20 years, respectively). Comparison A assessed the impact of switching patients’ treatment from rosvastatin to atorvastatin. RESULTS: In comparison A, rosuvastatin was estimated to result in greater reductions than atorvastatin in major adverse cardiac events (MACEs) at 5 and 20 years at all doses examined (relative risk [RR] 0.970; 0.892 and 0.931 at 20 years, respectively). Comparison A assessed the impact of switching patients’ treatment from rosvastatin to atorvastatin. RESULTS: In comparison A, rosuvastatin was estimated to result in greater reductions than atorvastatin in major adverse cardiac events (MACEs) at 5 and 20 years at all doses examined (relative risk [RR] 0.970; 0.892 and 0.931 at 20 years, respectively). Comparison A assessed the impact of switching patients’ treatment from rosvastatin to atorvastatin. RESULTS: In comparison A, rosuvastatin was estimated to result in greater reductions than atorvastatin in major adverse cardiac events (MACEs) at 5 and 20 years at all doses examined (relative risk [RR] 0.970; 0.892 and 0.931 at 20 years, respectively).
OBJECTIVES: To critically appraise the published network meta-analyses (NMAs) evaluating the safety of the new oral anticoagulants (NOACs) rivaroxaban, apixaban, and dabigatran compared to VKA and aspirin in the prevention of stroke in patients with non-valvular atrial fibrillation (AF). METHODS: A systematic literature review was performed to identify the relevant NMAs using MEDLINE®, EMBASE®, Cochrane Library, Database of Abstracts of Reviews of Effects, and Health Technology Assessment. The studies were evaluated using the ‘Questionnaire to assess the relevance and credibility of the NMA’. RESULTS: Eleven NMAs evaluating NOACs among adults with non-valvular AF were identified. Most NMAs included three large phase III RCTs comparing NOACs to adjusted-dose warfarin (RE-LY, ROCKET-AF, ARISTOTLE). The main differences identified related to potential treatment effect modifiers regarding the mean time spent in therapeutic range (TTR) in the warfarin arm, the risk of stroke in patients with systemic embolism across the trials (mean CHADS2 score: Cardiac failure: Age ≥ 75 years, Diabetes mellitus, Stroke, 2 two points for stroke) or primary versus secondary prevention, and type of populations used in the analysis. Kantaropoulos identified NOACs adjusted at the 12th International Conference on Stroke Prevention (2012) November 2012, were offered to participate. Clinical variables were recorded at the clinical session for treatment decision (Pulmonary endarterectomy – PEA: if operability was confirmed or medication therapy – MT: if inoperable), and after 6 months (last follow-up). The study's statistical power will be sufficient to confirm or not these trends at the final 6-year analysis.

RESULTS: Patients with severe pulmonary hypertension (PH) or chronic thromboembolic pulmonary hypertension (CTEPH) are often referred to secondary centers for treatment decision (Pulmonary endarterectomy – PEA- if operability was confirmed or medication therapy –MT- if inoperable), and after 6 months (last follow-up). The study's statistical power will be sufficient to confirm or not these trends at the final 6-year analysis.

CONCLUSIONS: The positive outcomes obtained, especially in those patients undergoing PEA, suggest the experienced management of CTEPH by this referral hospital and highlights the importance of detecting candidates for PEA.

PCV21 MANAGEMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION: CLINICAL AND REPORTED OUTCOMES FROM A REFERRAL HOSPITAL IN SPAIN

OBJECTIVES: To evaluate the management of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) in a referral hospital by assessing clinical variables, patient-reported outcomes and caregivers’ burden. METHODS: An observational, retrospective study was conducted. All patients (aged > 18 years) attending the specialised unit of CTEPH (12th International Conference on Stroke Prevention (2012) November 2012, were offered to participate. Clinical variables were recorded at the clinical session for treatment decision (Pulmonary endarterectomy – PEA: if operability was confirmed or medication therapy –MT: if inoperable), and after 6 months (last follow-up). The study's statistical power will be sufficient to confirm or not these trends at the final 6-year analysis.

CONCLUSIONS: The positive outcomes obtained, especially in those patients undergoing PEA, suggest the experienced management of CTEPH by this referral hospital and highlights the importance of detecting candidates for PEA.

PCV22 THE 3.5-YEAR MORTALITY IMPACT OF DRUGS IN SECONDARY PREVENTION OF MYOCARDIAL INFARCTION IN REAL-LIFE (INTERIM ANALYSIS OF THE EOLE COHORT)

OBJECTIVES: Few studies have assessed the real-life impact of secondary prevention drugs on all-cause mortality post-myocardial infarction (MI), especially in countries where new guidelines are not followed. The objective of this interim analysis after 3.5-year of follow-up was to assess the real-life all-cause mortality impact of drugs reimbursed for MI secondary prevention in France: acetylsalicylic acid (ASA), anti-platelet agents (APA), beta-blockers (ß), angiotensin converting enzyme inhibitors (ACEI), statins, and oral anticoagulants (OM3). METHODS: Cohort of 1 hospital patients (n ≤ 53 months) acute MI included by hospital and non-hospital cardiologists, with 6-year follow-up. Vital status was obtained from the National death registry, and failing that by patient relatives/physicians/investigators. Drug exposure was defined using both physician and patient reports at inclusion. Cox proportional hazard model was used to estimate for each drug, mortality hazard ratio (HR) of exposed versus non exposed patients, adjusted for gender, age, cardiovascular risk factors, other MI prevention drugs, and propensity score to be exposed at inclusion. RESULTS: Between May 2006 and June 2009, 596 physicians included 5538 patients: mean age 62.1 years, 77.6% male, 9.6% current smokers, 14.5% diabetic, 44.6% hypercholesterolemia, 43.6% hypertensive, 8.2% with LVF <40%. At inclusion, 97.5% were exposed to ASA, 91.0% to APA, 89.7% to ß, 71.1% to ACEI, 92.0% to statins, and 15.7% to Om3. The 3.5-year mortality was 7.8% (85/1127 [7.1%-8.5%]) with an incidence rate of 23.2 per 1000 patient-years. Adjusted HR were: 0.89 [0.60-1.21] for ASA, 0.86 [0.60-1.24] for APA, 0.84 [0.63-1.11] for ß, 0.80 [0.61-1.03] for ACEI, 0.67 [0.45-1.00] for statins, and 0.82 [0.58-1.16] for Om3. CONCLUSIONS: The 3.5 year interim all-cause real-life death reduction point estimates were close to those of large randomized controlled trials, except for ASA, for which almost all patients were exposed. The study's statistical power will be sufficient to confirm or not these trends at the final 6-year analysis.
OBJECTIVES: To estimate the cumulative incidence and hospital cost for venous and pulmonary thromboembolic events in France. We conducted a retrospective analysis of the EGB database, a 1979 random sample of the whole National health insurance database records linked to hospitalizations. All patients hospitalized in 2010 and 2011 with a diagnosis of deep vein thromboembolism (DVT) or pulmonary embolism (PE) were included. Patients were identified through principal diagnosis of hospitalization stay. Outpatients with a DVT were identified by: 1) an echo Doppler exam, 2) preceded or followed by a low molecular weight heparin prescription, 3) a subsequent Vitamin K antagonists delivery (0 to 7 days). Incidences and annual hospital cost of DVT and PE were estimated and extrapolated to the overall French population, and cumulative proportions of recurrences were calculated. RESULTS: For 2011, the estimated crude incidence of DVT was 141/100,000 patients for DVT, and 79/410,000 for PE (3/516,000 patients in France). Mean age of patients was 67.6±7.2 years for PE and 64.1±17.7 years for DVT. A majority of patients were females (57% in both groups). After index event occurrence, the cumulative incidence of venous thromboembolic recurrences were 2.6% at 1 month, 3.7% at 3 months, 5.1% at 6 months and 6.7% at 12 months. The cumulative proportions of death after a PE and a DVT first event were 0.2% at 1 month, 1.1% at 3 months, 2.6% at 6 months and 6.2% at 12 months. Annual hospital costs for pulmonary thromboembolic events was estimated at €712 million (€362 million € for DVT and €350 million € for PE). CONCLUSIONS: In 2011, around 143,000 patients suffered from venous and pulmonary thromboembolic events in France. Hospitalized events accounted for an important burden in France.

PCV27 COGNITIVE FUNCTION AND NON-ADHERENCE TO ANTIIHYPERURICEMIC MEDICATIONS
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OBJECTIVES: Antiihyperuricemic medication and pressure medicines is common, present in 30-50% of patients, and known to be associated with an increased risk for major cardiovascular events and increased health care costs. Prior research suggests that cognitive function is associated with medication adherence. Our aim was to determine if easily administered measures of cognitive function can be used to identify hypertensive patients at increased risk of medication non-adherence. METHODS: A convenience sample of 101 primary care patients (>101) with hypertension and controlled hyperuricemia were enrolled from two sites in ethnically diverse communities of New York City. Patients with overt dementia as noted by their primary care doctors were ineligible. Subjects completed three brief cognitive tests (≤5 minutes to complete each one) Trail Making Test-A, Trail Making Test-B, and the Symbol Digit Modalities Test. The primary outcome was adherence based on percentage of doses taken as prescribed, measured by a 4-component electronic pillbox (Medisignals). Multivariable logistic regression was used to determine if cognitive function was associated with self-reported adherence after adjusting for age, gender, ethnicity, education, and total blood pressure medications. RESULTS: Patients who were classified as impaired when screened by Trail Making Test-B had a three-fold (OR=2.91,95% CI, 1.02-8.35) increased likelihood of non-adherence compared with those who were not impaired, adjusting for age, education, gender, ethnicity, and number of BP medications (p=0.05). Trail Making Test-A and Symbol Digit Modalities Test were non-significant predictors of adherence in both adjusted and unadjusted analyses. CONCLUSIONS: Trail Making Test-B, a measure of executive function, may be a useful screening tool to identify patients without overt dementia who are at risk for non-adherence to antihyperuricemic medications. The findings from this study may provide an opportunity to identify a tailored approach to medication adherence interventions.

PCV28 RETROSPECTIVE ANALYSIS ON HOSPITALIZATION AND HEALTH CARE COSTS, ACCORDING TO SERUM URIC ACID LEVELS IN PATIENTS FROM A SAMPLE OF ITALIAN LOCAL HEALTH UNITS
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OBJECTIVES: Hyperuricemia is an independent risk factor for gouty arthropathy, renal disease, atherosclerosis and cardiovascular diseases (CVD). The objective of this study was to explore the relationship between serum uric acid (SUA) levels and hospitalization events and assess health care costs. METHODS: A retrospective analysis using a large administrative database and a clinical registry containing laboratory results was performed. Subjects, aged ≥18, were assigned to one of the 4 groups based upon the first SUA measurement between October 1, 2010 and September 30, 2011: ≤6 mg/dl [good-control], >6 mg/dl and ≤7 mg/dl [fair-control], > 7 mg/dl and ≤8 mg/dl [poor-control], >8 mg/dl [very-poor-control]. We calculated incidence rates to estimate the risk of hyperuricemia-related and CVD hospitalizations occurred until December, 2012. A Poisson regression model was used to assess the relationship between the number of hospitalizations and SUA level. Total annual costs included all the pharmacological treatments and the direct costs due to hospitalizations and outpatient services. RESULTS: Of 53,822 patients included, SUA level was ≤6 mg/dl for 33,638 (63.3%) patients, >6 mg/dl and ≤7 mg/dl for 5,973 (11%) patients, >7 mg/dl and ≤8 mg/dl for 5,571 (10.5%) patients, >8 mg/dl for 1,341 (2.5%) patients. Compared to very-poor-control, patients of good-control had a 43% lower risk of hospitalization (HR=0.57). The adjusted ORs of poor-control vs very-poor-control were: 1.35 (95% CI: 1.19-1.54), 1.47 (95% CI: 1.33-1.62), 1.66 (95% CI: 1.48-1.86) and 2.46 (95% CI: 2.17-2.81) for good-control, fair-control, poor-control and very-poor-control, respectively. Costs were €2,073.66 and €1,262.18 for good-control vs very-poor-control, respectively. CONCLUSIONS: The 36.3% of the patients in this study sample were at sub-optimal SUA control (<6mg/dl). This analysis indicates that higher hyperuricemia-related and CVD hospitalizations as well as total health care costs resulted associated with higher SUA levels.
PCV29

THE ASSOCIATION BETWEEN THE NATURE AND TIMING OF DENTAL VISITS AND CR-REACTIVE PROTEIN LEVELS
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OBJECTIVES: Previous studies have speculated that dental visits are an associated risk factor for cardiovascular disease (CVD). CR-proactive reactive protein (CRP), an inflammatory marker, has been implicated as a risk factor for CVD, and dental disease can affect CRP levels. Our study examined the relationship between the timing and nature of dental visits and CRP.

METHODS: Using data from the US-based 1999-2000, 2001-2002, and 2003-2004 National Health and Nutrition Examination Surveys, we examined the relationship between time since and reason for most recent dental visit and CRP from participants aged >20 years old. Participation was estimated if they were pregnant at the time of the survey, did not take part in the examination component of the survey, or were missing covariates for a logistic regression model: age, sex, race, BMI, WHR, CHD risk score, time since last dental visit, smoking status, cholesterol-lowering medication use, and history of asthma, cancer, rheumatoid arthritis, chronic bronchitis, or recent illness. A dichotomous elevated CRP measure was used, defined as CRP >0.30 mg/dL. Time since last dental visit was categorized as <6 months, 6 months to <1 year, 1 year to <2 years, and ≥2 years ago; respondents who reported never visiting a dentist were placed in the ≥2 years category.

RESULTS: A greater proportion of the normal (<0.30 mg/dL) CRP group last visited a dentist <6 months ago (P=0.046), and last visited the dentist for a “preventive” visit (P<0.001), while a greater proportion of the elevated CRP group last visited the dentist for a “symptom-driven” visit (P<0.001). Regression model results demonstrated that preventive visits are associated with a reduced likelihood of elevated CRP (OR=0.60; 95%CI 0.43-0.82).

CONCLUSIONS: The results of this study support the need for further research into the nature and timing of dental visits and their potential impact on CRP levels.
quitting smoking. Cost of 5-year reimbursement varenicline was estimated to be €16,018,683, while smoking cessation avoided costs reached €19,992, which is in line with €21.1 million savings in the not-reimbursed scenario: a net incremental cost-saving of €15.9 million. Savings were observed in the third year of modelling. CONCLUSIONS: The BI of the reimbursement of varenicline in smoking cessation should be included in the health policy in the Polish setting, and could produce cost-saving since the third year of implementation.

PCV37 BUDGET IMPACT ANALYSIS OF HYPERTENSION TREATMENT WITH INDAPAMIDE AND AMLODIPINE SINGLE-PILL COMBINATION IN THE POLISH SETTING

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OBJECTIVES: The aim of this study was to compare public payer and patient costs of hypertension treatment with indapamide 1.5 mg and amlopidine 5 mg or 10 mg single-pill combination (SPC) and free combination (FC), in the Polish setting. METHODS: The analysis compared two scenarios: existing and new. The cost of FC was calculated as an average cost of reimbursed indapamide and amlopidine products in corresponding doses. All costs present 2014 values, and are expressed in Polish zloty (PLN). Average monthly exchange rate of May 2014 was applied (IEUR=4.17909PLN). Difference in clinical effectiveness between SPC and FC was also included, in the form of cardiovascular events risk. RESULTS: Introduction of a new single-pill was associated with FC brought savings from public payer perspective and from patient perspective amounting to 509,259PLN (121,860EUR) and 5,893,941PLN (1,410,371EUR) in first year, 689,239PLN (164,929EUR) and 7,833,035PLN (1,874,373EUR) in second year, 725,965PLN (173,717EUR) and 8,328,408PLN (1,992,965EUR) in third year. As a result it resulted in avoidance of 808 cardiovascular events in the three-year horizon. CONCLUSIONS: Treatment with indapamide/amlopidine SPC in comparison to FC generates significant savings both from public payer perspective and from patient perspective in contemporary Polish setting, and reduces cardiovascular events.

PCV38 MODELING THE IMPACT OF A DIGITAL HEALTH FEEDBACK SYSTEM IN UNCONTROLLED HYPERTENSIVE PATIENTS

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OBJECTIVES: Despite the availability of numerous therapeutic agents and management tools, half of all hypertensive patients do not have their blood pressure (BP) at goal. A model was developed to estimate the incremental costs of uncontrolled vs. controlled hypertension and the impact of a digital health system (DHS) feedback via a unique digital health feedback system. This Proteus system utilizes an Ingestible Sensor to determine medication-taking patterns, and a wearable 7-day sensors. The data was used to calculate change rate of May 2014 was applied (IEUR=4.17909PLN). Difference in clinical effectiveness between SPC and FC was also included, in the form of cardiovascular events risk. RESULTS: Introduction of a new single-pill was associated with FC brought savings from public payer perspective and from patient perspective amounting to 509,259PLN (121,860EUR) and 5,893,941PLN (1,410,371EUR) in first year, 689,239PLN (164,929EUR) and 7,833,035PLN (1,874,373EUR) in second year, 725,965PLN (173,717EUR) and 8,328,408PLN (1,992,965EUR) in third year. As a result it resulted in avoidance of 808 cardiovascular events in the three-year horizon. CONCLUSIONS: Treatment with indapamide/amlopidine SPC in comparison to FC generates significant savings both from public payer perspective and from patient perspective in contemporary Polish setting, and reduces cardiovascular events.

PCV39 BUDGET IMPACT ANALYSIS OF APIXABAN VERSUS OTHER NOACS FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: Diabetics with a history of diabetes showed a marked improvement in quality of life with an overall satisfaction in certain aspects of health. CONCLUSIONS: This study demonstrates that Proteus feedback system appears to provide an effective way to mitigate the substantial costs of uncontrolled hypertension.

PCV40 THE BUDGET IMPACT OF NEW GENERATION CT SCANNERS FOR DIFFICULT-TO-IMAGE, LOW-RISK PATIENTS WITH SUSPECTED CAD

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE), issued diagnostic guidance on new generation computed tomography (CT) scanners recommending them as an option for the first-line imaging of coronary arteries in patients with suspected low-risk coronary artery disease (CAD) in whom imaging with conventional coronary angiography is contraindicated. The primary objective of this study was to compare the cost of a new generation scanner with a standard one, in terms of the patient's cost and the health economics. RESULTS: The model was developed to estimate up to a 10-year impact of acquiring a new generation CT scanner, compared to the existing standard care, with the benefits to patients being a reduction in radiation exposure and an improved diagnostic accuracy. CONCLUSIONS: The model is likely to be conservative as it focuses on difficult-to-image patients only, yet the scanner is available for all patients who will likely benefit from the better specificity and specificity associated with the new scanner. However, it highlights that even a low number of these difficult-to-image patients will result in a positive return on investment over the expected life-time of the scanner.

PCV41 SIMVASTATIN PLUS FENOFIBRATE AS A FIXED DOSE COMBINATION IN THE TREATMENT OF MIXED DYSLIPIDEMIA IN GERMANY: BUDGET IMPACT ANALYSIS

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OBJECTIVES: To evaluate the feasibility of switching patients already treated with the multi-pill of simvastatin and fenofibrate to the first simvastatin and fenofibrate fixed dose combination (FDC) product, for the management of mixed dyslipidemia in the Greek health care setting. METHODS: A budget impact model was locally adapted. The adaptation was conducted from a third-party payer perspective over a time horizon of 3 years. The population with mixed dyslipidemia in Greece, the market shares of available treatments and the corresponding drug acquisition costs were combined to estimate the total budgetary impact that will result from the penetration of FDC in the Greek market. Data on population with mixed dyslipidemia were derived from the National Statistical Service and published literature. Estimates of the current and future market shares were obtained from Abbott Hellas market research. Drug acquisition costs were calculated using the latest price list issued and the corresponding reimbursement prices. Reimbursement prices were reduced by the patient’s relevant co-payment and relative rebates. Since market prices for the FDC are not available yet in Greece, estimated retail prices were derived from the Medicare Fee Schedule and AHRQ databases. The impact of the FDC system on BP control was based on a real-world study evaluating this technology in 164 patients with a history of hypertension. CONCLUSIONS: Even in the short-term, a digital health feedback system appears to provide an effective way to mitigate the substantial costs of uncontrolled hypertension.

PCV42 BUDGET IMPACT ANALYSIS OF BOTULINUM TOXIN A THERAPY FOR UPPER LIMB SPASTICITY IN PATIENTS IN GERMANY

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OBJECTIVES: Upper limb spasticity (ULS) occurs to stroke to have a considerable patient and caregiver burden, particularly with regard to pain, activities of daily
living and mobility. Botulinum neurotoxin-A (BoNT-A) injections are effective in treating the bladder. We calculated annual cost of BoNT-A treatment cost at 75.25\,€ per-patient basis, and the expected overall annual budget impact of BoNT-A treatment in Germany using static and dynamic market share scenarios. **Methods:** A budget impact model was developed for BoNT-A use, adopting a German health care system perspective. The model was developed using a dynamic market share model, including the effect of the type of BoNT-A, patient management, and the treatment of patient follow-up. The cost and effectiveness of different treatments were compared with the health care system. The total cost savings were estimated at 12,085,263\,€ for the BoNT-A treatment scenario. The budget impact of BoNT-A treatment was estimated at 7,386,279\,€ in year 2 and 7,255,984\,€ in year 5. These results suggest that BoNT-A treatment could have a significant impact on the overall budget of the health care system in Germany.

**Conclusions:** The budget impact model suggests that BoNT-A treatment could have a significant impact on the overall budget of the health care system in Germany. Further research is needed to determine the long-term cost-effectiveness of BoNT-A treatment in treating the bladder.
Our results indicate that the Lp-LPA2 testing strategy is both cost saving and pro-

COST-EFFICACY AND BUDGET IMPACT ANALYSES OF RISK

attractive treatment option for MR patients at high-risk which increases survival.

STRATIFICATION OF PATIENTS WITH MODERATE RISK OF CARDIOVASCULAR

Sensitivity analysis shows that the cost of the initial surgery and the cost of

further deaths could be avoided by using Mitraclip strategy out of 1000 patients

and from French cost analysis.

The data included 4,734 new AMI patients, 1, Ohinmaa A.

3, Scharnagl H.

In Taiwan, NHI reimburses DES and BMS at the same price, and hospitals can balance

stent number, CCI and procedure for acute coronary syndrome (ACS).

30 NTD). The heart related inpatient cost was similar between two

groups ($1,293 vs $1,275 per person). The 3-year cumulative total outpatient cost at US$ 6,867 and heart related outpatient cost in DES group. KMSA estimates (discounted 3.5%) showed that DES group had a higher

cost were analyzed by com-

paring the mean and median differences between costs for each patient and trim-

ming out 5% of high and low cost patients and excluding patients with longer than

median CMG estimate for whole hospital episode

$1,499, respectively. For subsequent years (>1), expenditures were estimated at 348.9/ patient for HBPM vs 440.2/ patient for C/ABPM (p<0.001), whereas for a 5-year projec-
tion, both patient and hospital respectively. The methodology: C/ABPM strategy presented a higher first year cost compared to HBPM, while the same trend was unveiled in 5-year projection. Effective hypertension management through the appropriate strategies is of paramount importance considering its high prevalence, ergo, even small differences in the cost of applying them could have substantial impact on health expenditures.

The differences between actual hospital cost and C/ABPM cost were most accurate estimates for per diem costs, which was

50.4%, BP measurements

outpatient visits: 32.4%, pharmaceuticals: 17.1%). In HBPM

the costs between drug-eluting stenting (DES) and bare-metal stenting (BMS). We also

regressed against CMG

90 days of hospitalization. 15 comorbidities were derived from secondary diagnostic

PCV52 THE COST COMPARISON OF DRUG-ELUTING STENTS (DES) AND BARE-METAL STENTS (BMS) - A RETROSPECTIVE COHORT MATCHED STUDY

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OBJECTIVES: Literature has failed to demonstrate the clear superiority of Drug-Eluting Stenting (DES) over bare metal stenting (BMS). This study aimed to compare the health care utilization and the costs between drug-eluting stenting (DES) and bare-metal stenting (BMS). We also

examined factors that influenced cumulative costs of these two groups.

METHODS: We conducted a retrospective cohort study based on the NHIC program. Patients who had coronary stenting between Jan. 2007 and Dec. 2008 were recruited and followed through the end of 2010. Both groups were matched on 2:1 by propensity score which adjusted sex, age, stent number and Charlson comorbidity index (CCI). We compared cumulative medical cost for these two matched group by conducting the Kaplan-Meier Sample Average (KMSA) estimates. Regression analysis was used to explore the predictors of cost.

RESULTS: The mean age in both groups was around 66 years. After propensity score matching, we had a total of 966 patients; 644 in BMS group and 322 in DES group. KMSA estimates (discounted 3.5%) showed that DES group had a higher 3-year cumulative total outpatient cost at US$ 6,867 and heart related outpatient cost at US$ 2,548 as compared to BMS group, which were US$ 6,076 and US$ 3,302 respectively (US$—30 NTD). The heart related inpatient cost was similar between two groups. The significant predictors of heart-related outpatient costs were stent type, premium and CCI. The predictors of heart-related inpatient costs were stent type, stent number, CCI and procedure for an atrial fibrillation (AFS).

CONCLUSIONS: In Taiwan, NHI reimburses DES and BMS at the same price, and hospitals can balance billing for the DES. We found that even after adding the extra national average out-of-pocket payment to DES, DES still was a cost-effective procedure.

PCV53 THE IMPACT OF DIRECTED PEFUSION (GDP) ON DOPAMINE COST ANALYSIS WITHIN THE FRAMEWORK OF ACHIEVING BLOOD PRESSURE GOAL

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OBJECTIVES: High oxygen delivery (DO2) during cardiopulmonary bypass (CPB) is associated with better renal outcome in cardiac surgery. Traditional perfusion (TP) techniques, targeted on body surface area and CPB temperature, achieves high DO2 in about 50% of the cases while a goal directed perfusion (GDP) approach can lead to more than 90% of cases achieving high DO2 with a consequent reduction
in Acute Kidney Injury (AKI) rate of about 40%. Aim of this study is to perform an economic evaluation of GDP strategy with respect to TP in UK and US. METHODS: A Discrete Event Simulation model was developed to compare TP and GDP strategy in patients undergoing CPG. The patient's pathways from operation to discharge from hospital was simulated. AKI incidence, in-hospital mortality, hospital length of stay (LOS), unplanned readmission, and the cost per day both in ICU and in ward were considered. The model was solved for more than 3 days in hospital and 11% of AKI episodes. The cost-saving was 2,821 € in UK and 3,206 $ in US. The cost per day of card and DMS (79 € in UK, 110 $ in US) is completely offset by savings in hospital stay that result the main driver in cost savings. The cost-saving is 2,821 € in UK and 3,206 $ in US (1.337 € - 1.314 €) versus 0.001. Adjustment excluding polypill cost (1.528 € - 0.77 €) p < 0.001. Patients programmed with an ICD defibrillator (ICD) cost. The purpose of this Advance III secondary analysis was to assess the impact of long detection on hospitalizations (H), length of stay (LOS) and associated costs for the health care system. METHODS: 1902 patients enrolled in the ADVANCEIII Trial. 948 patients randomized to long detection (30/40) and 954 to short setting (10/20). All hospitalizations were reviewed and classified according to ICD9CM codes and, consequently, to the corresponding Diagnosis-Related Groups (DRGs). Costs correspond to the specific public tariffs for the DRGs applied. The prospective was of a single payer agent (Italian Ministry of Health). RESULTS: Over a median period of 12 months, rates of overall and cardiovascular hospitalizations (CV) were lower in the long detection group (431 610/1000 people/years (95% CI 58.9-64.8) versus 52.3 610/1000 people/years (47.7-57.3) IR: 0.84 (0.79-0.89) p < 0.001. The ICER cost per patient-per-month was 281 per patient. Median health service and medication claims data from a pragmatic randomised controlled trial Kanyini Guidelines Adherence to Polypill in Aboriginal health service and medication claims data. The primary outcome, estimated with generalised linear models, was survival with health and pharmacy expenditures by unit of effect was calculated for each effect: ICER or the domination approach. All costs during the trial, conducted from 2008-2012, were inflated to $AUD 2012 prices. RESULTS: A statistically significantly lower mean pharmacoeconomic expenditure per patient per year (P < 0.001, adjusted, excluding polypill cost) No significant differences were observed in annual non-hospital health service expenditure ($40, 95%CI -202 to 281 per patient). CONCLUSIONS: This study provides evidence that a cardiovascular disease polypill strategy has the potential to produce significant cost-savings to health systems. At an estimated reimbursement cost of $1 per day for the polypill, these savings would have amounted to over $600 per patient per year. Cost-savings would accrue to patients also, given fewer prescription charges. Linking health service and medication claims data with data from a pragmatic randomised controlled trial has provided an avenue to assess the real-world cost implications of introducing this new technology into clinical practice.

PCV54 CAN A CVD POLYPILL SAVE MONEY IN THE REAL WORLD? Lobo T1, Hayes A1, Jan S1, Rodrigues A1, Patel A1, Cass A1, Reid C1, Tinkin A1, Usherwood T1, Webster R2.
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OBJECTIVES: The use of polypills in the prevention of cardiovascular disease is mooted to reduce costs compared with current practice, yet there is very little prospectively-collected data to support this claim. The present study compares the real-world cost of a polypill strategy for cardiovascular disease prevention with established cardiovascular disease or at high estimated cardiovascular risk.
METHODS: A "within trial" cost analysis from the Australian health system perspective, care versus usual care, with separation for polypill and non-polypill patients. The time horizon was considered the initial procedure. Sensitivity analysis was performed to assess the impact of imputed data, and one-way sensitivity analysis was performed for each parameter.
RESULTS: The mean health service and pharmaceutical expenditure, per patient per year. The mean health service and pharmaceutical expenditure, per patient per year. Cost data was subsequently analyzed and compared using R software. The rising cost of treatment of peripheral arterial disease and the increasing prevalence of diabetes mellitus has been a growing public health concern in recent years, with estimates reaching 300 million in 2025. Developing countries concentrate two thirds of these patients and it is known that the economic burden of chronic diseases generates kgs in costs for the health system and social welfare as a function of mortality and premature disability. The objective of the study was to investigate the impact on hospital costs of treating a patient with ischemic heart disease and DM, compared with cardiac patients without DM, in a cardiologic hospital of high complexity Ministry of Health in Brazil. METHODS: observational study of historical cohort of 421 diabetic heart disease (CD) and non diabetic (CND), from 2004 to 2009. The data was mean health service and pharmaceutical expenditure, per patient per year. Cost-savings would accrue to patients also, given fewer prescription charges. Linking health service and medication claims data with data from a pragmatic randomised controlled trial has provided an avenue to assess the real-world cost implications of introducing this new technology into clinical practice.
the direct medical expenditures on the final outcomes. CONCLUSIONS: The treatment of disabled superficial femoral artery was compared from chosen clinical outcomes, economic expenditures and cost-effectiveness. On this basis, the recommendation was set for choosing the most effective treatment.

PV59 INTEREST OF A HOSPITAL DATABASE TO ANALYZE THE COST FOR ACUTE STROKE: THE EXAMPLE OF VERSAILLES HOSPITAL

Reappropriation 1, Milotievic R 2, Lemaire B 2, Le Lay K 1, Faillie S 2, Parussi S 2, Picq F 2, Lambert Y 2
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OBJECTIVES: Stroke generates an important socioeconomic burden and heavy hospital expenses. The objective of this study was to evaluate the impact of delay to manage stroke for patients transported by Mobile Intensive Care Units (MCIU) in a Versailles Hospital, and to analyze the cost, the cost-effectiveness, and the care and outcomes for complex cardiac surgery patients based on bleeding status. The purpose of this study was to estimate the burden and cost of stroke from the Spanish Health Care System perspective. METHODS: Admissions with a primary diagnosis of stroke and admissions for injuries and pacemaker/defibrillator implantations were retrospectively included in the hospital electronic Clinical Management System. We defined data was the Spanish Basic Minimum Data Set and the period 2001-2010. RESULTS: The annual incidence of stroke-related admission was 4.22 cases/10,000 inhabit. The annual average number of admissions was 15,703, including 77.5% syncope as a primary diagnosis. The total annual cost of stroke-related admissions was €46m, from which a 4.6% was associated to injuries where syncope was coded as a secondary diagnosis. The average cost of a patient admitted with syncope as a primary and secondary diagnosis was €13 556 – max £872) and 5 996 (min £719 – max £26 040) respectively. The average length of stay for patients with syncope as a primary and secondary diagnosis was 5 17 and 9 33 days respectively. Conclusions: Syncope resulted from the most important bleeding complications and the length of stay associated. The cost of a patient admitted with syncope as a secondary diagnosis was nearly 3 times higher than a patient with a primary diagnosis of stroke. It is important to implement health strategies to diagnose these patients in order to assure efficient management of the available resources.

PV63 CLINICAL MANAGEMENT OF NON-VALVULAR ATRIAL FIBRILLATION IN HONG KONG

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OBJECTIVES: The present study aimed to investigate the cost of non-valvular atrial fibrillation (NVAF) management in Hong Kong. METHODS: We analyzed consecutively all admissions with documentation (AF) managed in the Atrial Fibrillation Registry between February 2013 and February 2014. Patient clinical characteristics, prescribed therapies and adverse clinical events were extracted from the hospital electronic Clinical Management System. One year direct health care costs including costs of medications, accident and emergency admissions, hospitalizations, clinical visits, coagulation tests and computed tomography of brain scans were estimated from a health care provider perspective. RESULTS: Of 534 NVAF patients, 45.8% were male with a mean age of 75±10.2 years. The average CHADS2, CHA2DS2-VASc score and HASBLED scores were 2.44±1.39, 4.12±1.77 and 3.26±1.09, respectively. 66.7% of these results were a correlation between the delay in managing stroke and early hospital costs and improvement of NIHSS scores. These results are part of a study performed through the PMSI database aiming at calculating the average cost of reducing one point NIHSS impairment. They underline the importance of an early treatment of stroke.

PV64 THE ECONOMIC IMPACT OF CARDIOVASCULAR EVENTS IN PATIENTS POST MYOCARDIAL INFARCTION: UK HEALTH CARE PERSPECTIVE

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OBJECTIVES: There is a high risk of recurring cardiovascular (CV) events in patients post myocardial infarction (MI) despite the current standard of care (SoC). The aim of this study was to estimate the current economic burden of CV events for patients after having an MI event. METHODS: A lifetime markov model was developed from a UK health care perspective to capture progression post-MI. Recurrent MI, stroke and death were modeled for the next 10 years. A new CV event was captured. A perspectives cost of (2012 UK) and outcomes in terms of QALYs and life years (LYs) was made between the current scenario of patients receiving SOC and a hypothesized scenario where post-MI patients had no subsequent CV events. All cost and outcomes were discounted at 3.5% per annum. RESULTS: The current cumulative lifetime event rate of non-fatal MI, non-fatal stroke and CV death post-MI was estimated to be 0.432, 0.6 and 0.42/patient respectively. The total lifetime cost was estimated to be €6,926/post-MI patient. Risk of MI, stroke and death for the next 10 years was an €9,959/post-MI patient. At current rates of CV events there was an incremental lifetime loss of 4.3 LYs/patient and 3.5 QALYs/patient when compared to the hypothesized scenario where patients had no CV events. Considering the prevalence of MI to be 1.5 million, the economic burden posed by MI patients over lifetime if they...
had no recurrent CV events was estimated to be £10.4 billion versus £14.94 billion with recurring CV events under current SOC. This translated into a 43.8% higher economic burden on health care. CONCLUSIONS: The subsequent CV events in post-MI patients pose an additional economic burden of 44% on UK health care despite the current SOC. This indicates the need to design new interventions to reduce the risk of further CV events in post-MI patients.

PCV65 THE IMPACT OF ATHESOCRHEATIC AND HAEMORRHAGIC EVENTS ASSOCIATED WITH ACUTE CORONARY SYNDROME (ACS) IN TURKEY

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OBJECTIVES: To estimate the costs of atherosclerotic and haemorrhagic events associated with Acute Coronary Syndrome (ACS) treated with ASA + Clopidogrel, in Turkish settings. METHODS: An expert panel was organized to reflect the solid data regarding disease management patterns and options to Turkish payer for reimbursement process. Due to the multidisciplinary nature of the ACS, physicians from the cardiology, neurology and cardiovascular surgery participated to panel. Cost components of bleeding events, haemorrhagic stroke, ischemic stroke, myocardial infarction and revascularization have been identified. Experts have reviewed their daily clinical practices and local & global literature for the related complications along with medical procedures. All cost components including medications, hospitalization, surgical treatments follow up procedures and rehabilitation were considered. For the prices of medications, and diagnostic and therapeutic procedures from March 2014 local prices have been taken into account. For Turkish Lira: Euro conversion, Turkish Central Bank March 2013 currency rate (was used Tl/Euro = 3.06). RESULTS: The cost of MI in the first year is 2044€ and 376€ for the second year respectively. Annual cost of ischemic and haemorrhagic strokes are 2951€ and 3646€ for the first year. The main cost drivers for stroke are also non-pharmacological treatments such as inpatient rehabilitation and physical therapy for stroke. (<70-80 for the 1st year) Coronary revascularization costs 833€ for percutaneous interventions and 2354€ for coronary by-pass. Bleeding costs are relatively low compared to other complications. Major and minor bleedings are 189€/event and 17€/event. CONCLUSIONS: Costs of the ACS related complications are quite high. Especially acute phase of MI and stroke has significant burden of the budget. More effective secondary prevention of the ACS might reduce the burden of disease in the Turkish settings.

PCV66 PHARMAECONOMIC BURDEN OF STATINS IN PATIENTS WITH ISCHEMIC HEART DISEASE IN THE HEALTH CARE OF BELARUS

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OBJECTIVES: The aim of this study has been determination of the burden of statins in the treatment of acute coronary syndrome (ACS) and angina pectoris (AP). AP has a significant impact on the final “cost of illness” in the case of chronic cardiac failure. The burden of rosuvastatin (Mertenil) in patients with heart failure was 22.23€/year for the first year and 22.35€/year for the second and subsequent years. The cost of simvastatin was 39.47€/year for the first year and 32.62€/year for the second and subsequent years. The cost of statins had no significant value in the overall “cost of illness” for acute coronary pathology (ranged from 0.3% to 1.88%). The cost of statins was inpatient care, followed by drug therapies. CONCLUSIONS: AF resulted in a substantial medical cost, reflecting resource-intensive and long-term treatments. These costs accompanied with increasing prevalence of AF, justify increased attention to the management of patients with AF.

PCV69 COST OF ILLNESS: HEART FAILURE IN IRELAND

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OBJECTIVES: To map and cost the patient pathway for acute and chronic heart failure across healthcare providers in Ireland applying key cost parameters using a top down approach, whilst highlighting the economic and societal impact of this non communicable disease. METHODS: A prevalence based top down approach was applied to estimate the cost of heart failure in Ireland in 2012. Hospital Episode Statistics, IIHI data on primary and all case diagnoses were obtained from the National Hospital In-Patient Enquiry Scheme (HIPES). The study cohort included all subjects living in Lombardy, a region of Northern Italy, with a hospital discharge for AF or flutter (index event) in the time period 1st January 2009 to 31st December 2011. The costs for inpatient care were estimated at 3,600€ (≈3,900$) at one year from index event was 86%, 66% at four years and 53% at seven years. The main driver of direct medical cost during follow-up was inpatient care followed by drug therapies. CONCLUSIONS: The costs of heart failure are quite high, representing a substantial medical cost, reflecting resource-intensive and long-term treatments. These costs accompanied with increasing prevalence of AF, justify increased attention to the management of patients with AF.

PCV70 COST OF BLEEDING IN TRAUMA PATIENTS

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OBJECTIVES: Trauma patients often experience significant hemorrhage and, therefore, may require more resources during hospitalization than patients who do not hemorrhage. The cost of blood/blood products is poorly understood in trauma patients and not well documented in the literature. Our objective was to evaluate the outcomes and costs associated with on and off blood path at different times in trauma patients with costs and length of stay (LOS) greater than zero, discharged between January 1, 2010 and December 31, 2011, were identified in the Premier Hospital Database based on select codes. All costs were based on hospital reported costs. Patients who received blood products prior to the day of surgery were excluded. Multivariate regres-
sion models for costs and LOS used log transformation techniques. RESULTS: A total of 62 patients were included. 50 (80.6%) had bleeding; 12 (19.4%) did not. Patients who received blood/blood products were significantly different in a number of baseline characteristics including Charlson Comorbidity Index. Unadjusted outcomes demonstrated significant differences in mean total costs ($43,375 Bleeding; $18,411 Non-Bleeding) using patient level data. Indirect costs during the first year after an index stroke event were $15,573 for those who received blood products compared with those who did not. Multivariate models adjusting for patient characteristics demonstrated that patients who received blood/ blood products had 38.9% greater LOS and 34.9% greater ICU LOS. They were also 3.53 times as likely to be admitted to the ICU, 3.75 times as likely to be readmitted for bleeding and 4.09 times as likely to die in hospital (all p<0.001). Furthermore, they had 32.9% greater total cost of care including blood product cost and 31.8% greater total cost of care excluding blood product cost (both p<0.001). CONCLUSIONS: Preventing or rapidly controlling emergent bleeding in trauma patients would likely reduce patient risk and avoid elevated costs of hospitalization.

PCV71 THE ECONOMIC EFFECT OF HYPERTENSION IN HEALTH CARE SYSTEM OF PAKISTAN

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OBJECTIVES: Hypertension (HTN) is a severe public health issue across the globe and a major risk factor for various cardiovascular diseases. This study was aimed to examine the potential costs of prognostic utilities and direct and indirect health care costs of the treatment of HTN in patients visiting public hospitals in Pakistan. METHODS: A cross-sectional, convenient-sampling structured study was conducted in patients attending public hospitals in Pakistan. The direct and indirect health care costs were assessed by different variables i.e. consultation fees, cost of medicines, travelling costs, laboratory test expenses. All obtained data were analyzed using descriptive and inferential statistics. RESULTS: The mean annual direct health care cost for a HTN patient was around PKRs 1,097,898 (US$ 12,192) and the total health care cost for HTN patients was PKRs 1,097,898. It was also observed that the mean indirect health care costs per patient were significantly varied and indirect health care cost was PKRs. 11,990.90 (US$ 121.92). It was also observed that the mean annual direct health care costs of the HTN patients. Better management of HTN can favorably impact the disease burden as untreated HTN or its comorbidities increase the overall treatment costs which affect affordability of the patient.

PCV72 HOSPITAL COSTS OF ISCHEMIC STROKE AND TRANSIENT ISCHEMIC ATTACK IN THE NETHERLANDS

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OBJECTIVES: Advances in the prevention and treatment of ischemic stroke and transient ischemic attack (TIA) during the past two decades have resulted in changes of hospitalization. METHODS: A retrospective cost analysis was conducted using patient records from the Diagnosis Treatment Combination (Diagnose Behandeling Combinatie) casemix system. Four subgroups were analysed: inpatient ischemic stroke, inpatient TIA, outpatient ischemic stroke, and outpatient TIA. RESULTS: Based on 2012 reference prices of the Dutch Manual of Costing and tariffs provided by the Dutch Healthcare Authority. Ordinal least squares regression analysis was used to examine the association between hospital costs and various patient and hospital characteristics. RESULTS: A total of 35,863 ischemic stroke patients and 21,623 TIA patients were included. Inpatient costs for ischemic stroke were €5,328 while the costs for TIA were €4,740. Outpatient costs were estimated at €495 for ischemic stroke and €587 for TIA. Average hospital costs for carotid endarterectomy were estimated at €6,836. The number of inpatient days was the greatest contributor to hospital costs for ischemic stroke and TIA patients. Age, type of hospital, and region were strong predictors of hospital costs. CONCLUSIONS: This study is the most recent and extensive cost analysis of inpatient and outpatient hospital costs of ischemic stroke and TIA patients. Our results may be used as input for economic evaluations and health economic models to support decision making about reimbursement, investment, and pricing of health care interventions.

PCV74 COSTS OF TREATING CARDIOVASCULAR EVENTS IN GERMANY: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Cardiovascular events (CVE) are the number one cause of death (42%) in Germany. This study evaluates available literature regarding direct medical costs related to CVE in Germany. The CVE of interest included myocardial infarction, unstable angina, heart failure (HF), stroke, and peripheral artery disease (PAD). Update of a review conducted in 2012. METHODS: A systematic literature search was performed in the following databases: Medline, Embase, Centre for Reviews and Dissemination, TIBI, and Cochrane. In addition to core databases, literature from the year 2013 was added. Observational studies and randomized clinical trials were considered for the review. RESULTS: The search identified 400 publications; 13 were included in this review. For MI, average hospitalization costs were €5,319. For STEMI, in-hospital mortality between 2.5% and 7.5% per admission (PA). In the first year after MI, direct medical costs were €11,672 – 12,713 per patient. Average costs of treating unstable angina were €2,217 – 5,644 PA. Direct medical costs attributed to STEMI were €11,000 – 40,000 PA. Costs in year 2 were €4,352 – 4,793 PA. Costs in year 3 were €5,000 – 5,400 PA. In the year after STEMI, hospitalization costs in the acute phase were €4,186 PA, €2,138 during month 1-6 after initial hospitalization, €1,350 in month 7-12, and €1,172 in month 13-18. For stroke, total direct medical costs in year one were €11,408 per patient. Total direct hospitalization costs in year two were €12,408 per patient. For STEMI and stroke, patients were highest for MI with €11,672 – 12,713 per patient followed by stroke with €11,408 per patient demonstrating need for improvement in reducing CVE.

PCV75 ANNUAL COST OF CONSERVATIVE TREATMENT OF SUPRAVENTRICULAR TACHYCARDIAS IN POLAND

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OBJECTIVES: To evaluate the cost of management of patients with chronic atrial fibrillation (AF) in the conservative treatment group and to compare them with the results of the STARR-II study performed in the USA. METHODS: A retrospective cost analysis was conducted using patient records from the Diagnosis Treatment Combination (Diagnose Behandeling Combinatie) casemix system. Four subgroups were analysed: inpatient ischemic stroke, inpatient TIA, outpatient ischemic stroke, and outpatient TIA. RESULTS: A total of 35,863 ischemic stroke patients and 21,623 TIA patients were included. Inpatient costs for ischemic stroke were €5,328 while the costs for TIA were €4,740. Outpatient costs were estimated at €495 for ischemic stroke and €587 for TIA. Average hospital costs for carotid endarterectomy were estimated at €6,836. The number of inpatient days was the greatest contributor to hospital costs for ischemic stroke and TIA patients. Age, type of hospital, and region were strong predictors of hospital costs. CONCLUSIONS: This study is the most recent and extensive cost analysis of inpatient and outpatient hospital costs of ischemic stroke and TIA patients. Our results may be used as input for economic evaluations and health economic models to support decision making about reimbursement, investment, and pricing of health care interventions.

PCV76 LINKING HEALTH CARE ADMINISTRATIVE DATABASES AND NATIONAL REGISTRY DATA IN ORDER TO MONITOR ICD THERAPY IN ITALY

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OBJECTIVES: The main purpose of the study was to evaluate the utilization of implantable cardioverter defibrillator (ICD) with or without cardiac resynchronization pacing (CRT-D) in Lombardy, the most populated Italian region with universal health care coverage for about 10 million inhabitants, from 2000 to 2010. The second aim was to assess health care resources utilization after a first ICD implantation, highlighting the differences in the costs for TIA were €495 for ischemic stroke and €587 for TIA. Average hospital costs for carotid endarterectomy were estimated at €6,836. The number of inpatient days was the greatest contributor to hospital costs for ischemic stroke and TIA patients. Age, type of hospital, and region were strong predictors of hospital costs. CONCLUSIONS: This study is the most recent and extensive cost analysis of inpatient and outpatient hospital costs of ischemic stroke and TIA patients. Our results may be used as input for economic evaluations and health economic models to support decision making about reimbursement, investment, and pricing of health care interventions.

PCV77 DOES A 12-LEAD ECG MORE RELIABLY DETECT ATRIAL FIBRILATION THAN A 12-LEAD PCG77?

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OBJECTIVE: The 12-lead electrocardiogram (ECG) is the current gold standard for the diagnosis of atrial fibrillation, under the condition that the 12-lead ECG is cumbersome, expensive and time consuming compared to a rhythm strip alone. The AF detection rate using a single lead ECG compared with a 12-lead ECG among trainees of varying degrees of experience has not yet been reviewed in depth. METHODS: Five doctors of different grades and specialties and one Cardiology Specialist Nurse

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were each asked to review a different batch of ECGs with differing proportions of AF and Sinus rhythm. AF was present in 37% and non-AF rhythm in 63% of the ECGs. The 10-second strips were divided into 2 groups according to level of cardiology experience. The AF detection rate for the 12-lead ECG amongst specialists vs. non-specialists was 93% vs. 70% (P<0.001) and 92% vs. 73% (P=0.003) for the rhythm strip. CONCLUSIONS: Our findings indicate that a 10-second rhythm strip alone has a comparable AF detection rate to a 12-lead ECG in the hands of doctors and nurses when measured against the consultant’s diagnosis. With both the rhythm strip and a 12-lead ECG, the accuracy of AF detection improved with experience. Mass screening using a single strip could be acceptable and inexpensive particularly with mobile phone technology.

PCV78

OBJECTIVE: CONSEQUENCE COMPARISON OF HEMOSTATIC MATRIX AGENTS

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OBJECTIVES: Hemostatic agents are used in intraoperative bleeding in the presence of actively flowing blood when applied directly to the bleeding site. Recent published literature on animal studies and real-world outcome data indicated that the hemostatic matrix agent Floseal could stop bleedings and reduce complications more effectively than Surgifo with thrombin. The objective of this study is to quantify cost consequences in the Netherlands comparing Floseal versus Surgifo with thrombin on the basis of hospital inpatient costs. METHODS: The cost-consequence model was built on a large retrospective analysis of a Premier’s US Hospital database to assess the value of using Floseal to achieve hemostasis in mixed cardiac surgery procedures with or without with thrombin. The model incorporates the cost implications on the following parameters: (1) operating room time; (2) postoperative bleeding-related complication rates; (3) the need for surgical revisions due to bleeding, and; (4) the difference in 2-year postoperative bleeding-related complication and re-admission Costs ($). The costs were derived from published literature, the Dutch guideline for cost research and 2014 national list prices. The model assumed a surgical case load of 100 mixed cardiac surgeries. RESULTS: By reducing operating time, but moreover the number of complications and surgical revisions and post-operative complications, Floseal can lead to a cost saving of €2,933 per patient in comparison to the use of Surgifo with thrombin. CONCLUSIONS: Our preliminary analysis indicates that using Floseal to stop intraoperative bleeding could lead to significant cost savings for the hospitals in the Netherlands. Further studies are required to confirm these findings.

PCV79

COST-EFFECTIVENESS OF DABIGATRAN COMPARED WITH WARFARIN, ARIXIBAN, RIVAROXABAN AND LOW MOLECULAR WEIGHT HEPARINS FOR THE TREATMENT AND SECONDARY PREVENTION OF VENOUS THROMBOEMBOLISM IN COLOMBIA

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OBJECTIVES: To evaluate cost-effectiveness of dabigatran and new oral anticoagulants (NOA) compared to currently reimbursed warfarin and low molecular weight heparins for thromboembolic disease in patients with venous thromboembolism in Colombia. METHODS: Markov decision model based on efficacy, utilities and safety inputs from clinical trials (CT) (RE-COVER I and II, Einstein-DVT, RE-SONATE, AMPLIFY EE) and post-marketing data (PMD) for LMWH. The model included hospitalization costs and follow-up visits. A Markov model cycle of 4 weeks was used. Cost of medication was obtained from SISMED, Vademecum Med®, and government reference prices; costs of events were estimated from hospital billing records, POS tariffs, SOAT Manual and local experts. Costs are reported in euros (£ = COP 18,425.57 in 2016). RESULTS: The incremental cost-effectiveness ratio (ICER) was € 22,272/QALY for dabigatran compared with rivaroxaban (€36,398/QALY) and LMWH (€33,854/QALY) vs. warfarin (€33,922/QALY). Given a willingness-to-pay threshold of €35,000 per QALY gained, the probability of dabigatran being cost-effective was ≥ 95% in all age groups from 30 to 90 years. Costs were influenced mostly by the frequency of TDM testing, the rate of non-responders to TDM, and the magnitude of effect of TDM. CONCLUSIONS: The cost-effectiveness of dabigatran compared with warfarin and NOA was highly cost-effective health care intervention in patients diagnosed with RH. Importantly, this finding is valid for a wide range of patients, independent of gender and age.

PCV80

ECONOMIC EVALUATION OF FERRIC CARBOXYMALTOSE IN PATIENTS WITH CHRONIC HEART FAILURE AND IRON DEFICIENCY: AN ANALYSIS FOR GREECE BASED ON FAIR-HF TRIAL

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OBJECTIVES: To calculate the incremental cost-effectiveness of ferric carboxymaltose (FCM), in iron-deficient heart failure (HF) patients in Greece. METHODS: An international economic model was locally adapted to evaluate the use ferric carboxymaltose (FAH-HF) trial. The efficacy of therapy was evaluated based on the clinical response to treatment and the number of QALYs per patient accrued during the trial. QALYs were compared on the basis of magnitude cost-effectiveness ratios (CERs) were incorporated in the model, as the analysis was conducted from a third-party payer perspective. With respect to administration cost, two alternative scenarios were considered in the base case analysis: administration in day-case unit and administration in the hospital outpatient clinic. Cost-utility analysis was conducted. Primary outcomes were quality adjusted life years (QALYs) and incremental cost-effectiveness ratio (ICER). RESULTS: In the base case analysis, QALYs of FCM treated patients were higher compared to no iron treated patients by 0.04 QALYs. The total 24-week cost of FCM was higher by €969 and €204, it the two scenarios respectively. This difference was mainly attributed to the administration cost and drug acquisition cost related to FMC. Incremental cost-effectiveness analysis showed that treatment with FCM was a cost-effective option resulting in an ICER of €25,506 and €5,368 per QALY gained in the scenarios respectively. Probabilistic sensitivity analysis revealed that FCM was likely to be cost-effective in over 80% and 95% in the two scenarios respectively, at a willingness-to-pay threshold of €34,000 per QALY gained. CONCLUSIONS: Ferric carboxymaltose may be a cost – effective option in relation to no iron treatment for the management of iron deficiency of HF patients in Greece.

PCV81

POTENTIAL COST-EFFECTIVENESS OF THERAPEUTIC DRUG MONITORING IN PATIENTS WITH RESISTANT HYPERTENSION

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OBJECTIVES: Non-adherence to drug therapy pose a serious problem in the treatment of patients with presumed resistant hypertension (RH). It has been shown that therapeutic drug monitoring (TDM) is a useful tool for detecting non-adherence and identifying barriers to treatment adherence, leading to effective blood pressure (BP) control. However, the cost-effectiveness of TDM in the management of RH has not been investigated. METHODS: A Markov model was used to evaluate life-years, quality adjusted life-years (QALYs), death and all-cause deaths in patients receiving either TDM optimized therapy or standard best medical therapy. The model ran from the age of 30 to 100 years or death, using a cycle length of 1 year. Efficacy of TDM was modeled by reducing risk of hypertension-related morbidity and mortality. Costs analyses were performed from a payer’s perspective. Deterministic and probabilistic sensitivity analyses were conducted. RESULTS: In the age group of 60-year olds, TDM gained 1.07 QALYs in men and 0.97 QALYs in women at additional costs of €3,854 and €3,922 respectively. Given a willingness-to-pay threshold of €35,000 per QALY gained, the probability of TDM being cost-effective was ≥ 95% in all age groups from 30 to 90 years. Results were influenced mostly by the frequency of TDM testing, the rate of non-responders to TDM, and the magnitude of effect of TDM. CONCLUSIONS: Therapeutic drug monitoring is a highly cost-effective health care intervention in patients diagnosed with RH. Importantly, this finding is valid for a wide range of patients, independent of gender and age.

PCV82

COST-EFFECTIVENESS ANALYSIS OF IVAKRABINE IN HEART FAILURE WITH REDUCED LEFT VENTRICULAR EJECTION FRACTION IN SPAIN

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OBJECTIVES: SHIFT trial demonstrated that, by decreasing heart rate with ivabradine, hospitalizations due to heart failure due to left ventricular systolic dysfunction (USD) and heart rate (HR) over 70 bpm. A cost-effectiveness analysis demonstrated that this treatment strategy is cost-effective in United Kingdom, but less so in Canada. There are no publications in Spain. The objective of this analysis is to determine whether this treatment strategy is cost-effective in HF due to USD and HR over 70 bpm, in order to compare the treatment strategies of the SHIFT trial, ivabradine vs placebo, on top of standard treatment, was performed. A cost-effectiveness analysis analysis with a life-time horizon, under the perspective of the NHS. Spanish costs were used to feed the model, and it was assumed that quality of life was worse during hospitalizations. A probabilistic sensitivity analysis was performed. The model took into account the incidence of complications related with HF (admission for HF and death) and was fed with transition probabilities taken from the SHIFT trial and the SHIFT-hospitalization trial. Costs were obtained from cost data bases, the National Statistics Institute of Spain, institutions and scientific journals. RESULTS: Costs ($ = €) of IvaKrabine due to placebo in heart failure due to left ventricular systolic dysfunction is $17,488 i, well below the acceptability threshold accepted in our environment (around $30,000 i). Cost for PLYG was €13,044. Results were robust in the performed sensitivity analyses. CONCLUSIONS: In conclusion, treatment with ivabradine and heart failure care left ventricular systolic dysfunc- tion is cost-effective in Spain.

PCV83

PHARMACOECONOMIC ASSESSMENT OF ARIXIBAN VERSUS STANDARD OF CARE FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: The objective of this study was to evaluate the cost-effectiveness of apixaban in the prevention of thromboembolic events in patients with non- valvular atrial fibrillation (NVAF) relatively to standard of care (warfarin or aspirin) from the Italian National Health System (ISSN) perspective. METHODS: A previ- ously published Markov model was adapted for Italian NVAF patients. Clinical
effectiveness data were derived from head-to-head randomized trials (ARISTOTLE and AVEROES); main events considered in the model were ischemic and hemorrhagic stroke, systemic thromboembolism, bleeds (both major and clinically relevant) and cardiovascular hospitalizations. Expected survival was projected beyond trial duration using national mortality data adjusted for individual clinical risks. The risk weights for hospitalized patients were derived from a retrospective cohort study. Unit costs were collected from published Italian sources. Costs (2013 €) and health gains accruing after the first year were discounted at an annual 3.5% rate. Deterministic and probabilistic sensitivity analyses were performed. In the base case analysis, the cost-effectiveness was measured as cost per quality-adjusted-life-year (QALY) and cost per life-year-gained (LYG) over 1 year, 5 years and patients’ lifetime. Direct medical costs were those incurred by patients (e.g., use of cardiovascular medications, e.g., MI and stroke) and utility data were from published literature. All costs were presented as 2014 figures, cost and effectiveness were both discounted at 3% per annum. Sensitivity analyses were performed to test model robustness.

RESULTS: Despite the difference in the effect in the short- and long-term use of ticagrelor and generic clopidogrel (US$8 vs US0,10, US$7.89k), the overall cost of management between the 2 groups remains similar. Our study shows that the incremental cost-effectiveness ratios (ICER) of ticagrelor were reduced substantially from US$16,071/LYG and US$19,493/LYG in the first year to US$302/LYG and US$375/LYG over a lifetime horizon due to improvements in health outcomes. The ICER values were all cost-effective based on the WHO 3xGDP criteria (GDP 2013-US$57,860). The results are sensitive to comorbidities and patients with lifetime use of ticagrelor can potentially reduce the cost of management and increase the cost-effectiveness due to better health outcomes as compared to generic clopidogrel. Ticagrelor therapy appears to be cost-effective both on short- and long-term assessment in the public health care sector of Hong Kong.

PCV87

THE COST OF INCREASING PHYSICAL ACTIVITY AND DECREASING BODY MASS INDEX FOR MIDDLE-LIFE WOMEN

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OBJECTIVES: The purpose of this project was to evaluate the incremental costs of increasing physical activity and improving body composition for a lifestyle walking program for middle-age, overweight American women. The Women’s Lifestyle Physical Activity Program was a randomized behavioral trial that included a group intervention with social support and culturally relevant, tailored content about increasing physical activity and an automated telephone response system tied to the physical activity by means of an accelerometer. The primary outcomes were changes in waist circumference, body mass index (BMI) and waist-to-hip ratio over 24 weeks. Incremental cost-effectiveness ratios (ICER) were calculated for each outcome. The cost-effectiveness analysis included both program and participant costs and was calculated in 2013 US dollars.

RESULTS: For the 260 participants in the analysis, participant costs (e.g., group session attendance, logging physical activity in the app) were $1,444 per participant. The program costs (e.g., program facilitation, materials and supplies) were $164 + $21, for a total cost of $1,225. Walking increased by 200 minutes per week at 24 weeks, with an ICER of $1.46 (95% CI, 1.63 -1.66) per minute, moderate and vigorous physical activity increased by 117 minutes per week, with an ICER of $2.79 per minute, and BMI decreased by 0.09 points, with an ICER of $346 (95% CI, 500 - 9,950) per 1-point reduction. CONCLUSIONS: The Women’s Lifestyle Physical Activity Program is a relatively low cost strategy for increasing physical activity. The incremental cost of increasing walking minutes is substantially lower than for moderate and vigorous physical activity. The participant costs related to time in the program were more than half of the total costs, suggesting that practitioners and patients should consider the participant costs when disseminating group programs into practice.

PCV88

COST-EFFECTIVENESS ANALYSIS OF APAIXAN VERSUS OTHER NOACS FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: The study assessed the lifetime cost-effectiveness of apixaban in preventing thromboembolic events in non-valvular atrial fibrillation (NVAF) patients, as compared to novel oral anticoagulant agents (NOACs), from the Italian Health System (SSN) perspective.

METHODS: A previously published Markov model was adapted. Baseline clinical risks were assigned based on the demographic and clinical features of the patients; effectiveness parameters derived from adjusted indirect comparison using warfarin as a link. Expected survival was projected beyond trial duration using national mortality data adjusted for clinical risks and weighted by published utilities. Unit costs were collected from official and published Italian sources. Costs (2013 €) and health gains occurring after the first year were discounted at an annual 3.5% rate. Deterministic and probabilistic sensitivity analyses (DSA) were carried out.

RESULTS: In the short to medium term, apixaban was associated with marginal LYs and QALYs gains and slight savings. However, as apixaban extended expected survival versus the NOAC comparators, the long-term cost-effectiveness was marginally more effective with a WTP threshold of 20,000 €/QALY gained than $95% and $92% for the same comparisons. The most influential parameter according to DSA was weight-adjusted QALYs at 1 year, with simulated results of (0.20, 0.55, 0.65) QALYs, expected total lifetime costs exceeded those of these comparators ($19,282, 16, 4). Corresponding ICERs were estimated in 2,911, 1,456, and 1,040 €/QALY gained. The WTP upper limit of 20,000 €/QALY gained was cost-effective with a WTP threshold of 20,000 €/QALY gained were 99%, 92% and 92% for the same comparisons. The most influential parameter according to DSA was daily cost of NOACs, but the corresponding ICERs remained well below commonly accepted cost-effectiveness thresholds. Apixaban is more effective and more cost-effective than dabigatran and rivaroxaban in Italian NVAF patients, and marginally more costly due to costs in added years of life. The ICERs have a high likelihood of being below conventional thresholds of WTP for health benefits of the SSN and suggest that apixaban is cost-effective compared with other NOACs.
CZECH REPUBLIC

OBJECTIVES: Non-invasive molecular imaging tests are currently being developed to improve individual stroke risk prediction in patients with a recent transient ischemic attack (TIA) or minor ischemic stroke. We estimated the minimum performance (i.e., sensitivity and specificity) that a test must have in order to be more cost-effective than current clinical practice.

METHODS: The aim of imaging tests is to identify which patients should undergo surgery instead of receiving medicines. Decision modelling was used to estimate the minimum performance of a confirmatory test that is performed based on the result of an initial duplex ultrasonography. The comparators were patient management according to Dutch guidelines and three observed strategies. Sensitivity analyses were performed in which the sensitivity and specificity were varied to estimate the minimum test performance needed to be cost-effective versus the comparators.

RESULTS: A perfect confirmatory test (100% sensitivity and specificity) with a cost of €390 for a 60-year-old man is necessary to be more cost-effective. Moreover, the minimum values of sensitivity and specificity needed for a test to be cost-effective are dependent on the QALY threshold used.

CONCLUSIONS: An imaging test that improves risk prediction and early treatment advice for patients with a recent TIA or minor ischemic stroke has the potential to improve cost-effectiveness by reducing the risk of recurrent stroke. However, developers must consider if the minimum test performance required to be cost-effective can be achieved, other concerns of payers (e.g., budget impact) must also be considered.

PCV90

COST-EFFECTIVENESS OF APAIXAN COMPARED TO OTHER ANTICOAGULANTS FOR LIFETIME TREATMENT AND PREVENTION OF RECURRENT VENOUS THROMBOEMBOLISM

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OBJECTIVES: Guidelines suggest only 3-6 months of anticoagulant treatment in most venous thromboembolism (VTE) patients due to concerns that the bleeding risk with vitamin K antagonists (VKAs) outweighs the reduced risk of VTE recurrence in extended treatment. However, non-VKA novel oral anticoagulants (NOACs) have been used for extended treatment (VOCE, ROCKET-AF, LEVITRONIX). A Markov model was developed that includes the following health states: recurrent VTE, major bleed, clinically-relevant non-major bleed, chronic thromboembolic pulmonary hypertension, and death. Transition rates among health states were based upon AMPLIFY and AMPLIFY-EXT clinical trial data, network meta-analyses, disutilities of VTE-related clinical events, and FONDAPARINUX from UK NHS Healthcare Resource Group tables and utilities were from published literature. The primary outcome of interest was incremental cost per quality adjusted life year (QALY) gained.

RESULTS: Compared to other anticoagulants, lifetime treatment with apixaban was projected to result in fewer bleeds and fewer recurrent VTEs. The lower bleeding risk with apixaban led to fewer treatment discontinuations, longer time on treatment, and fewer recurrent VTEs. The reduced number of clinical events led to increased QALYs at a nominal cost increase, due primarily to longer treatment duration with apixaban. Incremental costs per QALY gained were €2,781, €619, and €10,820 for apixaban versus dabigatran, rivaroxaban, and LMWH/VKA, respectively. Sensitivity analyses indicated that results were robust to a wide range of inputs.

CONCLUSIONS: Apixaban for lifetime treatment of VTE can offer substantial clinical benefits and is a cost-effective alternative to other NOACs and LMWH/VKA.

PCV91

COST-EFFECTIVENESS OF EXTRACORPOREAL CARDIOPULMONARY RESUSCITATION IN PATIENTS WITH REFRACTORY CARDIAC ARREST

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OBJECTIVES: Extracorporeal life support (ECLS) has recently been introduced as a therapeutic option for refractory cardiac arrest (extracorporeal cardiopulmonary resuscitation - ECFR). Despite growing evidence demonstrating improved survival rates with ECFR, a number of questions remain unanswered and data on cost-effectiveness of this approach are still insufficient.

METHODS: Retrospective cost-effectiveness analysis was performed from the perspective of the hospital. Sixteen patients undergoing ECFR were compared to the analysis (ECFR group) and the data were compared with 35 subjects with conventional CPR for refractory cardiac arrest (non-ECFR group). RESULTS: In the ECFR group seven out of sixteen patients were weaned from ECMO, four of them with complete absence of clinical outcomes (CPC 1). Two patients survived without a need for CPR and one patient survived one year with severe neurological dysfunction (CPC 3) and one patient with persisting coma (CPC 4). In comparison, in the non-ECFR group all patients died within 24 hours. In the ECFR group, when using Levitronix Centrimag blood pump (Thoratec), the average annual costs per patient reached CZK885,044 (~EUR32,600), with the Cardiohelp device (Maquet, Germany) CZK788,542 (~EUR28,738). The cost utility ratio analysis revealed 3,963,970 CZK/QALY (~EUR144,413/QALY) with Cardiohelp, and 4,447,457 CZK/QALY (~162,109 EUR/ QALY) when using Levitronix Centrimag. However, if only patients with CPC 1 were included into the analysis, the cost-utility ratio decreased to 834,616 CZK/QALY (~33,007 EUR/QALY) and 903,106 CZK/QALY (~33,007 EUR/QALY) with Cardiohelp and Levitronix, respectively.

CONCLUSIONS: Our data indicate that ECFR for refractory cardiac arrest might be cost effective despite the high costs per individual patient. Further studies are required in this approach. Larger studies are, however, required to confirm these observations.

PCV92

COST EFFECTIVENESS OF IVABRADEINE IN CHRONIC HEART FAILURE PATIENTS WITH HEART RATE ABOVE BPM IN TAIWAN

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OBJECTIVES: Raised heart rate is a risk factor for cardiovascular events and death. Heart rate reduction could be an important role in management of chronic heart failure. However, the role of additional heart rate reduction therapy in chronic heart failure management in Taiwan is uncertain. Indeed there is great regional variation across the UK in how, and if, VV are treated. This analysis assessed the cost effectiveness of ivabradine in CHF with heart rate 75 bpm using the perspective of a middle-income country’s public health insurance system.

METHODS: Model-based analysis closely mirrored the SHIFT trial was performed. Micro-simulation method of CHF disease, mortality and hospitalization were used to compare ivabradine plus standard care with standard care only. A two state Markov model has been employed to simulate the natural history of disease progression and clinical health outcomes, using clinical research database in Taiwan, a single-payer program that offers universal health care coverage. And another estimated costs using a medical center in Taiwan with clinical examination. Due were performed to validate the accuracy of costs. Incremental cost per quality adjusted life year (QALY) gained is used to express the value of ivabradine over a lifetime horizon and 29 months of trial period. RESULTS: The incremental cost of additional QALY with ivabradine plus standard care has been estimated at €1,832 for trial period and €7,634 for lifetime. Ivabradine is cost-effective according to NICE threshold. And the result was robust in sensitivity analysis.

CONCLUSIONS: In a middle-income country like Taiwan, the use of ivabradine to treat the eligible CHF patients is likely to be cost-effective.

PCV93

ECONOMIC ANALYSIS OF THROMBO INCODE, A CLINICAL-GENETIC FUNCTION FOR ASSESSING THE RISK OF VENOUS THROMBOEMBOLISM

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OBJECTIVES: To conduct an economic analysis of the risk assessment of venous thromboembolism (VTE) from the perspective of the Spanish National Health System with Thrombo inCode versus conventional/standard method used to date (FACIT). The aim of this study was to conduct an economic model was created from the National Health System perspective using a decision tree in patients aged 45 with a life expectancy of 81 years. The predictive capacity of VTE based on the identification of thrombophilia with Thrombo inCode and of the standard method was obtained from two case-control studies (S. PAU and MARTHA). A single-payer program that offers universal health care coverage. And another estimated costs using a medical center in Taiwan with clinical examination. Due were performed to validate the accuracy of costs. Incremental cost per quality adjusted life year (QALY) gained is used to express the value of ivabradine over a lifetime horizon and 29 months of trial period. RESULTS: The incremental cost of additional QALY with ivabradine plus standard care has been estimated at €1,832 for trial period and €7,634 for lifetime. Ivabradine is cost-effective according to NICE threshold. And the result was robust in sensitivity analysis.

CONCLUSIONS: In a middle-income country like Taiwan, the use of ivabradine to treat the eligible CHF patients is likely to be cost-effective.

PCV94

A COST-EFFECTIVENESS ANALYSIS OF INTERVENTIONS FOR SYMPTOMATIC VARICOSE VEINS

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OBJECTIVES: Treatment of varicose veins (VV) has been shown to increase health related quality of life (HRQoL). However, the cost-effectiveness of such treatments remains uncertain. Indeed there is great regional variation across the UK in how, and if, VV are treated. This analysis assessed the cost effectiveness of the novel clinical guideline on VV, with an objective to investigate whether such treatments should be recommended across the UK.

METHODS: An economic analysis was conducted to compare...
cost-effectiveness of surgery, endocardial ablation (ETA), ultrasound guided foam sclerotherapy (UGFS) and compression stockings (CS). The analysis was based on a Markov decision model, which was developed in consultation with members of the NICE guideline development group (GDG). The model had a five year time horizon, and took the perspective of the UK National Health Service. Clinical inputs were based on published (NMA) and systematic reviews in the clinical literature. Outcomes were expressed as costs and quality adjusted life years (QALYs). RESULTS: All interventional treatments were found to be cost-effective compared to CS, with cost-effectiveness thresholds of £20,000 per QALY gained. ETA was found to be the most cost-effective strategy overall, with an incremental cost-effectiveness ratio of £3,161 per QALY gained compared to UGFS. Surgery and CS were dominated by ETA. CONCLUSIONS: Interventional treatment for VV is cost-effective in the UK NHS. Specifically, based on current data, ETA is the most cost-effective treatment in people for whom it is suitable. The results of this research were used to inform recommendations within the NICE guideline on VV. Funding: This work was undertaken by the National Clinical Guideline Centre, which received funding from the National Institute for Health and Clinical Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily of the institute.

PCV95
THE COST-EFFECTIVENESS OF DABIGATRAN ETILXILATE COMPARED WITH RIVAROXABAN IN THE TREATMENT OF ACUTE VENOUS THROMBOEMBOLISM IN THE UK
Jugrin A.V., Ustyugova A.V., Urbich M., Lamotte M., Sundllerland Tj

OBJECTIVES: Venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism (PE) is a common cardiovascular disorder. Acute VTE is often managed with long-term anticoagulant treatment due to the potential adverse effects of model drivers. The impact of dabigatran was followed by 3-6 months of a vitamin-K antagonist. Novel oral anticoagulants do not require routine coagulation monitoring and dose adjustment, thus potentially providing a better alternative for initiation and long-term use. The aim of this study was to compare rivaroxaban over a 6 months treatment course in the UK health care setting was evaluated in this research. METHODS: A life-time Markov model was developed, encompassing recurrent VTE events and VTE-related deaths, and the most common cardiovascular events following acute venous thromboembolism, including intracranial hemorrhage, systemic embolism, other major bleeds, clinically relevant non-major bleeds, myocardial infarction and cardiovascular hospitalizations. The results of this research were used to inform recommendations within the NICE guideline on VV. Funding: This work was undertaken by the National Clinical Guideline Centre, which received funding from the National Institute for Health and Clinical Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily of the institute.

PCV96
THE COST-EFFECTIVENESS OF DABIGATRAN ETILXILATE COMPARED WITH RIVAROXABAN IN THE TREATMENT OF ACUTE PULMONARY EMBOLISM IN THE UK
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OBJECTIVES: This economic evaluation aimed to assess the cost-effectiveness of dabigatran etilxilate for six months of treatment for acute pulmonary embolism (PE) compared with warfarin and rivaroxaban in the UK health care setting. METHODS: A Markov state-transition cohort model was used to project the lifetime recurrence of PE and occurrence of deep vein thrombosis (DVT) in patients with initial acute PE. The incidence of recurrent venous thromboembolism (rVTE) was based on the relevant study endpoints of RE-COVER and RE-COVER II dabigatran trials and the 6 months treatment duration subgroup of the rVTE was considered, namely chronic thromboembolic pulmonary hypertension and post-thrombotic syndrome. Following cardiovascular events were considered: ischemic and hemorrhagic stroke, myocardial infarction and cardiovascular hospitalizations. The results of this research were used to inform recommendations within the NICE guideline on VV. Funding: This work was undertaken by the National Clinical Guideline Centre, which received funding from the National Institute for Health and Clinical Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily of the institute.

PCV97
THE COST-EFFECTIVENESS OF AXPINAXAN COMPARED WITH WARFARIN AND ASPIRIN IN PATIENTS WITHOUT NON-VALVULAR ATRIAL FIBRILLATION (NVAF) IN THE RUSSIAN FEDERATION
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OBJECTIVE: To evaluate cost-effectiveness of the novel oral anticoagulant apixaban compared with warfarin and aspirin in patients with NVAF from the Russian Federation national health care system perspective. METHODS: Cost-effectiveness analysis was based on a Markov model that allowed estimation of the incremental costs and health outcomes of treatment options for NVAF over lifetime horizon in vitamin K antagonists (VKA) suitable and VKA unsuitable patients with NVAF, respectively. The model enclosed cardiovascular event rates derived from the randomized clinical trials: ARISTOTLE and AVERROES. The following cardiovascular event rates were used to inform recommendations within the NICE guideline on VV. Funding: This work was undertaken by the National Clinical Guideline Centre, which received funding from the National Institute for Health and Clinical Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily of the institute.

PCV98
THE COST-EFFECTIVENESS OF DABIGATRAN ETILXILATE COMPARED WITH WARFARIN IN THE TREATMENT AND SECONDARY PREVENTION OF ACUTE VENOUS THROMBOEMBOLISM IN THE UK
Jugrin A.V., Ustyugova A.V., Urbich M., Lamotte M., Sundllerland Tj

OBJECTIVE: This economic evaluation aimed to assess the cost-effectiveness of dabigatran etilxilate compared with warfarin, in the treatment and secondary prevention of acute venous thromboembolism (VTE) comprising deep vein thrombosis (DVT) and pulmonary embolism (PE), in the UK health care system perspective. The results of this research were used to inform recommendations within the NICE guideline on VV. Funding: This work was undertaken by the National Clinical Guideline Centre, which received funding from the National Institute for Health and Clinical Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily of the institute.

PCV99
ECONOMIC EVALUATION OF VALSARTAN VERSUS OLMESARTAN ADDITION TO AMLODIPINE AND HYDROCHLOROTHIAZIDE SINGLE-PILL TRIPLE ANTIHYPERTEERTHESIVE THERAPY
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OBJECTIVE: This economic evaluation aimed to assess the cost-effectiveness of valsartan versus olmesartan addition to amlodipine (A) and hydrochlorothiazide (H). METHODS: A Markov model with eight health states was constructed. The short-
term effect of antihypertensive treatment on blood pressure was extracted from relative risk (RR) data. These data were adjusted through the Hollander Durene, Framingham risk equations, estimating the long-term survival and quality-adjusted life-years (QALYs) gained. Costs and outcomes were evaluated over lifetime, divided into annual cycles and were discounted at 3% with 2014 as reference year. A deterministic economic analysis was conducted from the Greek third-party payer perspective (EOPY). Results: The total lifetime cost related to V/A/H combination was estimated to be lower (€10,970) compared to that of the O/A/H combination (€11,080), despite the higher drug acquisition cost. Moreover, the mean QALYs gained with the V/A/H combination were 10.88 vs. 10.80 for O/A/H combination. Therefore, the V/A/H combination was found to be a dominant alternative over O/A/H combination, as it was associated with lower cost and greater efficacy. A scenario when the very low blood pressure measurements were taken into account demonstrated that the V/A/H combination was far lower than the Greek GDP per capita (€6,845/QALY) vs. O/A/H combination, suggesting V/A/H combination to be a cost-effective choice. Extensive sensitivity and scenario analysis revealed robustness of the base case. The subgroup analysis also demonstrated that there was about 80% probability for the V/A/H triple combination to be cost-effective at a willingness-to-pay threshold of €16,000/QALY. Conclusions: This is the first study performed to compare the cost-utility of single-pill triple antihypertensive therapies. The V/A/H combination was proven dominant over the O/A/H combination for the treatment of moderate to severe hypertension.

PCV101

COST-EFFECTIVENESS OF HIGH-SENSITIVE TROPONIN ASSAYS FOR THE EARLY RULE-OUT ON DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI) IN PEOPLE WITH ACUTE CHEST PAIN: A NICE DISCRIMINATIVE ASSAYS STUDY

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Objectives: To assess cost-effectiveness of high sensitivity troponin (hs-cTn) assays for the management of adults presenting with acute chest pain at the emergency department (ED). Methods: An economic model was constructed to estimate lifetime costs and QALYs of five hs-cTn strategies (differing according to manufacturer, timing of the test, number of tests and cutoff point for a positive test result) compared to standard troponin (sTn) testing at presentation, and at 10-12 hours, which was considered the reference standard. In the base case, it was assumed that sTn testing had perfect accuracy for diagnosing AMI and only patients with a positive test for sTn were at increased risk for adverse events and would require treatment. In a secondary analysis, a proportion of patients with a positive hs-cTn test and a negative sTn test were at increased risk for adverse events and would benefit from immediate treatment. Results: Base case: Strategies cost-effective depending upon ICER thresholds were Abbott ARCHITECT hs-cTn 99th centile (thresholds <€6,597), Beckman Coulter hs-cTn 99th centile (thresholds ≤0.597 – €30,042), Abbott ARCHITECT hs-cTn optimal strategy (thresholds ≤0.042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194), and the sTn test (thresholds ≤30,042 – €103,194) for patients presenting with acute chest pain at the emergency department (ED). We aimed at estimating and comparing the total management costs of patients admitted to the emergency department (ED) with recent (≤48 hours) atrial fibrillation (AF) and to calculate an average AF management cost per strategy. The cardioversion success rates were based on published observational studies (DCQ 100%, amiodarone 68%, vernakalant 70%). In case of successful conversion the patient was released directly from the ED to home (DCC 50%, amiodarone 25%, vernakalant 20%) or admitted to the hospital for a median of 1 day (DCC) or 2 days (amiodarone) reflecting cardioversion-specific times to sinus rhythm. After a failed pharmacological cardioversion, patients were assumed to receive a DCC, failed DCC was followed by intravenous amiodarone. The associated inpatient costs were obtained using the IGS Hospital Disease Database (HDD2011). Treatment was using the national health care payer tariffs. Univariate and probabilistic sensitivity analyses were performed. Results: The total AF management costs from ED to home were €1,894 (amiodarone) and €1,354 (vernakalant). Given the relative frequencies of amiodarone (55%) and DCC (45%) to treat recent FA in Belgian ED, the weighted average management cost was €1,470 (€1,894×0.55 + €1,354×0.45). Based on a probabilistic sensitivity analysis, vernakalant was cost saving in 95% of the 1,000 simulations vs. current management. Conclusions: In patients with recent AF, the rapid cardioversion to sinus rhythm provided a chance of obtaining sinus rhythm within 48 hours, and its use was cost saving compared to the current average Belgian practice.

PCV104

COST MODEL ANALYSIS OF GORE® PROPATEN® VASCULAR GRAFT VERSUS STANDARD EPITEVE VASCULAR GRAFT FOR INFRAPOPLITEAL BYPASS TREATMENT IN PERIPHERAL ARTERIAL DISEASE (PAD) MANAGEMENT: SPANISH SCENARIO

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Objective: The objective of the present study was to assess efficiency of revascularisation programs for patients after traumatic brain injury and acute cerebrovascular accident (stroke) in Russia. Methods: Short-term clinical and social outcomes (health status and disability rates) of rehabilitation were analyzed in the database of the Moscow Center of Speech Pathology and Neurological Rehabilitation. Changes in the above outcomes were registered at 6 months and 1 year of follow-up for 3 different strategies of rehabilitation: hospital, day care and home care. The decision tree model was constructed to simulate disability rates, direct and indirect costs of rehabilitation. The scenario analysis was performed in order to assess the impact of different rehabilitation programs. Results: The Moscow Center of Speech Pathology and Neurological Rehabilitation is the only rehabilitation provider in Moscow. Conclusion: The decision tree model was able to estimate direct and indirect costs of rehabilitation in Russia. The Moscow Center of Speech Pathology and Neurological Rehabilitation is the only rehabilitation provider in Moscow.
PHARMACOECONOMIC ANALYSIS OF ROSUVASTATIN USE IN PATIENTS WITH HYPERCHOLESTEROLEMIA IN THE HEALTH CARE OF BELARUS

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OBJECTIVES: Pharmacoeconomic analysis of rosuvastatin use in patients with hypercholesterolemia in the health care of Belarus has been performed to determine economic advisability of its applying in Belarus. As there is own production of statins (generics of lovastatin, atorvastatin and simvastatin) in Belarus, the investigation of new rosuvastatin (in the clinical protocols) required pharmacoeconomic study.

METHODS: Overview of statins available in Belarus has been conducted. Equivalent effective dose to achieve target of low density lipoprotein cholesterol (CH-LDL) values were established on the basis of published data. Cost-effectiveness of the use of rosuvastatin in Belarusian CH-LDL values has been based on the basis of STELLAR trial. Statins doses required to achieve the target CH-LDL values have been calculated. The costs of achieving the target CH-LDL values have been evaluated. The cost of each statins treating during the year has been calculated. RESULTS: The highest cost has been obtained for the equivalent dose of lovastatin ($0.35) compared with atorvastatin ($0.31) and simvastatin ($0.28) manufactured in Belarus. Average price rosuvastatin (Merten €) was comparable to the cost ($0.21) of Belarussian generics. The average cost of achieving the target CH-LDL level was the lowest in the case of rosuvastatin: -170$ compared with atorvastatin ($200) and simvastatin ($286) considering available statins in national market. Due to rosuvastatin’s lower effective dose and price, the cost of one-year treatment with rosuvastatin is lower (on average 94 $) than with atorvastin (all manufacturers - $100) and simvastatin (202 $).

CONCLUSIONS: The study demonstrated pharmacoeconomic acceptability of rosuvastatin use in the health care of Belarus.

COST-UTILITY ANALYSIS OF HYPERTENSIIVE TREATMENT WITH INDAPAMIDE AND AMLODIPINE SINGLE-PILL COMBINATION IN THE POLISH SETTING

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OBJECTIVES: To assess cost-effectiveness of indapamide 1.5 mg + amlodipine 5/10 mg single-pill combination (SPC) compared with FC, in the Polish setting. METHODS: A Markov cohort simulation model was used. Results of meta-analysis by Gupta et al show a difference in patients’ compliance between SPC and FC. Better compliance results in lower systolic blood pressure, which influences risk of cardiovascular events. Hence, compliance is associated with life expectancy and quality of life. Cardiovascular disease risks were based on the Framingham risk equations. Life-time horizon, Polish public payer perspective, and only those with carotid stenosis above 50% were applicable. Cost-utility model was based on average pharmacy prices reported in April 2014 (18.13PLN and 19.75PLN per stand. respectively for 1.5 mg and 5 mg indapamide and amlodipine products in comparing doses. All costs present 2014 values, and are expressed in Polish zloty (PLN). Costs and effects were discounted with 0.020809. Difference in total costs from public payer perspective and from patient perspective were applied. Indapamide/amlodipine SPC cost is calculated from retrospective chart review (CAS). SPC versus FC generates additional life years (LYs) and quality adjusted life years (QALYs), and is expressed in Polish zloty (PLN). Costs and effects are discounted with 5% and 3.5% rates.

RESULTS: The incremental cost per life year and per QALY gained was €15,000/QALY. The results were consistent across different subgroups of ACS patient – hyper tension, for 5 years analysis SPC versus FC remains a cost-effective technology from public payer perspective.

CONCLUSIONS: Indapamide/amlodipine SPC compared with FC is a highly cost-effective treatment option for hypertension patients treated for hyperlipidemia.

COST-EFFECTIVENESS ANALYSIS OF CAROTID ARTERY STENTING VERSUS ENDARTERECTOMY FOR SYMPTOMATIC CAROTID STENOSIS PATIENTS

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OBJECTIVES: This study was conducted to determine the cost-effectiveness of carotid artery stenting (CAS) versus carotid endarterectomy (CEA) in patients with symptomatic carotid stenosis (70% to 99% stenosis) in Korean health care system. METHODS: We performed a cost-utility analysis. Costs were estimated from retrospective chart review (CAS = 346, CEA = 333), health insurance claims data, and a Web-based cost-utility model. Probabilities were estimated from retrospective chart and systematic review. Health utility index was assessed for general population using Time Trade Off (TTO) with health state. Sensitivity analysis was used to validate the robustness of the model. RESULTS: In the base case analysis, CAS produced 6.49 QALYs, compared with 6.71 QALYs for CEA. The incremental cost of stenting was €1,691,740 KRW. In the base case analysis, CAS for patients with asymptomatic stenosis had a greater benefit (in KRW, with lower costs). In subgroup for patients with stenosis more than 70% or patient with over 80 years old, CAS was cost-effective. Sensitivity analyses showed that the major slope or mortality influenced the results. However the results were consistent across different subgroups. CONCLUSIONS: Under the current circumstances in Korea, CAS was dominated by CEA in symptomatic stenosis. Therefore we concluded that CAS would be cost-effective intervention for carotid stenosis. To be economically competitive, the clinical effectiveness such as mortality and major stroke rates of CEA must be at least equivalent if not less than those of CEA.

COST-EFFECTIVENESS OF LDL-C-GUIDED STATIN THERAPY

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OBJECTIVES: Numerous trials have shown that lowering LDL cholesterol (LDL-C) reduces cardiovascular risk. Evidence from ASCVD guidelines point remaining LDL particle concentration (LDL-P) may be a better predictor of events, but no studies have evaluated its cost-effectiveness. We used the Archimedes model to evaluate the cost-effectiveness of a study was conducted. We evaluated the effectiveness of LDL-P treatment based solely on their LDL-P values.

CONCLUSIONS: From public payer perspective, indapamide/amlodipine SPC compared with FC is a highly cost-effective treatment option for hypertensive patients in contemporary Polish setting. From patient perspective, SPC is a dominant technology.
unknown risk cohort (n=2,497, 86 days). The annual indirect cost related to productivity loss was estimated at 209,704 SEK for treated hyperlipidemia patients with CV event history. Corresponding data for CV RE patients and patients at low/unknown risk were 168,517 SEK and 108,429 SEK, respectively. The higher CV risk levels were associated with greater productivity losses. Indirect costs varied within cohorts. In most cases, the diagnosis of the CV event history, a previous diagnosis of myocardial infarction was associated with the lowest annual indirect costs (189,114 SEK) while a past diagnosis of ischemic stroke was associated with the highest indirect costs (281,985 SEK). Within the CV RE cohort, a previous diagnosis of abdominal aortic aneurysm and transient ischemic attack was associated with the highest (264,441 SEK) and lowest annual indirect costs (156,254 SEK), respectively. CONCLUSIONS: The high level of productivity losses illustrates the heavy indirect load and differences in patients treated for hyperlipidemia. The type of past CV event affected the level of indirect costs.

PCV111 HEALTH CARE COSTS ASSOCIATED WITH CARDIOVASCULAR EVENTS IN PATIENTS WITH HYPERLIPIDEMIA - ESTIMATES FROM POPULATION-BASED REGISTER DATA IN SWEDEN
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OBJECTIVES: To estimate annual incremental health care costs of new cardiovascular (CV) events (myocardial infarction, unstable angina, revascularization, ischemic stroke, and transient ischemic attack or heart failure) in patients with a new CV event or prior CV events. METHODS: A retrospective population-based cohort study was conducted using Swedish electronic medical records and national registers. Patients were followed based on a prescription of lipid-lowering treatment starting between January 1, 2006 and December 31, 2006 or history of CV events (prior to 2006) and followed until December 31, 2012 for identification of new CV events and estimation of health care costs. In all, 113,141 patients were stratified into the following cohorts based on diagnosis: New CV event (n=84,821) and new CV event and unknown risk (n=28,320). Propensity score matching was applied to compare patients with new events to patients without new events and to estimate incremental costs. RESULTS: A new CV event resulted in increased costs during all follow-up years. Inpatient hospital stays were the main driver of the increase. The majority of the costs occurred in the first year following event when patients with CV event history (n=6,881) had an incremental cost of 74,758 SEK. This was similar to that of CV risk-equivalent patients (n=1,126, 75,415 SEK) and patients at low/unknown CV risk (n=2,497, 72,635 SEK). Ischemic stroke resulted in the highest first year cost all cohorts (88,739, 85,516; and 87,668 SEK) and transient ischemic attack the lowest (34,098, 36,042; and 29,052 SEK). Incremental costs during subsequent years remained elevated for all cohorts; first year’s criteria for cardiovascular events to be included in the analysis. Incremental costs varied between 10,689 and 15,082 SEK and third year costs varied between 85,516; and 87,668 SEK) and transient ischemic attack the lowest (34,098; 36,042; and 29,052 SEK). Incremental costs during subsequent years remained elevated for all cohorts; first year’s criteria for cardiovascular events to be included in the analysis. Incremental costs varied between 10,689 and 15,082 SEK and third year costs varied between 85,516; and 87,668 SEK) and transient ischemic attack the lowest (34,098; 36,042; and 29,052 SEK).

PCV112 INPATIENT CASE-RELATED TREATMENT COSTS FOR DIFFERENT CARDIOVASCULAR DISEASES IN GERMANY
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OBJECTIVES: As part of a non-interventional study, hospitalizations due to cardiovascular diseases (CVD) were documented at 10% of all German hospitals. The primary endpoint was the assessment of indirect costs including days off work and productivity loss. Medication compliance was based on patients’ self-report during each monthly visit. Taking 80% was applied to differentiate between compliance or non-compliance. Taking medication was based on patients’ self-report during each monthly visit. Taking medication was based on patients’ self-report during each monthly visit. The analysis was conducted for 2012 (SoT); 5,200 (for men) or 90 (for women) and other chronic greater diseases, verifying the occurrence of greater outcomes and related health care costs. CONCLUSIONS: Administrative databases offer huge potential for providing current (already available) regarding occurrence of outcomes occurring in a health care environment. These sources and their integrity are a powerful tool supporting conventional methods used in epidemiological studies and as tools for plan Health care policy.

PCV114 CARDIOVASCULAR RISK, GENDER AND MEDICATION ADHERENCE IN RURAL AREA OF VIETNAM
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OBJECTIVES: To examine the relationship between medication compliance, cardiovascular risk and gender in hypertensive patients visiting primary health care centers. METHODS: A prospective 1-year study was conducted in rural communities in Vietnam. Medication compliance was calculated as the number of days the drug divided by the number of days since the first day of the prescription. A threshold of 80% was applied to differentiate between compliance or non-compliance. Taking medication was based on patients’ self-report during each monthly visit. RESULTS: OF 717 patients, 638 were included in the final analysis. Compliance had a significant influence on health outcomes. For patients with a MI event history, gender, age, gender, blood pressure and blood test were collected at baseline. Medication adherence was based on the Cardiovascular Risk Prediction Model for populations in Asia. Medication compliance was calculated as the number of days taking the drug divided by the number of days since the first day of the prescription. A threshold of 80% was applied to differentiate between compliance or non-compliance. Taking medication was based on patients’ self-report during each monthly visit. The analysis was conducted for 2012 (SoT); 5,200 (for men) or 90 (for women) and other chronic greater diseases, verifying the occurrence of greater outcomes and related health care costs. CONCLUSIONS: Medication compliance rate was low among hypertensive patients in Vietnam. CVD risk at the baseline of significantly differentiate compliance from non-compliant patients. Yet, a major difference in compliance was found for gender. Rather than risk profile, gender should be considered for guiding the choice on who to target for improving medication compliance for hypertensive patients.

PCV115 HEALTH BEHAVIOR AND MEDICATION ADHERENCE
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OBJECTIVES: To explore the associations of selected health behaviors with medication adherence in elderly patients aged 65+ years with hypertension, diabetes, or hyperlipidemia. METHODS: The Korean National Health Insurance data between January 2010 and June 2011 were used. The study included 662,170 hypertensive, 179,285 diabetic, and 246,702 hyperlipidemic patients. Poor medication adherence was defined as < 80% medication possession ratio from January to June 2011. Health behavior data were from year 2010. Multivariable logistic regression was used. RESULTS: Patients with a waist circumference < 85 (for women) or 90 (for men) centimeters were more likely to adhere to their medications. Current smokers and moderate or heavy drinkers showed poor medication adherence than their counterparts. Mild physical activity was associated with better medication adherence. CONCLUSIONS: Public efforts need to focus on improving comprehensive control of both health behaviors and medication adherence.

PCV116 UNDERSTANDING MEDICATION ADHERENCE USING STATED-PREFERENCE DATA
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OBJECTIVES: More than half of people who have experienced a myocardial infarction (MI) are not adherent to their medication regimen, which leads to poorer health outcomes. We used a stated-preference (SP) study to examine factors that could influence patient compliance to prophylactic cardiovascular treatments, and discuss practical issues in using SP methods to explain medication adherence. METHODS: Preference data for treatments that lower the risk of cardiovascular events were collected from 464 respondents in the United States with self-reported history of MI using a discrete-choice experiment (DCE). All respondents answered 11 judgment
questions that presented a pair of virtual patients who were prescribed different treatments. Longitudinal reductions in the treatment-related risk of serious infection, mode and frequency of administration, and monthly medication cost. Half of the choice questions asked respondents to select the treatment to which they would most likely be nonadherent. The other half asked respondents to state which of two virtual patients would be more likely to adhere each was to each medication. Limited dependent-variable models were used to estimate weights indicating the impact of treatment and respondent characteristics on stated adherence and quantifying the stated impact of nonadherence on respondents' well-being. RESULTS: Results indicated that reductions in the risk of a nonfatal MI had the largest effect on stated adherence, followed by medication cost, the risk of serious infection, and lastly mode and frequency of administration. Results also show that reductions in compliance had a significant impact on the perceived overall benefits of prophylactic treatments. CONCLUSIONS: We find that both clinical and non-clinical factors can impact treatment adherence, suggesting that the ability to select a variety of factors with SF models can be useful in understanding patient compliance.

PCV117 PATIENT ADHERENCE AMONG ADOLESCENTS WITH ARTERIAL HYPERTENSION Nowakowska E, Paczkowska A, Bryl W, Hoffmann K Poznan University of Medical Sciences, Poznan, Poland

OBJECTIVES: The aim of the study was to assess the level of adherence by adolescents in the field of pharmacological and non-pharmacological methods of hypertension treatment. METHODS: The study included 62 patients (20 women, 42 men) diagnosed with hypertension and treated in specialist health care facilities. As a research tool we used questionnaire prepared on the basis of recent literature. RESULTS: The vast majority of respondents (72.7%) declared that regularly taking antihypertensive drugs. The proportion of patients regularly taking antihypertensive drugs was higher in respondents treated with mandatory low-sodium diet (48.5%, p = 0.0001). Among the methods of non-pharmacological treatment of hypertension the most accepted lifestyle change in the study population was smoking cessation (83.6% of respondents). The most accepted medical recommendation in the study population was to prescribed medication (70.7% of respondents). The least acceptable lifestyle change was to maintain proper body weight by eating a low-calorie diet (30.6% of respondents). CONCLUSIONS: Adolescents with hypertension in varying degrees adhere to a medical recommendations related to the hypertension treatment. From the available literature data indicate that the current effective way to improve cooperation with the patient's education.

PCV118 HEALTH STATE UTILITIES IN CHRONIC HEART FAILURE IN THE UK Nafees B, Cowie MR, Patel C, Deschaseaux C, Brewer P, Lloyd AJ1


OBJECTIVES: Previous research has shown the impact of chronic heart failure (CHF) on health-related quality of life (HRQoL). Less is known regarding the impact of reduced ejection fraction (HFrEF) on HRQoL. The aim of this study was to elicit utility values for CHF with HFrEF or preserved ejection fraction (HFpEF) by New York Heart Association (NYHA) classification system in the UK. In addition, utility values for events as state, the time-related impact of acute myocardial infarction (MI) and chronic MI on CHF health state utilities were estimated. METHODS: Health states were developed from concept elicitation interviews with CHF patients (N = 10) and cardiologists (N = 5). Draft health states were refined based on literature review, clinician interviews, and a pilot study. Three health states were developed from concept elicitation interviews: stroke, acute coronary syndrome (ACS) and heart failure. One-year acute health states represented the event and gradual recovery; post-event health states represented chronic impact. UK general population respondents to the health states in time trade-off tasks with time horizons of one year for acute states and ten years for chronic states. RESULTS: A total of 200 participants completed interviews (55% female, mean age = 46.6y). Among acute health states, stroke had the lowest utility (0.33), followed by heart failure (0.60) and ACS (0.82). Health states for stroke (0.52), heart failure (0.57), and ACS (0.82). For stroke and ACS, acute utilities were significantly lower than utilities for chronic post-event (difference = 0.20 and 0.15, respectively; p < 0.0001). CONCLUSIONS: Results add to previously published utilities for cardiovascular events by distinguishing between chronic post-event health states and acute health states that include the event and its immediate impact. Findings suggest that acute and chronic impact should be considered when selecting a time horizon for use in cost-effectiveness models. Thus, the current utility provides a unique option that may be used to represent the acute and chronic impact of cardiovascular conditions in economic models comparing treatments that may delay or prevent the onset of cardiovascular events.

PCV120 HEALTH STATE IN PATIENTS WITH ATRIAL FIBRILLATION ON NEW ORAL ANTICOAGULANTS AS ASSESSED WITH THE NEW EQ-5D-5L QUESTIONNAIRE AT BASELINE AND 12-MONTH FOLLOW-UP: PREFER IN AF REGISTRY Brugenier et al., Schliephacke B, Darius H, De Caterina R, Le Heuse YJ2, Reimetz PE1, Schilling RJ1, Schwertfeger M, Zamaro JU, Kirchhof P6

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OBJECTIVES: We aimed to understand the short-term impact on quality of life associated with different NOACs in patients with AF. METHODS: Baseline and 12-month data were obtained from the baseline (BL) and follow-up (FU) data on the health state of patients under everyday practice conditions in the PREFER in AF registry. RESULTS: We evaluated the index value increased from BL to 12-month FU. On the VAS (range 0–100), the mean score at FU was 68.8 ± 18.1 points, with no major differences between patients on NOACs (68.3–68.9), VKAs (68.9–70.9), or VKAs (70.1–70.6); respectively improved from baseline. CONCLUSIONS: Patients on VKA to 1.77 for those on AF. The overall utility index at FU was 0.80 ± 0.21. At FU the 409 patients on NOACs had a utility score of 0.79 (change from BL, -0.01), the 1789 patients VKAs 0.80 (± 0.01) the 237 patients on AP 0.78 ± 0.01 and the 745 patients receiving neither VKAs nor AP 0.80 (0.00). CONCLUSIONS: Patients with AF present with reduced self-reported quality of life compared to the general population. Patients receiving NOACs had similar HRQoL at baseline and after 12-month FU, when compared to alternative medications.


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OBJECTIVES: Non-VKA oral anticoagulants (NOACs), which do not need routine monitoring, have the potential to improve the quality of life (QoL) in patients on long-term treatment for venous thromboembolism (VTE). We aimed to obtain contemporary data on the health state of patients with VTE under daily practice conditions. METHODS: PREFER in VTE is a non-interventional study in 7 countries (France, Germany, Austria, Switzerland, Italy, Spain, UK). Patients included the same pair of questionnaires patients after an event of acute deep venous thrombosis (DVT) or pulmonary embolism (PE) in terms of clinical characteristics, management, quality of life and other outcome parameters. The EuroQol EQ-5D-5L descriptive system was used to derive utility scores and the visual analogue scale (VAS), and patients to prefer in AF at BL and FU to obtain the short-term and long-term utilities. CONCLUSIONS: No major differences between patients on NOACs (73.6–73.9), VKAs (73.9–74.8), AP (74.8–75.5) or VKAs (75.5–76.0). Patients on NOACs had slightly lower utility values (73.6–73.9) than patients on VKAs at FU. Overall the index value increased from BL to 12-month FU. The mean score at BL was 73.6 ± 10.9, with similar values in DVT patients (74.6, change from BL, +0.9) and in patients with PE (73.9, change from BL, +1.4). CONCLUSIONS: Health state utilities were compared to VTE patients at baseline (BL: 1640 DVT, 1150 PE ± DVT) and 723 patients at an interim 12-month follow-up (FU). CONCLUSIONS: Results add to previously published utilities for cardiovascular events by distinguishing between chronic post-event health states and acute health states that include the event and its immediate impact. Findings suggest that acute and chronic impact should be considered when selecting a time horizon for use in cost-effectiveness models. Thus, the current utility provides a unique option that may be used to represent the acute and chronic impact of cardiovascular conditions in economic models comparing treatments that may delay or prevent the onset of cardiovascular events.
PCV122
THE INTERMEDIATE BURDEN OF DISEASE MELLITUS IN PATIENTS WITH CARDIOVASCULAR DISEASE (CVD): A QUALITY ADJUSTED LIFE YEAR (QALY)
-ANALYSIS BASED ON PRIMARY LONGITUDINAL DATA
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OBJECTIVES: While the independent influence of metabolic and cardiovascular diseases on either quality of life (QoL) or survival is well studied, the evidence on the combined burden in terms of quality adjusted life years (QALY’s) is rather weak. Previous burden of disease studies mostly combined cross-sectional QoL data with mortality statistics from other data sources. Knowing these limitations, we aimed in this study to give a QALY estimate of patients with diabetes. METHODS: We used a dataset from the KORA Myocardial Infarction Registry (AMI) study (n = 1,000) and followed patients up for 10 years. Patient characteristics and clinical course was documented. QoL and mortality data was obtained. For the analysis, we fitted a discrete time survival model to estimate the QALYs lost due to having diabetes. RESULTS: The QALYs lost were 12.68 ± 3.28 months. There was no substantial difference in QALYs lost between men and women, patients younger than 65 years and patients older than 65 years. However, the difference between the two diabetes groups (Type I vs. Type II diabetes) was 1.29 ± 0.55 QALYs per patient. CONCLUSIONS: While the intermediate burden of diabetes in patients with CVD is considerable, further research should be invested in order to be able to exploit primary longitudinal data sources of population-based studies.

PCV123
SENSITIVITY OF THE SAFUCA QUESTIONNAIRE TO DETECT DIFFERENCES BETWEEN ATRIAL FIBRILLATION PATIENTS TREATED WITH VITAMIN-K ANTAGONISTS AND THOSE TREATED WITH NO ORAL ANTICOAGULANTS
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OBJECTIVES: A secondary analysis was carried out to test if differences existed in reported treatment satisfaction between non-valvular atrial fibrillation patients (NVAF) treated with vitamin K antagonist (VKA) anticoagulants and new oral anti-coagulants (NOAC). METHODS: A sample of 1318 patients was recruited at random in the FANTASIA study, between June 2013 and March 2014, from which 77% were using VKA and 23% NOAC at least 6 months before inclusion. The specific treatment satisfaction instrument SAFUCA was used to test differences between groups. The SAFUCA questionnaire is composed by 7 dimensions and overall score, measured in a 0 (least satisfied), 100 (most satisfied) scale. Guyatt’s d was used to estimate the effect size. RESULTS: Mean overall score and in all SAFUCA dimensions were higher in the NOAC group (84.30 vs. 80.30, p < 0.001), Impact on Daily Activities (92.70 vs. 81.97, p < 0.001), Satisfaction with Medical Care (89.21 vs. 79.21, p < 0.001), and Overall Satisfaction (80.30 vs. 69.38, d = 0.74, p < 0.001). CONCLUSIONS: SAFUCA questionnaire was able to detect satisfaction differences between NVAF patients treated with NOAC and those treated with VKA, presenting medium effect size in most dimensions. This new evidences offer additional support to the questionnaire validity.

PCV124
UNMET NEEDS AND SOLUTIONS FOR HEART FAILURE ADMISSION
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OBJECTIVES: Unplanned patient admissions to hospital with heart failure (HF) are on the increase due to an ageing population and increasing survival post coronary disease. Pre-discharge mortality is high, predictable and often occurs after many days stay for many patients and often without palliative care involvement, not aligned with guidance. METHODS: We audited palliative care input to HF patients admitted to our hospital as the predominant condition and subsequently passing away, both before and after an awareness campaign, publishing barriers to end of life discussions (EOLD) and the patient and clinician perspectives on the decision to die. The setting was a Get With The Guidelines (GWGT) risk assessment tool to predict mortality and introduction of a daily HF nursing team service. RESULTS: In 2009, amongst 57 HF patients were 36 deaths, of which 31% died in the hospital within 7 days post admission. We undertook a Delphi process to establish a Get With The Guidelines (GWGT) risk assessment tool to predict mortality and introduction of a daily HF nursing team service. CONCLUSIONS: The care of HF patients and their families can be greatly improved with early mortality prediction, sensitive dialogues, routine involvement of HF teams both to enhance survival for patients who will benefit from aggressive therapies such as complex devices or ultrafiltration, as well as enabling an enriched end of life experience for those beyond such therapies. Enabling end stage patients to die in their location of choice would also release considerable resources at the same time.

PCV125
CLINICAL PSYCHOLOGISTS: CLOSING THE COMMUNICATION GAP BETWEEN PHYSICIANS AND PATIENTS, LEADING TO HIGHER PATIENT SATISFACTION AND COMPLIANCE
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OBJECTIVES: To compare the patient satisfaction and compliance between a hospital with a trained clinical psychologist, acting as a mediator between physicians and patients and a hospital without one. METHODS: The comparison was done between two identical cardiac hospitals, which belong to the same network of cardiac facilities, for a period of six months. At each hospital, 200 patients were included. The patient characteristics, numbers and patient flow were comparable; the facilities were identical as level of comfort run in the four of the Bulgarian Cardiac Institute clinics. We used questionnaire. The level of attendance of control visits after discharge we measured with the hospital registry. How many of the 200 patients stick to the discharge therapy after 3 and after 6 months after discharge, we measured with the outpatient centre registry and by telephone interviews. RESULTS: In each hospital 200 patients were included and followed-up. For the hospital without clinical psychologist, patient satisfaction was 79% excellent marks (n = 158), control visits attendance was 89% (n = 156), and patient compliance was 72% (n = 143) on the 6th month after discharge. For the hospital with a clinical psychologist, patient satisfaction was 97% excellent marks (n = 194), control visits attendance was 96% (n = 178) and patient compliance was 85% (n = 170) on the 6th month after discharge. With the help of a trained clinical psychologist, we witnessed the following differences: 18% improvement in patient satisfaction after 3 visits, 20% for both the 3rd and 6th month after discharge. CONCLUSIONS: Trained clinical psychologists may play the role of a mediator and close the communication gap between physicians and patients and lead to improved patient satisfaction and compliance.

PCV126
EVALUATING THE GAP BETWEEN PHYSICIANS’ AND PATIENTS’ UNDERSTANDING OF PATIENT NEEDS
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OBJECTIVES: We wanted to establish the gap between physicians’ and patients’ understanding of patient needs in a hospital setting. METHODS: The study was conducted two times, at the beginning and within a period of two months, first we asked 30 physicians and 50 patients about what patient needs are according to their understanding. Based on the answers we defined 10 categories for each of the two groups. Then we asked 143 physicians and 250 patients, who can’t write, what is important for them by using the Maximum Difference Scaling technique. RESULTS: Courtesy, after discharge recommendations and information about the discharge discharge were the two categories which generally patient needs according to the patients. LIFE-SAT (Life satisfaction) was the third most important patient needs according to the physicians. CONCLUSIONS: The gap between doctors and patients perceptions of patient needs. It is very hard for the hospitals to take into account patients satisfaction relying on medical services only. Further research is needed to find ways to close that gap.

PCV127
BELIEFS ABOUT MEDICINES IN AN URBAN BLACK HYPERTENSION POPULATION
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OBJECTIVES: Given ethnic variation in attitudes toward hypertension (Ford 2010; Lewis 2010), study objectives are to determine 1) patient preferences concerning medication use as revealed by responses to Beliefs about Medicines Questionnaire (BMQ, Horne 1999) in an urban black population with hypertension (HTN) and 2) if these preferences were influenced by previous exposures with patients/friends HTN diagnoses. METHODS: After approval from Northeastern University’s Institutional Review Board, coded clinic appointment schedules were used to identify patients scheduled for routine HTN follow-up appointment at a Boston inner-city community health center. Researchers screened for eligibility (English speaking, black ethnicity, taking anti-hypertensive medication), described the study, and requested informed consent. Patients agreeing to participate and completing background questionnaires (i.e., Beliefs about Medicines Questionnaire [BMQ]: 18 items, 5 levels, strongly agree-strongly disagree) received a $10 CVS-provided gift card. RESULTS: 189 patients were approached. 94 (49.7%) completed the BMQ. Of those patients, 116 (61.6%) received one of the gift cards. 92 (50%) of the BMQ group had fair to poor English skills or had previously completed the BMQ. Patients averaged 55.69 ± 7.67, Female Overall BMQ factor scores were: Specific Necessity (SN), 3.41 ± 0.83, Specific Concerns (SC), 2.82 ± 0.8, General Overuse (GO), 2.98 ± 0.74 and General Harm (GH), 2.53 ± 0.74. CONCLUSIONS: Higher BMQ scores (p = 0.042) are not associated with whether a friend did/hadn’t have hypertension and whether a friend did/hadn’t have a stroke. SC were lower in patients with higher educational level (p = 0.002). No statistical associations occurred between
self-reported adherence results and any of the 4 factor scores. CONCLUSIONS: This study factors scores for urban black HTN patients, insight into how experiences of patient's parents can be used to target increased perception of anti-hypertensive medication necessity and reduce patient-specific medication harm concerns.

PCV128
PLACE OF RESIDENCE AND EMPLOYMENT STATUS AFTER STROKE


METHOds: We conducted an observational retrospective study among 569 post-stroke patients and employment status were assessed 1 year after hospital discharge. The investigation period was divided into 3 intervals: < 3.3-6 and >6 months after stroke. All patients had their mRS (modified Rankin Score, ranging from 0 full health to 5 severely dependent) measured at 3 months after stroke, plus an additional mRS assessment if their stroke was more than 6 months ago. Patients were recruited in 10 regional and university hospitals across Belgium using a convenience sample stratified by mRS. RESULTS: Before their stroke the majority of patients lived at home (99%) despite the fact that 13% had a previous stroke. At 3 months after stroke an association was found between the time spent in an inpatient care facility (hospital, rehabilitation facility, nursing home) and the mRS (p<0.001, Weibull survival analysis, average inpatient days were 5, 14, 27, 37, 34, 67, and 74 for mRS 0-5 respectively). At 1-year after stroke, 35% of patients were staying in a rehabilitation facility and 5% in a nursing home; these were mostly patients with mRS = 3. After six months all patients returned home, except patients with mRS ≥ 4 (38% home). Before stroke, 16-20% patients in those working before their stroke, 16-20% patients in mRS categories 0-2 were working again compared to none in mRS category 3-5, of which 14% took early retirement or leave of absence. CONCLUSIONS: Experiencing a mild stroke will not affect the patient's employment and living situation beyond the short-term horizon, however suffering a severe stroke is likely to lead to significant changes in place of residence and occupation.

PCV129
UISESS-B ORAL HEALTH QUESTIONNAIRE VALIDITY AND RELIABILITY IN A MEXICAN DIABETIC, SYSTEMIC HYPERTENSION AND OBSES PATIENTS

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METHOds: There is a need for health-related quality of life (HRQoL) in patients hospitalized by heart failure (HF). The main objective of the present study was to evaluate changes in HRQoL from baseline to 1-year post discharge in patients with HF through two questionnaires, SF-12, MLHFFQ. CONCLUSIONS: This has been a prospective study with 502 patients admitted by HF in Basque (Spain) through two questionnaires, SF-12, MLHFFQ. MLHFFQ is a more detailed questionnaire in 3 areas: physical (8 items) and emotional (5 items) subscales. MLHFFQ items are scoring from 0 (best) to 5 (worst). Total score ranges from 0 to 105, physical domain from 0 to 40, emotional domain from 0 to 50 to 100. We have used general linear model to study gains in each dimension adjusted by baseline score, age, gender and hospital readmissions in the previous 6 months. RESULTS: Mean age was 76.7 (SD 10.4), there were a 56% of women and 20.3% of readmissions in the previous six months. Since the introduction of non-vitamin-K-antagonist oral anticoagulants (OACs), an additional option for stroke prevention in patients with atrial fibrillation (AF) compared to vitamin-K-antagonists (VKAs) is available. The objective of this study was to assess patients’ preferences regarding the attributes of these different treatment options. METHOds: We conducted a multicenter study among randomly selected physicians who were asked to recruit AF patients. Patients’ preferences were assessed by computer-assisted telephone interviews. We used a Discrete-Choice-Experiment (DCE) with four treatment dependent attributes (need of bridging: yes/no, interactions with food/nutrition: yes/no, need of INR controls/ dose adjustment: yes/no, frequency of intake: once/weekly). We compared three treatments: OACs vs. VKAs vs. bridging powerful anticoagulant vs. no anticoagulant. CONCLUSIONS: Our study showed that the majority of patients preferred OACs vs. VKAs vs. bridging vs. no anticoagulant. No significant preference was found for bridging vs. VKAs vs. no anticoagulant. In favour of the options are shown. CONCLUSIONS: In our analysis, “once daily frequency of intake” was the most important attribute for patients’ choice followed by “no interactions” and “no need of INR controls/dose adjustment.” Thus, patients lack of AF with SF 10 or less can choose OACs or VKAs without need of INR controls and dose adjustment. Patients with AF with SF 11 or more can choose OACs or VKAs with additional dose adjustment and INR controls.

PCV130
THE "VENOUS AGE" - A NEW TOOL TO SENSITIZE PATIENTS TO THEIR VENOUS DISEASE


METHOds: The score calculation was based on an international epidemiological study conducted in 24 countries in the daily practice or general practitioners. The data base included patients with or without venous disease, whatever the reason for which they were consulting and whatever the level of their venous disease which was systematically described according the elements of the international CEAP classification. RESULTS: The study covers 126 countries with a total of available patients: 65,466. 84.8% had no sign of venous disease (C0), 22.9% had only functional symptoms (C1), 40.6% had Telangiectases or reticular veins, 34.8% varicose, 24.9% edema, 14.0% skin changes, 7.3% indurated ulcers and 4.3% active ulcers. The statistical analysis has determined the number of years which must be added to the real age to get the "venous age" by comparison of the age of somebody who has no venous functional symptoms or physical signs. The results provide that number for women and men according the different venous symtoms and physical signs, by sex and age. This first attempt at creating a "venous age" will be certainly improved in the next future, using more complex analysis based on risk factors or other criteria, but it seems already efficient to make people aware of their venous risk and to better adhere to lifestyle improvement and venous disease treatments.

PCV131
PREFERENCES REGARDING THE ATTRIBUTES OF ORAL ANTICOAGULANTS IN PATIENTS WITH ATRIAL FIBRILLATION RESULTS OF A DISCRETE CHOICE EXPERIMENT


METHOds: Since the introduction of non-vitamin-K-antagonist oral anticoagulants (OACs), an additional option for stroke prevention in patients with atrial fibrillation (AF) compared to vitamin-K-antagonists (VKAs) is available. The objective of this study was to assess patients’ preferences regarding the attributes of these different treatment options. METHOds: We conducted a multicenter study among randomly selected physicians who were asked to recruit AF patients. Patients’ preferences were assessed by computer-assisted telephone interviews. We used a Discrete-Choice-Experiment (DCE) with four treatment dependent attributes (need of bridging: yes/no, interactions with food/nutrition: yes/no, need of INR controls/ dose adjustment: yes/no, frequency of intake: once/weekly). We compared three treatments: OACs vs. VKAs vs. bridging powerful anticoagulant vs. no anticoagulant. CONCLUSIONS: Our study showed that the majority of patients preferred OACs vs. VKAs vs. bridging vs. no anticoagulant. No significant preference was found for bridging vs. VKAs vs. no anticoagulant. In favour of the options are shown. CONCLUSIONS: In our analysis, “once daily frequency of intake” was the most important attribute for patients’ choice followed by “no interactions” and “no need of INR controls/dose adjustment.” Thus, patients lack of AF with SF 10 or less can choose OACs or VKAs without need of INR controls and dose adjustment. Patients with AF with SF 11 or more can choose OACs or VKAs with additional dose adjustment and INR controls.
lization-related PROs were identified: 1) Sawicki questionnaire (assesses treatment satisfaction and HRQoL) for the Perception of Anticoagulant Treatment Questionnaire (PACT-Q); 3) Duke Anticoagulation Satisfaction Scale (DASS); 4) Anti-Clot Treatment Scale (ACTS) (based on the DASS conceptual model); and 5) Deep Venous Thrombosis Quality of Life (DVTQoL) (assesses HRQoL outcomes related to a primary event of DVT and its complications). METHODS: ANCOVA was used to analyze the impact of using local versus UK tariffs in the analysis. CONCLUSIONS: Although some of the identified measures have shown responsiveness in clinical trials, this review concluded that no existing measure likely to support an ANCOVA was used to identify those factors (i.e. age, sex etc.) that could possibly influence the quality of life comparing to healthy people. Considerable discrepancies in terms of the quality of life of patients with hypertension is determined by numerous social and clinical factors. Thus, there is a need to consider the problem of hypertension and its treatment among adult people - especially in the social and clinical fields significantly influencing the quality of life of respondents. METHODS: 112 people took part in the study (38 women and 78 men), aged between 19 and 65 years old – in all cases hypertension was diagnosed and treated in a particular health care centre. As a main study tool a questionnaire WHOQOL-BREF in a Polish version was applied. In addition, in order to evaluate the social and clinical factors that influence the quality of life participants were asked to fill anonymous questionnaire prepared specially for this study. RESULTS: The results of the conducted studies indicate that people suffering from hypertension experience remarkably lower quality of life comparing to healthy people. Considerable discrepancies in terms of the quality of life were visible in physical and psychological domains of the WHOQOL-BREF questionnaire. It has been assumed that the quality of life of patients with hypertension is determined by both social (age, gender, education, economic status), and clinical (level of blood pressure, weight, the type of hypertensive therapy, the presence of coexisting diseases) consequences. CONCLUSIONS: Chronic diseases, including hypertension, disturb quality of life of patients. The problem of hypertension is determined by numerous social and clinical factors. Thus, there is a need to consider the problem of hypertension and its treatment among adult people multidimensionally – in order to improve their lives.

OBJECTIVES: This study aimed to determine anti-coagulant treatment patterns and stroke- and bleeding-related risk factors and to evaluate quality of life (QoL) in non-valvular atrial fibrillation (NVAF) patients receiving oral anticoagulants. The study population included ≥18-year-old patients (n = 213) diagnosed with NVAF. CHADS2, CHA2DS2-VASc, HAS-BLED scores and EQ-5D scale were used to assess risk factors and QoL. Scores on the ANCOVA were recalculated at 12 months.

RESULTS: The rate of adverse events was 6.7%, major bleeding was 10.8%, stroke was 5.9%, and hospitalization was 25.5% in one-year follow-up. The patients' treatment patterns were grouped as warfarin, new oral anticoagulant (NOAC) (dabigatran, rivaroxaban), and antiplatelet agents (AA) (acetylsalicylic acid, clopidogrel). Patient numbers for the groups at baseline, and 6th and 12th months, respectively, were 92, 74, 41 for warfarin, 2, 13, 4 for NOAC, and 39, 25, 26 for AA. The distribution of patients into the warfarin, NOAC and AA groups regarding CHADS2 score was 53.8% (n = 99), 50% (n = 1), and 62.3% (n = 24), respectively, and regarding CHA2DS2-VASc score was 86.8% (n = 79), 50% (n = 1), and 89.5% (n = 34), respectively, and regarding HAS-BLED score was 23.1% (n = 21), 0% (n = 0), and 18.4% (n = 7), respectively. EQ-5D scale scores were 0.85±0.12 and 0.76±0.13 at baseline and 0.67±0.29 and 0.60±0.37 at 12th month for the warfarin and AA groups, respectively; the decrease was significant in the warfarin group (p = 0.002) but not in the AA group (p = 0.249). The mortality rates (p = 0.002) and the duration of hospitalization, NOAC, and AA groups in one-year follow-up were 7.6%, 10.3%, and respectively. CONCLUSIONS: Our study has demonstrated that a significant number of patients who should be on oral anticoagulants are still treated with AA and the negative impacts of warfarin on QoL of NVAF patients as compared to AA. More data is needed with long-term-head comparison of warfarin and NOAC.

OBJECTIVES: This study investigates several factors and QoL and clinical features were recorded at baseline, and 6th and 12th months. At the study end 91.9% had normal/high-normal BP. Patients’ baseline MINICHAL and EQSDI were 6.3 days. Calculated by Malaysian tariff weights, health utility is 0.75 during initial admission, increasing to 0.82 after 12 months (p = 0.012). Among the statistically significant factors associated with lower baseline utility were diagnosis of NSTEMI/unstable angina compared to STMI (p = 0.045), and female sex (p = 0.038). Utilities calculated using the Malaysian tariff was consistently higher than those calculated using the UK tariff. ACS utility at baseline was 0.75 and 0.06 (p < 0.001) while utility after 12 months was 0.82 and 0.06 (p < 0.005) respectively. CONCLUSIONS: This study investigated several factors that may impact the QOL outcomes of Malaysian ACS patients. It also found significant differences in utility values calculated by Malaysian and UK tariffs, which indicate that the use of local tariffs is more appropriate.

OBJECTIVES: To compare the health utility of Acute Coronary Syndrome (ACS) patients from an Asian population at baseline admission and 12 months post-ACS. Secondary objectives were to investigate the factors that affect health utility and the impact of age on QoL in the analysis. METHODS: Health-related utility data was obtained from ACS patients who were admitted to a tertiary-care, general hospital in Malaysia and agreed to participate in the study. Quality of life (QoL) of ACS patients was assessed using validated language versions of the EQ-5D (three-level severity level) patient reported outcome instrument. QOL data was collected at baseline during initial admission for ACS and at 12-months post-admission. Patient demographics and medical records data were extracted from hospital records. Health utility scores were calculated using EQ-5D utility tariffs from Malaysia and the UK population tariff. RESULTS: A total of 112 subjects were recruited into the study of which 104 were used in the primary analysis: Mean age of patients in the analysis dataset was 56.1 years, 88% were male and duration of admission was 6.3 days. Calculated on QoL. The knowledge about the differences in the field of family state and in age social and clinical factors significantly influencing the quality of life of respondents. METHODS: 125 patients were included in the study. OQl was measured on the Slovak Health Index. In the Slovak Republic there was not realised the study oriented on QoL in the patients with this treatment. METHODS: 100 patients with PCFM were studied, women 58, men 42. The average age was 66.47, duration of illness - 6.93, 57 patients were married, 31 divorced or a widower, single 18.4% (n = 34), 4-months, respectively; and regarding HAS-BLED risk was 23.1% (n = 21), 0% (n = 0), and 18.4% (n = 7), respectively. EQ-5D scale scores were 0.85±0.12 and 0.76±0.13 at baseline and 0.67±0.29 and 0.60±0.37 at 12th month for the warfarin and AA groups, respectively; the decrease was significant in the warfarin group (p = 0.002) but not in the AA group (p = 0.249). The mortality rates (p = 0.002) and the duration of hospitalization, NOAC, and AA groups in one-year follow-up were 7.6%, 10.3%, and respectively. CONCLUSIONS: Our study has demonstrated that a significant number of patients who should be on oral anticoagulants are still treated with AA and the negative impacts of warfarin on QoL of NVAF patients as compared to AA. More data is needed with long-term-head comparison of warfarin and NOAC.
OBJECTIVES: Following an acute deep vein thrombosis (DVT) or pulmonary embolism (PE), women and men can choose from randomized controlled trials that compare the benefits and harms of vitamin K antagonists (VKA), and Non-VKA oral anticoagulants (NOAC) for therapy. We assessed patients’ satisfaction with their ongoing anticoagulation treatment.

METHODS: FREEVENT (Randomized open-label thrombosis – European Venous Thromboembolism) was an ongoing non-interventional study in France, Germany, Austria, Switzerland, Italy, Spain and UK. The Perception of Anticoagulant Treatment Questionnaire (PACT-Q2) is a valid and reliable instrument that allows the assessment of patients' satisfaction regarding anticoagulant regimens, as well as their opinion about convenience of use.

RESULTS: At baseline (BL), a total of 2311 patients with acute VTE (1366 DVT, 945 PE) met the eligibility criterion of current anticoagulant treatment. 665 patients were eligible for an interim analysis at 6 months. 7.8% have received heparin only, 33.2% initial heparin/VKA and 9.0% uninterrupted NOAC. In the “convenience” dimension, the score (0–100 range) at BL/6-month was 78.9 ± 16.6/76.2 ± 18.0 points for heparin only, 81.0 ± 16.36/80.5 ± 16.34 for heparin/VKA, and 88.9 ± 12.14/93.9 ± 7.30 for NOACs (all patients: 81.5 ± 16.78/81.6 ± 17.26). Compared to BL, the score improved the most in the NOAC group. In the “anticoagulant treatment satisfaction” dimension, the score at BL/6-month was 62.4 ± 14.26/64.3 ± 16.68 points for heparin only, 65.8 ± 14.92/68.7 ± 14.46 for heparin/VKA and 68.2 ± 16.65/72.6 ± 16.70 for NOACs (all patients 65.4 ± 15.26/68.5 ± 15.76). CONCLUSIONS: Overall, patients on current anticoagulation reached relatively high values on the convenience scale, but moderate values on the satisfaction scale. Patients on NOACs rated their convenience and treatment satisfaction substantially higher than patients on heparin/VKA.

**PCV410**

TREATMENT SATISFACTION IN PATIENTS WITH ATRIAL FIBRILLATION ON CURRENT ORAL ANTICOAGULANTS AS ASSESSED WITH PACT-Q2 AT BASELINE AND 12 MONTHS FOLLOW-UP IN A REGISTRY: FREEVENT

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OBJECTIVES: To estimate the clinical impact over three years of switching atrial fibrillation (AF) patients receiving no treatment or aspirin to rivaroxaban, or vitamin K antagonist (VKA) to rivaroxaban in China.

METHODS: A prevalence-based, deterministic budget impact model was developed. The incidence of DVT patient discharges previous to the surgery. There were no significant differences between the genders in terms of characteristics like race, primary payer, age, etc. However, more men had ER visits than women (52.4% vs 47.7%). The top diagnosis in the ER for men was MI (31.8%), Syncope (25.9%), and Heart failure (14.0%). In atrial fibrillation was the only ER diagnosis which women experienced more than men.

CONCLUSIONS: The findings of the study were inconsistent in showing significant differences between the genders in terms of characteristics and ER diagnosis among recipients of primary pacemaker.

**PCV142**

LDL-C GOAL ATTAINMENT IN PATIENTS WITH HYPERLIPIDEMIA - ESTIMATES FROM POPULATION-BASED REGISTER DATA IN SWEDEN

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OBJECTIVES: To estimate low-density lipoprotein cholesterol (LDL-C) goal attainment in patients with hyperlipidemia or prior cardiovascular (CV) events. METHODS: Retrospective population-based cohort study conducted using electronic medical records showing significant differences between the genders in terms of characteristics and ER diagnosis among recipients of primary pacemaker.

**PCV143**

THE CLINICAL IMPACT OF RIVAROXABAN TO CHINESE AT ATRIAL FIBRILLATION PATIENTS RESULTS FROM A SIMPLE COMMUNICATION TOOL

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OBJECTIVES: To estimate the clinical impact over three years of switching atrial fibrillation (AF) patients receiving no treatment or aspirin, or vitamin K antagonist (VKA) to rivaroxaban.

METHODS: A prevalence-based, deterministic budget impact model was developed. The incidence of DVT patient discharges previous to the surgery. There were no significant differences between the genders in terms of characteristics like race, primary payer, age, etc. However, more men had ER visits than women (52.4% vs 47.7%). The top diagnosis in the ER for men was MI (31.8%), Syncope (25.9%), and Heart failure (14.0%). In atrial fibrillation was the only ER diagnosis which women experienced more than men.

CONCLUSIONS: The findings of the study were inconsistent in showing significant differences between the genders in terms of characteristics and ER diagnosis among recipients of primary pacemaker.

**PCV144**

THE CLINICAL IMPACT OF RIVAROXABAN TO CHINESE AT DEEP VEIN THROMBOSIS PATIENTS RESULTS FROM A SIMPLE COMMUNICATION TOOL

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OBJECTIVES: To estimate the clinical impact over three years of switching atrial fibrillation (AF) patients receiving no treatment or aspirin, or vitamin K antagonist (VKA) to rivaroxaban.

METHODS: A prevalence-based, deterministic budget impact model was developed. The incidence of DVT patient discharges previous to the surgery. There were no significant differences between the genders in terms of characteristics like race, primary payer, age, etc. However, more men had ER visits than women (52.4% vs 47.7%). The top diagnosis in the ER for men was MI (31.8%), Syncope (25.9%), and Heart failure (14.0%). In atrial fibrillation was the only ER diagnosis which women experienced more than men.

CONCLUSIONS: The findings of the study were inconsistent in showing significant differences between the genders in terms of characteristics and ER diagnosis among recipients of primary pacemaker.

**CARDIOVASCULAR DISORDERS – Health Care Use & Policy Studies**

**PCV141**

PRIMARY PACEMAKER INSERTION: GENDER DIFFERENCES IN PRIOR ER UTILIZATION

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OBJECTIVES: Men’s and Women’s health care experiences differ as they age. These differences lead to disparate health and treatment outcomes between the genders, especially in the area of cardiovascular health, which has significant disease burden in the US. Women experience symptoms that ‘devalue’ them from the oncologist’s guidebook. The emergency room (ER) also serves as a medical space for initial diagnosis of heart conditions. Thus, looking at the gender based use of ER prior to a cardiac event may help us understand the disparities from a systems perspective.

Cardiac pacemakers are used to treat severe and/or symptomatic bradyarrhythmia, heart block or a combination of both. This study explored gender differences in characteristics and ER diagnoses associated with pacemaker implants in an inpatient setting. METHODS: The study used discharge data from the Centers for Medicare and Medicaid Services, Discharge Data for a 10% sample of non-Federal short-stay hospitals in the US, for patients aged 20 years and older who received pacemaker implants at a non-Federal short-stay hospital. The data were collected from the hospital discharge data from the Florida HealthCare Utilization Project for years 2009 and 2010. Patients with a primary insertion of initial pacemaker and with a diagnosis of bradyardycia or heart block or both were included. A unique patient identifier helped map patients across the inpatient and emergency settings. Descriptive statistics were used to look at items of interest. RESULTS: There were 1403 discharges meeting the inclusion criterion. These were linked to 1402 ER discharges previous to the surgery. There were no significant differences between the genders in terms of characteristics like race, primary payer, age, etc. However, more men had ER visits than women (52.4% vs 47.7%). The top diagnosis in the ER for men was MI (31.8%), Syncope (25.9%), and Heart failure (14.0%). In atrial fibrillation was the only ER diagnosis which women experienced more than men.

CONCLUSIONS: The findings of the study were inconsistent in showing significant differences between the genders in terms of characteristics and ER diagnosis among recipients of primary pacemaker.
following with 15% of the rest patients switching to rivaroxaban per year. Then the model estimates the number of DVT, pulmonary embolism (PE), intracranial bleeds (ICH) and major extracranial bleeds (ECH) per year. RESULTS: The new DVT patients are 287,813 per year. For those patients, with 20% patients switching to rivaroxaban from LMWH+VKA in the first year, the recurrent venous thrombosis embolism (VTE) events, including DVT and PE, reduced 4.6%, and bleeding events including ICH and ECH reduced 7% with 1% minor bleeding increasing. To the third year, the recurrent VTE events reduced 11.4%, major bleeding events reduced 17% with 2% minor bleeding increasing compared with the control group. Observational data from France showed rivaroxaban may decrease the clinical burden of DVT in China by reducing the incidence of recurrent VTE and fatal bleeding events. Decision-makers can find the exact value of rivaroxaban easily by the simple tool in different situations.

PCV145 COST-EFFECTIVENESS OF DISEASE MANAGEMENT PROGRAMS FOR CARDIOVASCULAR RISK ASSESSMENT AND COPD IN THE NETHERLANDS Tejschristas A1, Burgers LT1, Rutten-van Mölken MPMH1 Eramus University Rotterdam, Rotterdam, The Netherlands OBJECTIVES: Disease management programs (DMPs) for cardiovascular risk (CVR) and chronic obstructive pulmonary disease (COPD) are increasingly implemented in the Netherlands to improve quality of care and patient's lifestyle. The aim of the study was to provide evidence about the (cost-)effectiveness of Dutch DMPs as implemented in daily practice. METHODS: We compared the 2-year costs and changes in physical activity, smoking behaviour, and utilities between the most and the least comprehensive DMP in four disease categories: primary CVR-prevention, secondary CVR-prevention, both types of CVR-prevention, and COPD (total CVR-prevention). The primary outcome measure was the incremental cost-effectiveness of DMP development and implementation costs on the cost-effectiveness of DMPs for the patient. The least comprehensive DMPs increased physical activity and had higher smoking cessation probabilities after 2 years in most disease categories. From a health care perspective, the most comprehensive DMPs showed a higher adherence to antithrombotic agents. Patients in the most comprehensive DMPs had a higher smoking cessation probability and higher physical activity. CONCLUSIONS: The most comprehensive DMPs for CVR and COPD were cost-effective compared to the least comprehensive DMPs. The challenge for Dutch stakeholders is to find the optimal mix of interventions.

PCV146 COMPARING QUALITY EFFECTS OF PATIENT CARE IN INTEGRATED AND REGULAR CARE FOR PATIENTS WITH HYPERTENSION Weihlert L1, See J1, Engelhardt J2, Altmann V1, Kostev K2 1Presenius University of applied sciences, Idstken, Germany, 2IMS Health, Frankfurt am Main, Germany OBJECTIVES: This study examines the extent to which Integrated Care Programs lead to an improvement in the quality of patient care. The aim of the study is to carry out a quantitative analysis of differences in quality between patients participating in Integrated Care Programs (ICP) and patients receiving regular care, regardless of health insurance status, program, or region. METHODS: The study used data from the representative IMS Disease Analyzer database, which includes claims of over 80 million patients. A confirmed diagnosis of hypertension was detected and patients in the therapy group were matched to patients in the control group. The primary variable for the study was the change in blood pressure after 12 months of therapy. RESULTS: The patient characteristics were very similar with respect to demographic variables and antihypertensive therapy. The proportion of patients with blood pressure values <140/90 after one year of treatment was 33.6% in the group of ICP participants and 22.7% in the group of non-ICP participants (p<0.0001). The chance of reaching the treatment goal was significantly higher in the group of patients participating in an integrated health program (OR: 1.73; 95% CI: 1.45-2.05). Thus, it can be established that integrated health care programs have a positive effect on quality.

PCV147 SEGMENTATION IS A KEY STRATEGIC TOOL FOR EFFECTIVE PRIORITISATION AND TARGETING OF PAYERS IN HIGHLY COMPETITIVE MARKETS; A CLIENT’S PERSPECTIVE Agence de l’Ambassade Double Helix Development, London, UK OBJECTIVES: The research aimed to develop an attitudinal based, payer segmentation approach to inform behaviour towards the aged entity of novel agents in the anticoagulation area in the health care systems of countries within the EU. The segmentation exercise explored payers’ drivers, motivations, barriers and limitations when assessing, endorsing or restricting new agents. METHODS: Qualitative in-depth telephone interviews with key stakeholders were conducted to explore payers’ views, along with perceived challenges relating to the entry of novel class of anticoagulation agents. Followed by a quantitative data collection and advanced statistical-analysis methodology to employ with regional and local payers in each of the researched markets to define the segmentation accord-

PCV148 IMPACT OF LAWS AND DECREES ON ACTIVITIES: THE ILDA STUDY Citarella A1,2, Di Liguoro FP1, Di Martino P1, Iarronnino A2, Nava E2, Ragone F1, Vercellone A1, Cammarota S1 1LinkHealth s. r. l., Naples, Italy, 2Medicop VESEVO - GPs Association, Torre del Greco, Italy, 1PFPCOCAT - GPs Association, Castellammare di Stabia, Italy, 2Department of Pharmacy, Local health Naples Sud, Castellammare di Stabia, Italy, 1PFPCOCAT - GPs Association, Castellammare di Stabia, Italy OBJECTIVES: To assess whether the prescribing pattern of statins changed after reimbursement criteria revision and regional policies in a general practice in southern Italy. METHODS: Analysis has been performed on a database of 123 medical practitioners that have managed an average of 190,000 inhabitants in the Naples Sud Local Health Authority Region (southern Italy). Prevalence of use and incidence of new users of statins, non-ICP patients were stratified into three groups (Moderate Cardiovascular Risk, MR, High Cardiovascular Risk, HR, Very High Cardiovascular Risk, VHHR) according to new criteria for reimburse-

PCV149 ASSESSMENT OF THE IMPACT OF LEGISLATION ON THE UTILIZATION OF STATINS IN SLOVAKIA Misková F1, Malovecká I1, Foltan V1, Lehocká L1 1Comenius University, Bratislava, Slovak Republic, 2Faculty of Pharmacy, Comenius University, Bratislava, Slovak Republic OBJECTIVES: To study the impact of frequent legislative changes that have brought the Slovak health care reform over the past decade, reflected also on drug policy and especially on the prices of medicines and total consumption of medicines. Generic substitution was introduced in 2008 to save both health insurance and patient’s finances. Related data on prices and consumption of lipid-lowering agent medicines were collected from Slovak Ministry of Health and Health insurance. Data processing, we used a uniform methodology recommended by the WHO - ATC/DDD classification and basic statistical methods of observing. In case of national data, we reported consumption in units of DDD per 1,000 inhabitants for one day (DDD). RESULTS: A class of lipid-lowering agent medicines (C10A) poses in recent years on Slovak market expanding group. Its consumption in 2014 was €70,1% (81,8% in 2013 compared to second quarter of 2012). Stratified by level of CV risk, the prevalence of use in MR is 24.9% with 15% to HR and 5.9% to VHHR, while incidence of new users of 22.4%, 34.5% and 45.8% respectively. In the second quarter of 2013, at a level of CV risk, 45.3% was prescribed in 57.5% of patients in MR group (45.3%), rosuvastatin 5.9% with (60.1%) and 1.6% with simvastatin and atorvastatin (57.5%); in HR group, 40.7% (20.8) atorvastatin, 5.3% (57.0%) simvastatin and 2.1% (42.3%) simvastatin + ezetimide, in VHHR, 56.3% (15.8) atorvastatin, 12.3% (37.5) rosuvastatin and 2.1% (27.1) simvastatin + ezetimide. CONCLUSIONS: The revision of reimbursement criteria and the regional poli-

PCV150 THE IMPACT OF PHARMACEUTICAL POLICIES ON PHARMACEUTICAL SALES PATTERNS IN SWEDEN AND JAPAN Imai S1, Anderson Sundell K2, Fushimi K1 1National Hospital Organization, Tokyo, Japan, 2Sahlgrenska Academy, University of Gothenburg, Goteborg, Sweden, 1Tokyo Medical and Dental University Graduate School of Medicine, Tokyo, Japan
OBJECTIVES: Pharmaceutical expenditure accounted for between 11% to 13% of total health care expenditure in Europe in 2010, and was 20% in Japan for the same year. We expect that big changes in sales pattern will happen as a result of patent expiry. Other changes have been seen when prescribers get negative/positive information on drugs. In this article we study the impact of patent-expiration information relating to pharmaceutical policies on pharmaceutical sales patterns of selected drugs in Sweden and Japan. METHODS: we selected angiotensin-converting enzyme inhibitors (ACEIs) and Angiotensin II antagonists (ARBs) including those widely used in inclusion and Japan. Several auto-regressive integrated moving average (ARIMA) modeling with intervention analysis was used to estimate the change of sales volume. RESULTS: Losartan had a positive change (0.77650, p = 0.0068) in October 2010, Candesartan had a negative change (-0.50760, p = 0.0058) in July 2010. There were no significant differences in the sales volume of Losartan, Telmisartan, except for Candesartan in Japan (p = 0.04868, p = 0.7995, -0.38547, p = 0.0880, and - 1.21215, p = 0.001, respectively). In this study, we used a published study [1] comparing the prescription rate of Candesartan and mortality by a journal July in 2009 as negative information. CONCLUSIONS: We found that the sales pattern of selected drugs were changed by negative information and not by the expiry of their patents in Sweden. Whereas in Japan the negative information on the like the therapeutic substitution of Trandolapril and the possibility of switching from Candesartan to a combination drug was seen. Further assessment will be needed since factors associated with the changing use of drugs will be infinite.

PCV151
THE IMPACT OF MODIFICATIONS OF THE FORMULA FOR GENERIC DRUG PRESRIPTION RATE ON THE SWITCH TO NEW BRAND-NAME DRUGS WITH SIMILAR THERAPEUTIC USES
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OBJECTIVES: From April 2013, the method of calculating the prescription rate of generic drugs in Japan was changed and protected brand name drugs were excluded from the denominator. In the case of Japan, which does not have a reference pricing system, it is thought that this may lead to a change in substitutions toward protected brand name drugs rather than drug substitution to generic drugs. The objective of this study is to clarify the trends in relation to the prescription of generic drugs, through the use of administrative data on a nationwide level.
METHODS: We used survey data from dispensing pharmacies from April 2012 to March 2014. As a comparison, we used the prescription data of 1139 acute care hospitals in which incentive measures for drug substitution to generic drugs had not been placed during the same period. The products in question were drugs for diabetes and hypotensive drugs. For data analysis used SQ. Server. 2008 R2 and R. RESULTS: As the dispensing pharmacy receives additional compensation based on the rate of generic drugs dispensed by that pharmacy in the most recent 3 months, the dispensing rate of generic drugs will have a direct impact on their business. The change in the method of calculating generic drugs has a major impact on the dispensing pharmacies, and in this study we have shown the possibility of dispensing pharmacies shifting more to protected brand name drugs. The dispensing rate of generic drugs by acute care medical facilities has always been low, and thus the impact of the change in calculation of the dispensing rate on the business is low. CONCLUSIONS: the results of this study show that when encouraging drug substitution to generic drugs as a policy to reduce drug expenditure, it is necessary to consider measures in relation to the shift to protected brand name drugs.

PCV152
ANALYSIS OF CARDIAC IMPLANTS RECALLS IN THE LAST DECADE: AN INTERNATIONAL COMPARISON
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OBJECTIVES: The objectives of this research are to provide an overview of the recalls of cardiac implant medical devices in the last decade according to the different categories of cardiac implant medical devices and to analyze the recall reasons. On the basis of this analysis, this research will provide recommendations on how to build a high quality implant registry. METHODS: a systematic search was performed focusing on regulatory bodies’ homepages from a range of middle and high-income countries worldwide. RESULTS: 4,154 cardiac implant medical devices including 3,135 devices were recalled in 79 countries from 1990 to 2015. 3,769 recalls were reported in 52 countries. The products in question were drugs for diabetes and hypotensive drugs. For data analysis used SQL Server. 2008 R2 and R. RESULTS: As the dispensing pharmacy receives additional compensation based on the rate of generic drugs dispensed by that pharmacy in the most recent 3 months, the dispensing rate of generic drugs will have a direct impact on their business. The change in the method of calculating generic drugs has a major impact on the dispensing pharmacies, and in this study we have shown the possibility of dispensing pharmacies shifting more to protected brand name drugs. The dispensing rate of generic drugs by acute care medical facilities has always been low, and thus the impact of the change in calculation of the dispensing rate on the business is low. CONCLUSIONS: the results of this study show that when encouraging drug substitution to generic drugs as a policy to reduce drug expenditure, it is necessary to consider measures in relation to the shift to protected brand name drugs.

PCV153
IMPACT OF DRUG POLICY REGULATIONS ON THE CONSUMPTION OF ANTAGHYPERTENSIVE DRUGS IN SLOVAKIA
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OBJECTIVES: In 2011, various legislative measures were adopted in Slovakia regarding drug policy. The aim of the submitted work is to evaluate links between the introduction of regulations and the consumption of antihypertensive drugs (AH), expenditure on AH and co-payments. We evaluated the changes based on IMS Data. Patient co-payments data were taken from the National Health Information database. When evaluating the average amount of co-payments, we applied a weighted average, which takes into account the level of co-payment and consumption. RESULTS: The consumption of AH (in DOT) increased continually in 2006-2013 (+36%) and the turnover of AH dropped by 4% as a consequence of introducing new regulations. The impact of new regulations was expressed foremost in the consumption of ARBs and the increase in the level of co-payment, where the decrease in turnover after introduction of clusters in 2012 was 14%. In the evaluated period, the final price of AH was reduced by 35% (from € 8.86 to € 5.78) and the reimbursement was reduced by 52% (from € 7.87 to € 3.65) and the patient co-payment increased by 100% (from € 0.99 to € 2.03). In the evaluated period, the patient co-payment for a fixed AH almost quadrupled (from € 1.05 to € 4.05). The patient paid an average of € 0.93 more for one pack of fixed AH than for a free combination. After the introduction of regulations the consumption of fixed combinations grew at a slower pace than in the case of monocomponents. CONCLUSIONS: The legislative changes in drug policy had a significant impact on the consumption of antihypertensive drugs and on the expenditure of antihypertensive treatment in Slovakia.}

PCV154
INITIATION OF ORAL ANTICOAGULANT DRUGS: IDENTIFICATION OF DRIVERS OF PRESCRIBING OF NEW AGENT VS. WARFARIN
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OBJECTIVES: Oral anticoagulants (OACs), used for stroke prevention in atrial fibrillation, include warfarin and the newer drugs (NOACs) dabigatran, rivaroxaban and apixaban. High direct drug costs of the NOACs to the health care payer prompt monitoring of real-world NOAC uptake patterns. This study aimed to identify factors associated with anticoagulation initiation with NOACs versus warfarin. METHODS: Analyses were performed using national pharmacy claims data from a means-tested state medical services scheme. First-time initiators of an oral anticoagulant between January 2009 and December 2013 with ≥ 1 year scheme eligibility and ≥ 50 were selected and compared to patients who were not prescribed anticoagulation. Patient characteristics, and number and type of concomitant medications at the time of first oral anticoagulant were recorded and considered when identifying the NOAC initiators. RESULTS: Of 10,308 patients, 30.8% were NOAC initiators (30.9% for DOACs, 0.2% warfarin and 0.5% Cin). CONCLUSIONS: 3,494 new initiators of oral anticoagulants were included. In 2009, 7.6% of new initiators received a NOAC; this figure rose to 41.2% in 2013. The following were positively associated with NOAC initiation in multivariate analyses: female gender (OR: 1.14, 95% CI 1.04-1.25), age ≥ 85 (OR: 3.2, 95% CI 1.9-5.2) and concomitant of NSAID drug (OR: 4.04, 95% CI 3.72-4.38). Receipt of multiple concomitant medications was negatively associated with NOAC initiation; patients receiving 15 drug classes had a 42% decreased odds of NOAC receipt (versus ≤ 5 drug classes) (OR: 0.58, 95% CI 0.51-0.66). Specific concomitant drugs negatively
local prescription behavior. Local variation (the fifth hurdle of market access) should be considered by pharmaceutical companies when developing market access strategy.

**PCV159**
**DETERMINANTS OF TICAGRELOR USE IN ENGLAND:**
**DATA ANALYTICAL APPROACHES AND INSIGHTS TO INVESTIGATE A RETROSPECTIVE COHORT STUDY**

**OBJECTIVES:** The objective of this study was to investigate the determinants of ticagrelor use in England. A retrospective cohort study was conducted using the MarketScan® database to identify patients prescriptions for ticagrelor in England between August 2011 and February 2013. The proportion of total spend on ticagrelor in England in February 2013 ranged from 0% to 34.9%, respectively. Ticagrelor is clustered around the Yorkshire region. **CONCLUSIONS:** The ticagrelor usage suggests that a positive National Level (NICE) recommendation does not necessarily lead to local prescription behaviour. Local variation in ticagrelor use is a common phenomenon. It is important to consider local market access strategies when developing market access strategy.

**PCV160**
**IMPLEMENTATION OF AN AUTOMATIC LABORATORY DATA CHECKING SYSTEM TO REDUCE DEDUCTION OF STATINS REIMBURSEMENT IN A TEACHING HOSPITAL IN TAIWAN**

**OBJECTIVES:** This study aimed to reduce the deduction of statins reimbursement in a teaching hospital in Taiwan. **METHODS:** An "Automatic Laboratory data Checking System" was established in order to enhance rational use of statins and to reduce deduction rate of statins reimbursement. **RESULTS:** The study aims to analyze the economic outcomes after implemented the system. **CONCLUSIONS:** The major cause of deduction was the lipid profile fragmented in the medical record. Therefore, disallowed/deduction of reimbursement from Administration of National Health Insurance (NHI) was relatively higher than other drugs. An "Automatic Laboratory data Checking System" was established in order to enhance rational use of statins and to reduce deduction rate of statins reimbursement. This study aims to analyze the economic outcomes after implemented the system. **CONCLUSIONS:** The major cause of deduction was the lipid profile fragmented in the medical record.
Apixaban (74.82±11.39 years) patients were older versus those who switched to dabigatran (72.46±10.89 years) or rivaroxaban (73.50±11.27 years). Apixaban users (45.4%) were more female compared to dabigatran (38.4%, p<0.0037) and rivaroxaban (40.4%, p=0.0499). The mean CHADS2 score was higher for apixaban users (meanSD 2.28±1.25) as compared to dabigatran (1.94±1.20, p<0.0001) and rivaroxaban (2.18±1.25, p<NS) users. Apixaban patients had significantly higher baseline rates for congestive heart failure (p=0.0111), hypertension (p<0.0002), renal disease (p=0.0017) and ischemic stroke/ transient ischemic attack (p=0.0004) as compared to the two former groups. Apixaban users (2.3±2.12) also had higher mean charlson comorbidity index scores as compared to dabigatran users (1.98±1.96, p=0.0002).

CONCLUSIONS: Patients who switch to apixaban are older and sicker as compared to those switching to dabigatran or rivaroxaban. A detailed evaluation of patient characteristics on the treatment outcomes in NVAF patients switching from warfarin to NOAC is warranted in future.

PCV162 TREATMENT PATTERNS IN HYPERLIPIDEMIA PATIENTS WITH NEW CARDIOVASCULAR EVENTS - ESTIMATES FROM POPULATION-BASED REGISTER DATASET IN SWEDEN

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OBJECTIVES: To assess treatment patterns of lipid-lowering drugs in patients with hyperlipidemia or prior cardiovascular (CV) events (myocardial infarction, unstable angina and cardiovascular death) or diabetes mellitus. Patients were included in the study based on the presence of a lipid-lowering treatment between January 1, 2006 and December 31, 2011 for identification of CV events (prior to 2006) and followed until December 31, 2012 for identification of new CV events and assessment of treatment patterns. Patients were stratified into three cohorts based on CV risk level. The index was the date of first new CV event during follow-up. All outcomes were assessed during the year following index date. Adherence was defined as medical possession ratio (MPR) >0.80. Persistence was defined as having at least 40 days in supply during the index treatment and post-index treatment.

Results of estimated model indicated that the variable used to capture health care utilization was the number of visits to the hospital (beta=0.37, p-value <0.0001). The use of DRG-based reimbursement has a positive effect on CA-AT diffusion, not significant for LAAC. The rank in adoption is an important factor only for CA-AF. The impact of the number of other hospitals contemporaneously adopting the technology is negative for both technologies, but significant only for CA-AF. The average time between two subsequent uses is negatively correlated with the diffusion for both technologies. Regional contextual variables, including type of funding, do not show significant impact. The exception of per capita public health expenditure, that enhances the diffusion of both technologies, and the ratio between public health expenditure and GDP in the case of CA-AF. The average frequency of use decreases over time for both technologies. Neither hospital-level variables nor regional-level ones do not show significant effects. The only variable with a significant and negative impact on the frequency of use of CA-AF is the number of competitors. CONCLUSIONS: These results are consistent with previous literature.

PCV163 DETERMINANTS OF HEALTH CARE UTILIZATION IN HYPERTENSIVE PATIENTS: A LONGITUDINAL ANALYSIS

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OBJECTIVES: There is evidence that in Greece, economic crisis has substantially affected chronic patients’ access to health care services. The aim of the study was to identify the current situation and to provide an insight to policies regarding the management of chronic diseases, in times of economic crisis and austerity from the aspect of both providers and patients.

METHODS: The study was conducted among 1600 chronic patients suffering from diabetes, hypertension, COPD and Alzheimer. Patients were asked to indicate the amount they spent for primary and secondary health care services and for pharmaceuticals. Current and past health care utilization (including willingness to pay) was estimated as well. The study was conducted in two phases: 2007 (baseline) and 2013 (subjected to CHE, compared to 3.6% in 2010). The analysis by disease showed that 11.4% of patients were affected by diabetes, 10.3% by COPD and 5.9% by Alzheimer. In 2013, 7.8% of all households with at least one chronic condition patient were subjected to CHE, compared to 3.6% in 2010. The analysis by disease showed that 11.4% of patients were affected by diabetes, 10.3% by COPD and 5.9% by Alzheimer. The analysis by age showed that the highest percentage of patients faced CHE, while the respective figures were 8.7% vs. 2.9% for the COPD patients, 7.1% vs. 3.4% for diabetic patients, and 4.2 vs. 1.7% for the hypertensive patients. Pharmaceutical expenditures alone were deemed catastrophic for 4.6% of all the above patients in 2013 vs 1.6% before the introduction of the austerity measures and the health care reform. The result of the Kaiser Permanente study was that 6.2% in 2013 vs 2.8% in 2010 faced CHE due to out-of-pocket payments for drugs, while the respective figures were found to be 3.4% vs. 1.8% for the diabetic patients, 2.9% vs. 0.9% for COPD patients and 1.7% vs. 0.9% for the hypertensive patients.

CONCLUSIONS: After the introduction of austerity measures...
in Greece a substantial increase of the households with at least one chronic condi-
tion patient which are subjected to CHIE is recorded. There is a need for counter-
measures or/and an alternative policy context in order to reduce this catastrophic
effect of economic crisis.

PCV167 SNAPSHOTS OF PRESCRIBING PRACTICE FOR CLOPIDOGREL AND ESOMEPRAZOLE CO-PRESCRIPTION AND COST EVALUATION OF GUIDELINES APPLICATION
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OBJECTIVES: Through CVF2019, the antiplatelet clopidogrel and the proton-pump inhibitor esomeprazole demonstrate a pharmacokinetic interaction that could translate into clinical inefficacy of clopidogrel. No medical consensus has been reached to date and therefore different guidelines are available. We aimed to evaluate the prescribing practices in the University Hospitals of Geneva (HUG) by means of pharmacokinetic simulation. The prescription was studied in different hospitals measuring the Omeprazole-Clopidogrel-Aspirin (OCLA) study impact on clopi-
dogrel use in our hospital. METHODS: Patient's medical orders and nurse’s drug administration planning’s were analysed from January 2013 to April 2014 and the hospital discharge abstracts were used to evaluate the extra costs of the implementation of different guidelines we built scenarios assum-
ing the clopidogrel or esomeprazole replacement with prasugrel or ticagrelor and pantozole or ranitidine, respectively. RESULTS: Fifty seven percent of patients under clopidogrel had a co-prescription of esomeprazole during the study period. Among them 15% (154/’1000) had a medical order staggering the co-prescription (more than 10 hours apart), 16% a concomitant prescription and 64% no clear information. Five patients had 40 mg twice daily esomeprazole and the possibility of staggering. Surprisingly we found a higher rate of patients hav-
ing a nurse’s schedule of more than 10 hours (39%, 417/1071). Switching drugs would in our internal settings costs for HUG of €307 for esomeprazole, €347 for pras-
grel, €9590 for pantozole and €5’205 for ranitidine. A statistical significant decrease in trend of clopidogrel use was observed after the OCLA study pub-
cation. New guidelines indicate the medical order staggering of clopidogrel should be mandatory in order to improve the transmission throughout the whole informa-
tion system and allow a clear staggering of clopidogrel-esomperazole co-prescrip-
tion avoiding drug-drug interactions when possible. Nurses take the initiative to stagger the co-prescription when these are not clearly defined by medical orders.

PCV168 REGIONAL VARIATION IN HOSPITAL MORTALITY, LENGTH OF STAY AND COST OF ISCHEMIC STROKE PATIENTS IN ALBERTA
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OBJECTIVES: This study compares the outcome and health care performance among five health zones in Alberta by evaluating 30 days in-hospital mortality and length of stay (LOS) of ischemic stroke patients with acute ischemic stroke hospitalization costs over one year. METHODS: Ischemic stroke (ICD-10 code I63) patients (without previous stroke within one year, N=1,445) hospitalized between April 1, 2006 and March 31, 2007 were followed for one year using hospital Discharge Abstract Database. The severity of the stroke was obtained from the ambulatory care database in the University Hospitals of Geneva (HUG) by means of pharmacokinetic simulation. The prescription was studied in different hospitals measuring the Omeprazole-Clopidogrel-Aspirin (OCLA) study impact on clopi-
dogrel use in our hospital. RESULTS: The adjusted mean LOS varied from 16.3 (13.8-19.3) days in South Zone to 26.7 (24.0-35.8) days in Edmonton and North zones, respectively. The model included data of the personnel needed in the proce-
sure and cost model was developed to assess the cost per procedure of Reveal LinQ™ and

PCV170 OPTIMIZING PROCESS EFFICIENCY THROUGH IMPLANTING REVEAL LINQ VERSUS REVEAL XT/DX FROM THREE SPANISH HOSPITAL PERSPECTIVE
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OBJECTIVES: Implantable loop recorders (ILR) are devices that continuously moni-
tor heart rhythm in patients with suspicion of cardiac arrhythmias. Reveal LinQ™ is a new insertable holter, an 8% smaller than Reveal® XT/DX that records abnor-
mal heart rhythm up to 3 years. The objective was to develop an economic tool which allows hospitals to quantify their cost savings from the simplified procedure of inserting Reveal LinQ™. The tool was used to compare the costs of implanting Reveal® XT/DX in the cath lab to the costs of inserting Reveal LinQ™ out of the cath lab in three public hospitals of the Spanish National Health Care System. METHODS: A cost model was developed to assess the cost per procedure of Reveal LinQ™, and Reveal® XT/DX. The model included data of the personnel needed in the proce-
dure, the hospital setting, the hospitalization previous to the procedure, remote monitoring and post-procedure follow-up. RESULTS: The additional savings of LinQ™ vs. Reveal® XT/DX in Virgen de la Salud, Puerta de Hierro and Virgen de la Arrixaca Hospitals were €345 (13.3%), €363 (13.1%) and (517 (19.2%), respectively. CONCLUSIONS: This tool showed that the cost saving of Reveal LinQ™ is associated with mean savings of €406 from a hospital perspective compared to previous devices; mainly derived from moving the procedure out of the catheter lab, a reduction of the specialists’ time and in-hospital follow up visits due to remote monitoring.
OBJECTIVES: Hospital admissions for congestive heart failure (CHF) are a major driver of costs for health systems, and CHF is especially prevalent in patients aged 65 and older. This study assessed whether provision of oral nutritional supplements (ONS) in the hospital can reduce these costs, by estimating the effect of ONS use on 30-day readmission rates, length of stay (LOS), and hospitalization episode costs. METHODS: Using the 2000-2010 Premier Research database, a large hospital database, we estimated a sample of 904 patients aged 65 years and older with a primary diagnosis of CHF. We excluded episodes involving tube feeding and those ending in death (due to censoring). Using propensity score matching, we created a 1:1 matched sample of ONS and non-ONS edge transfer. RESULTS: 132 ICs from 11 countries (3 Asian: Malaysia, Hong Kong, Singapore and 8 European: Germany, Italy, UK, The Netherlands, Belgium, Denmark, Russia and Serbia) were invited to complete an online survey using a 4-point scale regarding their (i) familiarity with delayed arterial healing associated with DES (ii) how concerned they are about delayed arterial healing; (iii) frequency they discuss this risk with their patients and (iv) frequency this risk influence the type of stent they use. Responses from Asian cardiologists were compared with Europeans. RESULTS: 43.2% of ICs were Asians and 56.8% were Europeans. Majority of ICs were extremely concerned about delayed arterial healing associated with drug-eluting stents (DES) (59.6% vs. 32.4%, respectively, p < 0.01), there were no significant differences in the frequency this risk was discussed with patients (often/always: 24.6% Asian vs. 26.7% European, P=NS) or influence the type of stent used (often/always: 74.4% vs. 35.7%, P=NS). CONCLUSIONS: Many patients are not well informed of the risk associated with DES despite high level of physician awareness and concern of this risk. This knowledge transfer gap exists in both Asia and Europe.
reduction. A predefined questionnaire was delivered to physicians’ and primary care patients’ (n = 50) anonymous anticoagulation care and asked them their opinions about the value of this tool. RESULTS: Overall opinion from 30 physicians and 11 primary care deciders (geographically distributed) was positive, averaging 3.9 in a likert scale from 1 (strongly disagree) to 5 (strongly agree). Physicians averaged a value of 4.2 and primary care deciders averaged 4.3. 37.5% of total consumption. Other agents (alprazolam, nitrazepam, midazolam, klonazepam) accounted for less than 3% altogether. The BZD consumption increased with age and was highest in age group 70-80 years. BZD were more often prescribed to female patients. Valium (10.2%) and Librium (7.43%) were the most commonly used BSD agents. Bromazepam (51.38%) and diazepam (37.56%) were the most commonly used BSD agents.

CONCLUSIONS: This study confirmed that the percentages of individuals at high risk for morbidity and mortality. Individuals at high risk for cardiovascular events who fail to achieve a target LDL-C level of 100 mg/dL, as defined in the American Heart Association/American College of Cardiology (AHA/ACC) guidelines, should be considered for consideration for BZD initiation, given the high risk of recurrent cardiovascular disease associated with untreated hypercholesterolemia.

PCV179 TREATMENT PATTERNS AMONG HEART FAILURE PATIENTS WITHIN 30 DAYS POST DIAGNOSIS: RESULTS FROM A US CLAIMS DATABASE ANALYSIS
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OBJECTIVES: Clinical guidelines recommend ACEIs (angiotensin converting enzyme inhibitors), ARBs (angiotensin receptor II blockers) for patients intolerant to ACEI, beta blockers (BBs), aldosterone antagonists (AAs) and diuretics as the pharmacological treatment for heart failure (HF). This study assesses the treatments prescribed within 30 days of first HF-related medical claim among patients with HF diagnosis between April 2009 and March 2012, with a minimum of 12 months pre- and post-index continuous medical and pharmacy eligibility were included. Index date was defined as the first HF-related medical claim, with a minimum of 90 days post-index and 90 days pre-index period for each patient. Consumption was calculated using the ATC/ Anonymizer 2011-2013 database (n = 4,297,071). Consumption was calculated using the ATC/Anonymizer 2011-2013 database (n = 4,297,071).

RESULTS: Among 121,904 patients included in the analysis, 48.3% were >75 years of age and 41.6% were characterized as being ≥65 years of age. 26% and 16.3% were the most prevalent comorbidities. Overall, 37.6% of total consumption. Other agents (alprazolam, nitrazepam, midazolam, klonazepam) accounted for less than 3% altogether. The BZD consumption increased with age and was highest in age group 70-80 years. BZD were more often prescribed to female patients. Valium (10.2%) and Librium (7.43%) were the most commonly used BSD agents. Bromazepam (51.38%) and diazepam (37.56%) were the most commonly used BSD agents.

CONCLUSIONS: This study confirmed that the percentages of individuals at high risk for morbidity and mortality. Individuals at high risk for cardiovascular events who fail to achieve a target LDL-C level of 100 mg/dL, as defined in the American Heart Association/American College of Cardiology (AHA/ACC) guidelines, should be considered for consideration for BZD initiation, given the high risk of recurrent cardiovascular disease associated with untreated hypercholesterolemia.
INDIVIDUAL’S HEALTH – Clinical Outcomes Studies

PH1


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OBJECTIVES: Adverse drug events (ADEs), hospitalizations, and emergency department (ED) visits are important sequelae of inappropriate prescribing. Explicit measures are useful methods to detect inappropriate prescribing in the elderly. This study compares the predictive validity of the 2002 Beers, 2012 Beers, and the STOPP criteria for these outcomes. METHODS: A retrospective cohort design was implemented using commercial claims data between 2006 and 2009. Subjects included those 65 years and older continuously eligible for medical and pharmacy benefits for at least 6 months. Prevalence of ADEs and hospitalizations were calculated using the Time-to-event Cox proportional hazard models were estimated using a monthly time interval where indicators of inappropriate prescribing exposure in month t-i was minimized by adjusting for confounders and diagnoses that may have the highest share of older inhabitants compared to other European counterparts.

PH2

PREVALENCE OF CHRONIC DISEASES AMONG OLDER PATIENTS (>65 YEARS) IN GERMAN GENERAL PRACTITIONER PRACTICES

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OBJECTIVES: In Germany, the share of persons aged >65 years is 21.5%. Germany therefore has the highest share of older inhabitants compared to other European counterparts. The aim of the present study was to evaluate the prevalence of defined chronic diseases among older patients (>65 years) in German general practitioner (GP) practices. METHODS: Data from Disease Analyzer database including 1,110 GPs were used. 2,722,706 patients with at least one consultation in the time between April 2013 and March 2014 were included and analyzed. RESULTS: Overall, 774,361 (28.4%) of patients by GPs were over 65 years. In patients aged >65 years 66% were diagnosed with hypertension, 28% with diabetes mellitus type 2, 12% with chronic obstructive pulmonary disease, 14% with heart insufficiency. CONCLUSIONS: Patients older than 65 years make up 25% of the German population. The prevalence of chronic diseases is in this age very high. On account of their multimorbidity, the care of these patients is challenging. It is therefore important to place particular emphasis on geriatric patient care as a part of the study of medicine as well as in physicians assistant degree programs.

PH3

CURRENT SITUATION OF PEDIATRIC AND ADULT PATIENTS WITH FRAGILE X SYNDROME: PRELIMINARY DATA FROM THE EXPLAIN FXS REGISTRY


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OBJECTIVES: The Fragile X syndrome (FXS), caused by a CGG repeat expansion in the FMR1 gene on the X chromosome, is the most common inherited form of mental retardation and autism. Representative data on the characteristics and management of FXS patients in Germany are lacking. METHODS: EXPLAIN FXS is an ongoing prospective longitudinal observational study which evaluates characteristics and management of patients with a genetically confirmed diagnosis of FXS in ambulatory care. The registry uses a non-probability sampling approach to collect data. Data collection is performed either by non-observing medical practitioners or psychosocial parameters, quality of life, caregiver burden, and health economic parameters such as hospitalisation days. RESULTS: After an average 9-month recruitment period, 53 patients had been included (86% males, mean age 16.2 years, age range 2-82 years). Only 1 and 4 patients attended regular school, or regular school with integration measures, whereas the others were in special schools for the mentally impaired. Siblings were affected by FXS in 59.0% (2012 Beers [95% CI = 58.5%]; 2002 Beers [95% CI = 59.0%]). Autistic behaviour was diagnosed in 59.7% of patients in 2012 Beers, 62.4% in 2002 Beers, and 60.7% in the STOPP criteria. Twelve studies were assessed for risk of bias and data extracted. Studies were evaluated for the feasibility of inclusion into a network meta-analysis. RESULTS: A total of 1,670 titles and abstracts were screened. Sixty-nine papers relating to 62 studies were identified as eligible for inclusion. Forty-three of the 62 were excluded due to high risk of bias, a further 21 did not present sufficient data. The remaining 27 studies showed clinical heterogeneity in the measurement of disease severity and efficacy outcomes and quality of reporting. Efficacy outcomes were measured using various methods and at different time points (3, 6 to 12 months). All but one measured pain, 12 studies measured the Biberberg and Behran method and 4 used a visual analogue scale. Quality of life was measured in 7 studies, most commonly by a generic HRQoL instrument, the SF-36. Adverse event recording varied across studies. CONCLUSIONS: This systematic review formed the basis of a quantitative analysis assessing effectiveness of FXS treatments for moderate to severe endometriosis over 6 months. A network meta-analysis would potentially be feasible using more commonly reported pain outcomes, (modified B&K), HRQoL and reported adverse events.

PH4

FEASIBILITY OF A NETWORK META-ANALYSIS IN ENDOMETRIOSIS

van Nooten FE, Novak A, Langham J

1Tehran University of Medical Sciences, Tehran, Iran, 2Aesop, Novartis Services, Apeldoorn, The Netherlands, 3PhMR Associates, London, UK

OBJECTIVES: To conduct a systematic review of randomised controlled trials comparing effectiveness of GnRHa in the treatment of endometriosis in order to assess the feasibility of meta-analysis. METHODS: Inclusion criteria were all randomised controlled trials comparing GnRHa versus any other pharmacological treatment or placebo in the treatment of laparoscopically confirmed moderate to severe endometriosis. RESULTS: The registry is expected to provide much-needed data for comparison. CONCLUSIONS: The registry is expected to provide much-needed data for allowing comparisons with other countries, and to enable gap analyses based on current guidelines for management of these patients. ClinTrials.gov identifier is NCT01711606.

PH5

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best of 53%. The safest treatment in terms of caesarean section risk was titrated (low dose) vaginal misoprostol solution with a probability of being the best of 65%. Giving equal weight to both outcomes, titrated low dose oral misoprostol solution had the best overall outcomes (average rank of 1.5) followed by vaginal misoprostol ≥50μg (average rank of 1.6). Cost and utility data are now being gathered to inform the cost-effectiveness analysis. CONCLUSIONS: The implementation and cost-effectiveness analysis will be of value to clinicians, pregnant women, guideline developers and policy makers within the NHS. We will discuss how the model can be extended to include other types of intervention for induction of labour. PH1H

EXAMINATION OF THE EFFICIENCY OF ELECTRICAL STIMULATION IN CASE OF STRESS AND URGE INCONTINENCE
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OBJECTIVES: Electrical stimulation is one kind of conservative treatment in urological incontinence. Electrical stimulation can trigger the contraction of pelvic floor muscles. Muscle contraction can be increased as well. The aim of this research is to examine the efficiency of electrical stimulation treatment in case of stress and urge incontinence.

METHODS: In the course of the examination non-random, purposive sampling was applied. Self-made questionnaires were given to the participants before and after treatment. Incontinence Impact Questionnaire (IQ-7) and Urgent Incontinence Distress Inventory (UDI-6) international valid questionnaires were applied to measure quality life. The target group was woman clients between the age of 30-65 and above 65 years. The examination took place at Kaposi Mór Teaching Hospital, Somogy County, from 15 February, 2013 to 15 February, 2014. The analysis of results was performed with MS Excel 2000 program. R statistics was used. The research was conducted with 100 participants. In the course of the examination 45% of the participants reported improvement after treatment regarding stress incontinence while in case of urge incontinence 15% experienced positive change. Due to the treatment with electrical stimulation the number of the regular liner users was decreased. The number of users was 75 (75%) before treatments, which reduced to 44 (44%) after treatment. Electrical stimulation proved to be more efficient in case of stress incontinence than in urge incontinence.

CONCLUSIONS: Follow-up of the participants for several months would give information about the long-term benefits of electrical stimulation. In the future the improvement of the knowledge of patients on incontinence including the methods of conservative treatment is important. PH1H

EFFECTS OF A MULTIDISCIPLINARY HOME-BASED MEDICATION REVIEW PROGRAM ON HOSPITAL ADMISSIONS IN OLDER ADULT SINGAPOREANS
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OBJECTIVES: The study aimed to (i) evaluate the effectiveness of a multidisciplinary home-based medication review (HMR) program in reducing hospital admissions; and (ii) determine the prevalence of drug-related problems (DRP) in older adult Singaporeans.

METHODS: A retrospective observational study was conducted at an acute care hospital in Singapore in 2012. Out of which 50 % of the inappropriate medication found exclusively in asthma patients. Also, the use of OTC drugs and dietary supplements is commonly taken by the elderly. In addition, the elders with chronic diseases, higher income, and/or lower education level are inclined to take OTC medicines. PH1I

DETERMINING POTENTIALLY INAPPROPRIATE MEDICATION (PIM) AND MAJOR RISK FACTORS FOR HOSPITALIZATION FOR ELDERLY PATIENTS ADMITTING TO TEACHING HOSPITAL: STUDY FROM INDIAN PERSPECTIVE
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OBJECTIVES: Inappropriate polypharmacy is a particular concern in older people and is associated with negative health outcomes. Objective of this study was to identify potentially inappropriate medication (PIM) and major risk factors for hospitalization in elderly patients. METHODS: It was an observational prospective study in semi government teaching hospital situated in south India (Karnataka). This study was performed for 3 months and data were collected from elderly patients having age above 60 who were admitted to medical ward. RESULTS: Current analysis involving data of 150 (64 % male) elderly in patients with mean (SD) age of 67.9 (8.13) years. Majority of patients (30 %) were diagnosed with asthma followed by cancer (16 %). Mean participants had 15 years of first treatment for 30 days for asthma patients. Total 24 prescriptions were found with PIM as per beer’s criteria 2012. Out of which 50 % of the inappropriate medication found exclusively in asthma patients. In the single PIM for adults were 4. CONCLUSIONS: Asthma was found to be the single most common disease leads to hospitalization among elderly patients. Cancer was found to be the single common disease which increases hospital stay. Group of patients with asthma were receiving highest numbers of inappropriate medication compare to other patients.
between 2001 and 2012. One study was on early screening using maternal markers, and concluded that the diagnostic accuracy of a novel diagnostic test, concluded that the savings associated with this test from the payer perspective. Three other studies focused on treatment and management, and concluded that induced delivery is the most cost-effective option in term preclampsia. Also, magnesium sulphate was found to be a cost-effective treatment, but more so in low income countries. OBJECTIVES: To determine and quantify the level of price variation in inpatient care for obstetrical services across hospitals in the State of Vermont, USA. METHODS: We used data from Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES) for the calendar year 2012. We generated single-line summaries for all inpatient obstetrical services with an admission date in 2012. We excluded records for Medicaid, secondary payments either to Medicare or another commercial insurance, denied claims, non-respondent claims and adjustments to existing claims. We developed a total of 4,619 records for the evaluated services from 13 Vermont hospitals. We calculated the allowed amount for each Diagnosis Related Group (DRG) (total amount a hospital received from a payer, including any prepaid amounts unrelated to the payer of service, plus any reimbursement of this study of administrative data led to the evaluation of cost of illness which varies from 230.5 million to 501.6 million.

24,291.93 in the annual cost per patient diagnosis. It is important to differentiate between threatened PTL associated with potentially avoidable hospitalization and PTL resulting in a preterm birth (PTB) with respect to their burden to the health care system. The prevention and diagnosis of reduced such hospital admissions for observational reasons are supposed to reduce costs. The aim is to analyze the epidemiological and financial impact of programs to prevent avoidable hospital admissions due to threatened PTL. METHODS: A cohort of singletons at the University hospital Greifswald with PTL-related hospital admissions prior to birth was analyzed with respect to resource use and obstetrics outcomes. This bottom-up analysis was conducted from the perspective of the statutory health care system based on accounting information claims from the hospital’s database for the period 2007 to 2012. ICD-10 codes were used to identify the study population. All costs were inflated to 2012 using the German index. RESULTS: Out of 4,408 singleton births, potentially avoidable hospital admissions were found in 248 cases (5.6 %). In this subgroup, 17 infants were delivered preterm (avg. 34.8 weeks), resulting in a PTB rate of 6.9 % compared to a general rate of 8.7 % in Germany. These hospitalizations led to average costs of about 1,600 EUR per case (min. 300 EUR, max. 5,600 EUR). CONCLUSIONS: Although the intervention affects one singleton pregnancy in 20, the fraction of costs resulting from observational admissions associated with threatened PTL is less than 0.7 percent compared to the total department costs. This finding conflicts with the cost-saving potential of prevention programs (e. g. pH self-assessment) suggested in the literature.

Burden and cost of multiple chronic diseases in a large cohort of elderly in Italy

Adopting measures to reduce the prevalence of malnutrition in Ukraine as the model of health insurance is worth 24,291.93 in the annual cost per patient diagnosis. It is important to differentiate between threatened PTL associated with potentially avoidable hospitalization and PTL resulting in a preterm birth (PTB) with respect to their burden to the health care system. The prevention and diagnosis of reduced such hospital admissions for observational reasons are supposed to reduce costs. The aim is to analyze the epidemiological and financial impact of programs to prevent avoidable hospital admissions due to threatened PTL. METHODS: A cohort of singletons at the University hospital Greifswald with PTL-related hospital admissions prior to birth was analyzed with respect to resource use and obstetrics outcomes. This bottom-up analysis was conducted from the perspective of the statutory health care system based on accounting information claims from the hospital’s database for the period 2007 to 2012. ICD-10 codes were used to identify the study population. All costs were inflated to 2012 using the German index. RESULTS: Out of 4,408 singleton births, potentially avoidable hospital admissions were found in 248 cases (5.6 %). In this subgroup, 17 infants were delivered preterm (avg. 34.8 weeks), resulting in a PTB rate of 6.9 % compared to a general rate of 8.7 % in Germany. These hospitalizations led to average costs of about 1,600 EUR per case (min. 300 EUR, max. 5,600 EUR). CONCLUSIONS: Although the intervention affects one singleton pregnancy in 20, the fraction of costs resulting from observational admissions associated with threatened PTL is less than 0.7 percent compared to the total department costs. This finding conflicts with the cost-saving potential of prevention programs (e. g. pH self-assessment) suggested in the literature.

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OBJECTIVES: Although the relationship between use of glucocorticoids (GC) and occurrence of AE is widely acknowledged, the estimated size of specific AE is still imprecise. The aim of study was to quantify the incidence and economic cost of selected steroid-related AE in GC-users regardless of baseline chronic disease. METHODS: Review of the available data about the consequences of low-dose (LD), medium-dose (MD), high-dose GC (HD) (depending on specific dose and period of use) was conducted. From 162 full-text publications (10024 abstracts), four with mixed population and >5 years median follow-up were valuable. Hip fracture (HF), cataract (CAT) and diabetes mellitus (DM) were chosen as the common and most cost generating AE connected with oral GC treatment. A Markov model with a lifetime horizon (30 years) was developed to forecast incidence and health care cost of three regimen (non-GC, low dose GC <2.5 mg, high dose GC ≥2.5 mg). Direct medical costs were included in the analysis. RESULTS: For a lifetime horizon the incidence of HFr, CAT, and DM increased from 0.77% to 4.94%, 23.48% to 91.04% and 12.34% to 17.02% (7, 3, 9, 14 fold increase) respectively for comparison non-GC, low dose GC, and high dose GC. The simulated cohort of 1,000 you need to treat 34, 22 patients respectively (low dose GC instead of high dose GC) to prevent one additional case of HFr, CAT, DM. Shorter duration of steroid therapy (5 years) provide two Quality-Adjusted Life Months gained (per one patient) and leads to 2,305,7460,-(54.3% of total reimbursement). Reimbursement for Solifenacin was 325.9 million and 305.7 million (54.3% of total reimbursement). Reimbursement for Solifenacin was €630,831,022, on which €54,098,847 is attributable to treatment costs (ingredient, consultations, removal/insertion costs) and €576,732,175 to the cost of unintended pregnancies (live birth, miscarriage, abortion, ectopic pregnancy). CONCLUSIONS: The study supports that unintended pregnancies will result in a significant reduction in the number of unintended pregnancies, with consequent savings to the NHS across the UK.

PH22 COST-EFFECTIVENESS ANALYSIS OF USE OF DYdroGESTERONE IN PREMENSTRUAL SYNDROME

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OBJECTIVES: The primary objective of the study was the analysis of pharmaco-economic expediency of administration of dydrogesterone (Duphaston®) for premenstrual syndrome (PMS) treatment in comparison with micronized progesterone (Ul trogestan®). METHODS: The mathematical modeling with dydrogesterone or micronized progesterone was applied in the study. For the calculation of the efficacy data of clinical trials were used. Costs were calculated on the basis of Russian prices (price per mg) for Duphaston® and Ul trogestan®, respectively. The price per mg of Duphaston® was 5.82, and of Ul trogestan® was 3.25. The cost included drug administration (INR, costs of hospitalization, costs of diagnostic tests, costs of physician consultations). The treatment of PMS was compared with placebo (INR, costs of physician consultations, costs of diagnostic tests, costs of hospitalization). RESULTS: The cost of treatment for placebo was higher than for the treatment of PMS. The cost of treatment for placebo was 5.82 INR, and for the treatment of PMS was 3.25 INR. CONCLUSIONS: The treatment of PMS with dydrogesterone is more effective and more economical than the treatment with placebo.

PH23 COST-BENEFIT MODEL OF VARYING NexPLANON AND OTHER LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) METHODS: UPTAKE COMPARED TO THE ORAL CONTRACEPTIVE PILL: UK PERSPECTIVE

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OBJECTIVES: Cost is considered one of the major barriers to greater use of LARC (Long-Acting Reversible Contraceptive) methods, especially cost of treatment initiation. However, when considering their contraceptive efficacy alongside cost of pregnancy, LARC methods are deemed by NICE to be more cost-effective than combined oral contraceptive pills even at one year of use (NICE LARC CG80 2005). METHODS: A 3 year time-horizon cost-benefit model was developed to assess budgetary impact of introducing LARC in the UK (in place of, or in addition to, oral contraception). RESULTS: A 3 year time-horizon cost-benefit model was developed to assess budgetary impact of introducing LARC in the UK (in place of, or in addition to, oral contraception). We estimated the cost and cost-effectiveness of all combined oral contraceptive pill methods and a variety of LARC methods compared to the oral contraceptive pill in women aged 16-49 who currently use the following contraceptives: non-LARC method (defined as contraceptive pill only) or LARC method (which includes IUD, IUS, injectable, implant and patch). Sensitivity analyses were also performed using a range of LARC methods, and health states considered are healthy, HZ, PHN, HFr, CAT, DM and healthy, HZ, PHN, HFr, CAT, DM. Shorter duration of steroid therapy (5 years) provide two Quality-Adjusted Life Months gained (per one patient) and leads to 2,305,7460,- (54.3% of total reimbursement). Reimbursement for Solifenacin was 325.9 million and 305.7 million (54.3% of total reimbursement). Reimbursement for Solifenacin was €630,831,022, on which €54,098,847 is attributable to treatment costs (ingredient, consultations, removal/insertion costs) and €576,732,175 to the cost of unintended pregnancies (live birth, miscarriage, abortion, ectopic pregnancy). CONCLUSIONS: The study supports that unintended pregnancies will result in a significant reduction in the number of unintended pregnancies, with consequent savings to the NHS across the UK.

PH24 MISPROSTOL VAGINAL INSERT PHARMACOECONOMIC MODEL FOR 5 EUROPEAN COUNTRIES


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OBJECTIVES: Our aim was to assess the costs and consequences of labour induction using misoprostol vaginal insert (MVI) compared with currently used therapies using a specifically developed user-friendly decision model developed for Austria, Poland, Romania, Russia and Slovakia. METHODS: The model was developed in an Excel platform and compared clinical and safety aspects like time to vaginal delivery, time to active labour, occurrence of cesarean delivery and adverse events of MVI with select comparators. Efficacy and safety data were retrieved from targeted literature review, conducted in the main medical databases. Country-specific information about costs and resource use was incorporated into the model. Local data were collected for each country via a specifically developed questionnaire. The model compared the hospital and public payer perspectives. The model generated results as an incremental difference between the total costs related to labour induction with MVI or a comparator. The threshold price of MVI was also calculated. RESULTS: Local Key Opinion Leaders recommended the following comparators: dinoprostone vaginal insert (DVI, Austria), dinoprostone vaginal tablets (Dtab, Austria, Slovakia), dinoprostone cervical gel (Dgel, Poland, Russia, Slovakia) and oxtotin (Austria, Poland, Romania, Russia). The hospital perspective was chosen as default (additionally the public payer perspective was adopted for 2 countries). The use of MVI in most scenarios was related to a reduction in time consumption of hospital staff and in the length of patients’ stay in hospital wards. MVI was less costly or marginally more expensive in 80% of cases. CONCLUSIONS: Our model was developed in an Excel platform, compared clinical and safety aspects like time to vaginal delivery, time to active labour, occurrence of cesarean delivery and adverse events of MVI with select comparators. Efficacy and safety data were retrieved from targeted literature review, conducted in the main medical databases. Country-specific information about costs and resource use was incorporated into the model. Local data were collected for each country via a specifically developed questionnaire. The model compared the hospital and public payer perspectives. The model generated results as an incremental difference between the total costs related to labour induction with MVI or a comparator. The threshold price of MVI was also calculated. 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RESULTS: Local Key Opinion Leaders recommended the following comparators: dinoprostone vaginal insert (DVI, Austria), dinoprostone vaginal tablets (Dtab, Austria, Slovakia), dinoprostone cervical gel (Dgel, Poland, Russia, Slovakia) and oxtotin (Austria, Poland, Romania, Russia). The hospital perspective was chosen as default (additionally the public payer perspective was adopted for 2 countries).
Fuller results are presented elsewhere. METHODS: A cost-effectiveness analysis was performed on the results of interventions performed with TVT-O (2005-2008) and SIMS (2008-2011) in women with a diagnosis of SUI was performed. The clinical effectiveness was defined as an objective cure at 12 months (pad-test < 1 g).

A perspective of the hospital payer was adopted; therefore, only direct health care costs (diagnostic and surgical procedures, medical devices, medications, hospital stay times and staff) were included. C19% of total cost was estimated by bootstrapping; later, different sensitivity analyses were conducted. RESULTS: Procedures were carried out in 81 women (44 in the SIMS group and 37 in the TVT-O). A small difference (6.7%) in clinical effectiveness was observed in favour of SIMS, however, it was not statistically significant (SIMS: 93.1% vs TVT-O: 86.5%). The total annual cost per patient with SIS was lower (2,059€; C195%: 1,914-2,285) than with TVT-O (2,821€; C195%: 2,661-2,997), showing a statistically significant cost saving of 762€ (C195%: 702-822) in the long-term case, the probability of success for SIMS TVT-O was 100%. The sensitivity analysis showed that the cost determinant was the length of hospital stay, observing that an equivalent cost was only achieved if there was 100%.

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for RT intervention and US $17.88/DALY for RPR intervention. Cost-effectiveness ratios (CERs) were higher relative to the prevalence rate, sensitivity of tests, and DALY discount rate. **CONCLUSIONS:** Using the on-site antenatal rapid testing, same day testing for pregnant women, COLFAR, and the incremental cost/QALY is lower when compared to RPR intervention.

**PIH32 COST EFFECTIVENESS OF CALCIUM SUPPLEMENT IN REDUCING PREECLAMPSIA IN PATIENTS WITH MODERATE AND SEVERE SYMPTOMS OF UTERINE FIBROIDS IN ROMANIA**

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**OBJECTIVES:** To estimate the cost-effectiveness of the supply of calcium of 1200 mg per day from 1 week to 14 weeks of pregnancy to all pregnant women. Sensitivity analysis was performed by adjusting the values of the prevalence rate, pregnancy rate, and the cost per tablet of calcium of 1200 mg.

**RESULTS:** The incremental cost-effectiveness ratio (ICER) of R$ 81,627.31/QALY, value above of World Health Organization (WHO) recommended CER of R$ 33,780/QALY.

**CONCLUSIONS:** The cost-effectiveness of calcium supplementation is above the recommended threshold, and more study is needed for a decision-making perspective.

**PIH33 ECONOMIC EVALUATION OF ULIPRISTAL ACETATE FOR THE TREATMENT OF PATIENTS WITH MILD, MODERATE AND SEVERE SYMPTOMS OF UTERINE FIBROIDS IN ROMANIA**

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**OBJECTIVES:** Ulipristal acetate is a selective progesterone receptor modulator that has been demonstrated to be an effective 3-month pre-operative treatment. This study is to evaluate the cost-effectiveness of 5 mg ulipristal acetate as an add-on therapy to standard pre-surgical observation and treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The aim of this analysis was to assess the cost-effectiveness of 5 mg ulipristal acetate as an add-on therapy to standard pre-surgical observation and treatment or immediate hysterectomy in Romania.

**METHODS:** A Markov model was developed using a 10-year time horizon. Ulipristal acetate was compared with pre-operative observation and immediate hysterectomy. The Markov model was comprised of the following mutually exclusive health states: mild, moderate, severe, or persistent excessive bleeding disorder; myomaectomy; post-myomaectomy with severely excessive bleeding disorder; hysterectomy; post-hysterectomy; post-menopause; and death.

**Transition probabilities and utility values were obtained from clinical trials and the scientific literature. Sensitivity analysis and unit costs were derived from the health-care system panel of clinical experts and the Romanian National Insurance House tariffs. Cost vectors in IQN were converted to EUR by using 2013 Romanian National Bank average exchange rate (1 EUR = 4.419 IQN).

**CONCLUSIONS:** The results were the most sensitive to the utility value of the post-hysterectomy health state but responsive to changes in other model parameters. The cost-effectiveness ratio was lower than the WHO recommended threshold.

**PIH34 THE COST-EFFECTIVENESS OF EMERGENCY HORMONAL CONTRACEPTION WITH ULIPRISTAL ACETATE VERSUS LEVONORGESTREL FOR MINORS IN FRANCE**

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**OBJECTIVES:** To compare the cost and effectiveness of two emergency contraceptive methods in minors in France and to support the payer's analysis if it is worth to deliver ulipristal acetate for free to minors. **METHODS:** Based on a decision-analytical model, the cost-effectiveness of two emergency contraceptive methods is compared. Pregnancy rates, outcome of unintended pregnancy in minors and resource utilization are derived from literature. Resources and costs are considered until termination or a few days after delivery. Costs are taken from a collective perspective. Sensitivity analyses are performed on the most important model parameters. **RESULTS:** Using emergency contraception is superior to no method. The cost of an unintended pregnancy in a French minor is estimated to be €36,143,550 (1330 €/1-3 17 minced) and 4 million (3-1.13 million) could be saved by using ulipristal acetate instead of levonorgestrel. The incremental cost of avoiding an additional unintended pregnancy with ulipristal acetate as compared to levonorgestrel is estimated to be €241,000. Ulipristal acetate is most cost-effective in the subgroup of intake within 24 hours, where it is more efficacious at a lower cost compared to levonorgestrel. **CONCLUSIONS:** Ulipristal acetate is a cost-effective alternative to levonorgestrel, given that the cost of avoiding an additional pregnancy with ulipristal acetate is less than the average cost of said pregnancy. Therefore, French minors should have free access to ulipristal acetate directly in a pharmacy. Ulipristal acetate should be used rapidly after unprotected intercourse (within 24 hours) to benefit from its cost-saving potential compared to levonorgestrel use.

**PIH35 CERVICAL ASSESSMENT WITH PROGESTERONE IN THE PREVENTION OF PRETERM BIRTH: A STRATEGY BASED ON COST-EFFECTIVENESS**

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**INTRODUCTION:** Preterm birth (PTB) complications are estimated to be the second most common cause of death in under-five children and responsible for 3.1 million neonatal deaths. According to a worldwide analysis, Brazil is one of the top countries with the highest number of PTB. Considering its long-term costs, strategies that reduce incidence may be cost-effective. Treatment with progesterone is one of the interventions recommended for PTB prevention due to the evidence supporting its efficacy in women with short cervix and prior history of preterm delivery. **OBJECTIVES:** Determine whether treatment with progesterone for pregnant women with a short cervical length <25mm identified in routine surveillance or PTB prevention should be cost-effective. **RESULTS:** The inclusion of screening test, prenatal consultation, progesterone and hospitalization costs was US $204 per PTB avoided in cost/QALY. The results were most sensitive to the prevalence rate, sensitivity of tests, and cost/QALY. **CONCLUSIONS:** Cervical assessment with progesterone shows significant economic savings of USD74 million. Although the situation is different on drug, pre-test and prenatal consultation, a 10% increase in the total costs, the reduced number of PTB (263,052 vs 278.100) and neonatal UTI hospitalisation length (4,098,543 days vs 4,518,056 days) resulted in a total economic savings.

**PIH36 COST-EFFECTIVENESS OF PALIVIZUMAB USE IN HIGH RISK CHILDREN FROM BRAZILIAN HEALTH SYSTEM PERSPECTIVE**

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**OBJECTIVES:** This study aimed to investigate the cost-effectiveness of palivizumab to different combinations of risk groups, such as premature children born with gestational age (GA) ≤ 28 weeks, children with bronchopulmonary dysplasia (BPD) and bronchopulmonary dysplasia. **METHODS:** Literature review was performed to search effectiveness data. One Markov model (base case), and one decision tree (alternative scenario) were developed to estimate the effectiveness data were obtained from systematic reviews, meta-analysis and scientific literature. Resource utilisation and unit costs were derived from the Brazilian health care system.

**RESULTS:** The incremental cost-effectiveness ratio (ICER) was $81,627.31/QALY for children born with GA ≤ 28 weeks who were isolated, $163,141.50/QALY for children born with GA ≤ 28 weeks who were not isolated, and $17,720.32/QALY for children born with GA ≤ 28 weeks. The effective strategy was used in the decision tree for the different combinations of risk groups, such as premature children born with gestational age (GA) ≤ 28 weeks, children with bronchopulmonary dysplasia (BPD) and bronchopulmonary dysplasia. The effectiveness data were obtained from systematic reviews, meta-analysis and scientific literature. Resource utilisation and unit costs were derived from the Brazilian health care system.

**CONCLUSIONS:** The economic evaluation was used to estimate the palivizumab to different combinations of risk groups, such as premature children born with gestational age (GA) ≤ 28 weeks, children with bronchopulmonary dysplasia (BPD) and bronchopulmonary dysplasia. The effectiveness data were obtained from systematic reviews, meta-analysis and scientific literature. Resource utilisation and unit costs were derived from the Brazilian health care system.

**PIH37 COST-EFFECTIVENESS ANALYSIS OF THE NEW BIOMARKERS FOR DIAGNOSIS OF ACUTE KIDNEY INJURY IN CHILDREN AFTER CARDIAC SURGERY**

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**OBJECTIVES:** Children undergoing cardiac surgery for congenital heart disease are more likely to experience development of acute kidney injury (AKI) in the immediate postoperative period. In current clinical practice, AKI diagnosis is based on a rise in serum creatinine (SCr) levels, which occurs 12-24 h from the initiating renal insult. Many new biomarkers offer promise for earlier AKI diagnosis. The objective
was to assess the incremental cost-effectiveness of using serum Cystatin C (sCysC), urinary NGAL (uNGAL) and urinary L-FABP (ul-FABP) for the diagnosis of AKI in children after cardiac surgery compared with current diagnostic method (monitoring of Scr level). **METHODS:** We developed a decision analytical model to estimate quality-adjusted life years (QALY), lifetime costs and incremental cost-effectiveness of different diagnostic strategies, which can be used in clinical practice compared to the current strategy. This model simulates detection of AKI, progression to chronic kidney disease (CKD) and CKD treatment in cohorts of patients younger than 18 years. **RESULTS:** The cost-effectiveness ratios were between $95,995/QALY for Scr and $357,995/QALY for uNGAL. uNGAL and sCys C strategies yielded higher costs and lower effectiveness (ie. dominated) compared to ul-FABP strategy. ul-FABP added 1.43 QALY compared to current diagnostic method at an additional cost of $80,718. ICBR for ul-FABP compared to sCr was $5,959.5/QALY. Probabilistic sensitivity analyses indicated that the ul-FABP strategy was cost-effective for all 10,000 patient simulations at specified $5000/QALY threshold. **CONCLUSIONS:** Our results suggest that ul-FABP is likely to be recommended for an economic evaluation strategy for early AKI diagnosis in children after cardiac surgery. However, we need rapid screening ul-FABP test to ensure timely and efficient AKI treatment.

**PIH41**

**COST-UTILITY ANALYSIS COMPARING PROPRANOLOL WITH CORTICOSTEROIDS IN THE TREATMENT OF PROLIFERATING INFANTILE HEMANGIOMA IN ITALY**

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**OBJECTIVES:** Infantile Hemangioma (IH) is one of the most common childhood benign tumours. Recent studies have demonstrated the success of propranolol for involvement of IH and the higher clinically effective and safe compared with corticosteroids. The purpose of this study is to estimate the cost-utility of propranolol, a novel medicinal product authorized for this specific paediatric indication ($3.75\,mg/\,mL$) oral solution for paediatric use) in clinical practice in absence of other authorised therapies of proliferating IH requiring systemic treatment. **METHODS:** A life-time (30 years) mixed decision tree model was developed to describe the pathway of infants with IH and to assess costs and outcomes (Quality-Adjusted Life Years – QALYs – gained) from the perspective of the Italian National Health Service (INHS). Clinical inputs derive from the manufacturer’s clinical report and incremental costs are derived from INHS’s cost database. The economic evaluation considers direct medical costs associated with IH (drug acquisition, hospital admissions and outpatient visits) derived from public sources. The atopic dermatitis as a proxy for IH utilities, the Infantile Dermatitis Quality of Life Index (IDQoL) was used to estimate quality of life. Probabilistic sensitivity analyses (PSA) were performed to investigate model parameter uncertainties. Costs and health benefits have been discounted at an annual rate of 3.0%. PSA results are presented in terms of incremental cost-effectiveness ratio (ICER). Both deterministic and probabilistic sensitivity analyses were performed to approximate the effect of parameters’ variation on model results. **RESULTS:** A population of patients with HZ aged between 60 and 79 years was hypothesized. The ICER of the vaccination equaled €12,155 per QALY under the NHS perspective and €11,138 per QALY under the societal perspective. Moreover, under NHS perspective the cost per HZ episode avoided and the cost per PHE-episode avoided amounted to €1,098 and €8,742 respectively. Considering a cost-effectiveness threshold of €30,000/QALY, the probabilistic sensitivity analysis showed that vaccination is cost-effective regardless of the perspective adopted, in 99% of simulations. **CONCLUSIONS:** Results showed that a vaccination program against herpes zoster and post-herpetic neuralgia is cost-effective in Italian patients aged between 60 and 79 years.

**PIH42**

**COST-EFFECTIVENESS ANALYSIS OF A VACCINE TO PREVENT HERPES ZOSTER AND POSTHERPETIC NEURALGIA IN ITALY**

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**OBJECTIVES:** the aim of this study was to assess the cost-effectiveness of Hz vaccination compared to no vaccination strategy which only involves the treatment of patients affected by Hz, within the Italian context. **METHODS:** The natural history of Hz infection was modeled using data from the literature, and adopted a Markov model to simulate episodes lasting one month. Both third party payer (the Italian National Health Service) and societal perspectives were adopted. Costs and Effectiveness data was derived from literature and discounted by 3.5%. Model results are expressed in terms of incremental cost-effectiveness ratio (ICER). Both deterministic and probabilistic sensitivity analyses were performed to approximate the effect of parameters’ variation on model results. **RESULTS:** A population of patients with Hz aged between 60 and 70 years was hypothesized. The ICER of the vaccination equaled €12,155 per QALY under the NHS perspective and €11,138 per QALY under the societal perspective. Moreover, under NHS perspective the cost per Hz episode avoided and the cost per PHE-episode avoided amounted to €1,098 and €8,742 respectively. Considering a cost-effectiveness threshold of €30,000/QALY, the probabilistic sensitivity analysis showed that vaccination is cost-effective regardless of the perspective adopted, in 99% of simulations. **CONCLUSIONS:** Results showed that a vaccination program against herpes zoster and post-herpetic neuralgia is cost-effective in Italian patients aged between 60 and 79 years.

**PIH43**

**COST-UTILITY ANALYSIS FOLLOWING UP WITH FOLLOW-UP FOR OLDER PEOPLE WITH POLYPHARMACY IN COMMUNITY PHARMACIES IN SPAIN:**


**OBJECTIVES:** the objective of this study was to assess the cost-effectiveness of Hz vaccination compared to no vaccination strategy which only involves the treatment of patients affected by Hz, within the Italian context. **METHODS:** The natural history of Hz infection was modeled using data from the literature, and adopted a Markov model to simulate episodes lasting one month. Both third party payer (the Italian National Health Service) and societal perspectives were adopted. Costs and Effectiveness data was derived from literature and discounted by 3.5%. Model results are expressed in terms of incremental cost-effectiveness ratio (ICER). Both deterministic and probabilistic sensitivity analyses were performed to approximate the effect of parameters’ variation on model results. **RESULTS:** A population of patients with Hz aged between 60 and 70 years was hypothesized. The ICER of the vaccination equaled €12,155 per QALY under the NHS perspective and €11,138 per QALY under the societal perspective. Moreover, under NHS perspective the cost per Hz episode avoided and the cost per PHE-episode avoided amounted to €1,098 and €8,742 respectively. Considering a cost-effectiveness threshold of €30,000/QALY, the probabilistic sensitivity analysis showed that vaccination is cost-effective regardless of the perspective adopted, in 99% of simulations. **CONCLUSIONS:** Results showed that a vaccination program against herpes zoster and post-herpetic neuralgia is cost-effective in Italian patients aged between 60 and 79 years.

**PIH44**

**EVALUATION OF THE ECONOMIC BURDEN OF MENOPAUSAL WOMEN IN THE U.S. MEDICAID PROGRAM**


**OBJECTIVES:** the objective of this study was to estimate the incremental cost-effectiveness ratio (ICER) of a medication review with follow-up (MRF) service for older people with polypharmacy in community pharmacies against the alternative of receiving usual dispensing. **METHODS:** The study was designed as a longitudinal cluster randomized trial carried out over six months of follow-up. The target
population consisted of older people (≥65 years) with polypharmacy (≥5 drugs) and the study was conducted in 178 community pharmacies in Spain. A total of 1,403 patients were enrolled, 688 in the intervention group (IG) and 715 in the control group (CG). The analysis adopted the perspective of the National Health Service (NHS). In order to analyze the uncertainty of ICER results, we performed a non-parametric bootstrap with 5,000 replications. RESULTS: Both groups reduced the average number of prescribed medications, although this reduction was greater in the IG (0.28 drugs, p < 0.001) than in the CG (0.07 drugs, p = 0.063). Patients in the IG showed an improvement in their quality of life by 0.0228 in the utility score (p < 0.001). By contrast, patients in the CG showed no differences in their quality of life by 0.0022 in the utility score (p = 0.815). We obtained an ICER of 8,542/QALY and €7,777/QALY for the first and second scenario respectively, and a MRF as dominant strategies in the third, fourth and fifth scenario. For willingness to pay of €30,000/QALY, the probability of the MRF being cost-effective, compared to usual dispensing, is in a range between 98.2% and 100% for the five scenarios. CONCLUSIONS: MRF is an effective intervention in optimizing prescribing, medication and improving the quality of life of older people with polypharmacy in community pharmacies. The results from the cost-utility analysis suggest that MRF is cost-effective.

PATIENTS’ ACCEPTANCE Of THEIR mEdICATION: RESULTS fROm A fRENCH PATIENT gROUP

To evaluate health care resource utilization and costs of patients diagnosed with Alzheimer’s disease (AD) and residing in long-term care facilities. METHODS: A retrospective database analysis was performed using the Minimum Data Set (MDS) linked to 5% of Medicare Beneficiaries from data of 03/1997 to 12/2010. AD patients were identified using International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code 331.0. The first diagnosis, as the index date, was used to identify the group of AD patients without an AD diagnosis, using 1:1 propensity score matching (PSM) to control for baseline characteristics (age, gender, index year, baseline Charlson Comorbidity Index [CCI] score). For the comparison cohort, the index date was randomly assigned to reduce selection bias. Patients in both cohorts were required to be ≥65 years, with at least two consecutive quarterly assessments in MDS data in the 6 months pre-index date and 1-year continuous medical and pharmacy benefits enrollment pre- and post-index date. Study outcomes (health care costs and utilizations) were compared between the cohorts. RESULTS: After 1:1 matching, a total of 2,158 patients were identified for the disease and comparison cohorts, and baseline characteristics were balanced: The AD cohort had a higher percentage of index MDS inpatients (38.73% vs. 24.93%, p < 0.0001), outpatient visits (92.22% vs. 89.99%, p < 0.01) and skilled nursing facility (SNF) (32.53% vs. 28.41%, p < 0.01) and hospice admissions (11.03% vs. 7.14%, p < 0.0001) than the comparison cohort. The AD cohort also incurred higher inpatient ($5,442 vs. $4,001, p < 0.0001), SNF ($5,679 vs. $4,523, p < 0.01) and hospice stay costs ($1,164 vs. $2,047, p < 0.0001) as well as carrier claim ($2,907 vs. $2,686, p < 0.03) and pharmacy costs ($5,043 vs. $4,722, p < 0.01), compared to the comparison cohort. CONCLUSIONS: AD was associated with higher health care resource utilization and a significantly higher economic burden.

INDIVIDUAL’S HEALTH – Patient-Reported Outcomes & Patient Preference Studies

VALIDATION OF THE ADHERENCE BARRIERS QUESTIONNAIRE (ABQ) – AN INSTRUMENT FOR IDENTIFYING POTENTIAL RISk FACTORS ASSOCIATED WITH MEDICATION-RELATED NON-ADHERENCE

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OBJECTIVES: Medication-related non-adherence is a major challenge in the real-life treatment of patients. To meet this challenge successfully, adherence inter-

ventions with a tailored approach towards patient-specific adherence barriers are needed. Therefore, a reliable and practicable questionnaire for identification of those adherence barriers in specific patients is needed. The aim of this investigation is to develop and validate such a questionnaire. METHODS: The “Adherence Barriers Questionnaire (ABQ)” was developed and tested in 432 patients with atrial fibillation in a multicenter observational cohort study. Evaluation of the questionnaire included the assessment of internal consistency as well as factor analysis. Criterion-

related external validity was appraised by comparing the ABQ score with the score of a self-report adherence measure and with a clinical parameter (time in therapeutic range (TTR)) in patients with 5,000 repetitions and 5 items (13.5% of the variance) of the VA-based study. RESULTS: The final 14-item ABQ scale demonstrated high internal consistency (Cronbach’s α = 0.82). Factor analysis identified a three-factor solution, representing intentional adherence barriers with 5 items (31.9% of the vari-

ance), treatment barriers with 5 items (28.6%), and unintentional adherence barriers with 4 items (7.7% of the variance). Patients with ≥0.500 Pearson Chi-Square > 6.98 vs. 6.15, p = 0.009) as well as TTR (Spearman’s rho = -0.161, p < 0.01). Patients with average ABQ scores (increased number of existing adherence barriers) were significantly negatively correlated (TTR) than patients with a lower ABQ score (44.6% versus 25.4%, p < 0.0001). In the intervention (IG) group, the ABQ is used as a tool for identifying specific barriers to medication-related adherence. Future research is required to test the ability of the ABQ to identify patient perception/behavior changes over time which may be important for the measurement of success of adher-

ence interventions.

PLAQUE LOAD FACTORS IN THE SCOPE OF STUDENTS

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OBJECTIVES: We examined the effects of stress in university students during the exam period, compared with demographic data. METHODS: Prospective research was made in the exam period. Altogether 181 university students par-

ticipated in the course of which online questionnaire were applied. In the first part of the questionnaire demographic questions were listed, while Student Nursing Stress Index (SNSI) questionnaire was applied to measure stress level. Emotions perceived in a given moment could be evaluated by the Brunel Mood Scale. RESULTS: The percentage of students having a Risk of Multiple Dependency Scale (MRF) was 18.8% vs. not higher in patients with at least 50 respondents and currently receiving a treatment for this dis-

ease.

To evaluate health care resource utilization and costs of patients diagnosed with Alzheimer’s disease in the United States Huang A1, Shrestha S2, Baser O3, Wang L4

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OBJECTIVES: To evaluate health care resource utilization and costs of patients diagnosed with Alzheimer’s disease (AD) and residing in long-term care facilities. METHODS: A retrospective database analysis was performed using the Minimum Data Set (MDS) linked to 5% of Medicare Beneficiaries from data of 03/1997 to 12/2010. AD patients were identified using International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code 331.0. The first diagnosis, as the index date, was used to identify the group of AD patients without an AD diagnosis, using 1:1 propensity score matching (PSM) to control for baseline characteristics (age, region, gender, index year, baseline Charlson Comorbidity Index [CCI] score). For the comparison cohort, the index date was randomly assigned to reduce selection bias. Patients in both cohorts were required to be ≥65 years, with at least two consecutive quarterly assessments in MDS data in the 6 months pre-index date and 1-year continuous medical and pharmacy benefits enrollment pre- and post-index date. Study outcomes (health care costs and utilizations) were compared between the cohorts. RESULTS: After 1:1 matching, a total of 2,158 patients were identified for the disease and comparison cohorts, and baseline characteristics were balanced: The AD cohort had a higher percentage of index MDS inpatients (38.73% vs. 24.93%, p < 0.0001), outpatient visits (92.22% vs. 89.99%, p < 0.01) and skilled nursing facility (SNF) (32.53% vs. 28.41%, p < 0.01) and hospice admissions (11.03% vs. 7.14%, p < 0.0001) than the comparison cohort. The AD cohort also incurred higher inpatient ($5,442 vs. $4,001, p < 0.0001), SNF ($5,679 vs. $4,523, p < 0.01) and hospice stay costs ($1,164 vs. $2,047, p < 0.0001) as well as carrier claim ($2,907 vs. $2,686, p < 0.03) and pharmacy costs ($5,043 vs. $4,722, p < 0.01), compared to the comparison cohort. CONCLUSIONS: AD was associated with higher health care resource utilization and a significantly higher economic burden.

PATIENTS’ ACCEPTANCE Of THEIR mEdICATION: RESULTS fROm A fRENCH PATIENT gROUP

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OBJECTIVES: Lack of adherence and persistence can be major barriers to treatment efficiency in real world, for many chronic diseases. Measuring patients’ acceptance of their medication is thus gaining importance as it is likely to help better under-

stand and predict patients’ behavior towards treatment. The generic ACCEPT questionnaire by the Patients of their Treatment (ACCEPT©) questionnaire was developed to measure patients’ acceptance of their medication. The objective of this study was to evaluate for a variety of diseases the level of acceptance in real life using a patient online community tool. METHODS: This study was observational, cross-sectional, con-

ducted through the French Carenity platform. All patients connected were invited to complete an online questionnaire including demographics, chronic disease and treatment characteristics and a measure of acceptance. RESULTS: Among 1,838 patients who actually participated in the ACCEPT© questionnaire, 29.4% were breast cancer patients, 30.9% patients with multiple sclerosis (n = 3,110; 2.6%), 23.9% diabetes mellitus type 2 (n = 3,200; 2.7%), 15.3% rheumatoid arthritis (n = 998; 0.8%), multiple sclerosis (n = 260), ankylosing spondylitis (n = 134) or bipolar disorder (n = 65). Most respondents were female (49% to 100%), with mean age 44 to 61. Mean (SD) ACCEPT General score was: 36 (3) for breast cancer, 64 (21) for type 1 diabetes, 54 (32) for type 2 diabetes, 39 (31) for fibromyalgia, 39 (31) for rheumatoid arthritis, 50
Strategies comparisons of HS preference (2 concave, 2 convex, 1 linear). A score for each HS was the difference between each pair of HSs. We describe 5 approaches to structure pairwise
This was subsequently transformed into a scale indicating the significance of the preferred to each of the others was measured and represented by a 45*45 matrix.

PIH50
PATIENT PERSPECTIVE: PRO COMPLIANCE AND EFFECTIVE REMINDER STRATEGIES
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OBJECTIVES: Survey data results providing patient perspectives on compliance and reminder-use in studies including Patient Report Outcomes (PROs) is shared. This presentation looks at patients’ preferred reminder modes, identifies what may impact their recall, and assesses reminder strategies conducted in 2013, including patients globally (N=405) who participated in at least one clinical trial in the past two years with patient diaries. Patients were asked about their most preferred diary experience (including compliance and trial participation (including preferences for receiving reminders-content/modality/timing), and personal technology behaviors. RESULTS: Only 53.6% of patients reported always being compliant with completing diary entries. Factors associated with non-compliance were age, dissatisfaction, and habit to remember diaries. Reasons for non-compliance included: “They Forgot” (51.4%), “Too Busy” (41.1%), “Access” (27.6%), and “Other” (2.7%). Patients (77.2%) provided high attractiveness ratings for reminders in future trials. Preferred reminder modalities indicated a preference for text messages (64.3%), phone calls (34.1%), calendar alerts (32.6%), and email (6.2%). The majority of patients want to receive reminders for: diaries (97.3%), appointments (95.8%), and medication (95.0%). Most patients indicated checking text messages and reminders daily. Significantly more patients check text messages immediately compared to email suggesting that text

PIH51
USING THE ANALYTIC HIERARCHY PROCESS TO DERIVE HEALTH STATE UTILITIES FROM ORDINAL PREFERENCE DATA
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OBJECTIVES: EQ-SD is a standardised instrument for use as a measure of health outcome. There are well-documented problems regarding how best to measure worse than dead states using the Time Trade Off (TTO) approach. We attempted to generate a utility value for these states, which has five million combinations with health states (HSs) to overcome these issues, using the Analytic Hierarchy Process (AHP) approach. AHP is a multiple criteria decision analysis technique based upon pairwise comparisons, useful for prioritization problems. This has been widely used in health settings. METHODS: The technique outlined was applied to the Measurement and Valuation of Health (MVH) study dataset. The number of occasions that each HS was preferred to each of the others was measured and represented by a 45*45 matrix. This matrix was subsequently transformed into a scale indicating the absolute difference between each pair of HSs. We describe 5 approaches to structure pairwise comparisons of HS preference (2 concave, 2 convex, 1 linear). A score for each HS was derived from this matrix’s principal eigenvector and the matrix’s consistency index calculated. RESULTS: All approaches predicted the rankings of HSs found in the MVH report well. However, the utilities subsequently derived followed an unconventional, bunched shape compared to the original study. By optimizing the parameters in order to minimize the sum of squared errors between approaches, a more suitable approach (“Beta rank fit”) was identified. Utilities could in principle therefore be derived using this method alone, without recourse to TTO models. CONCLUSIONS: This study demonstrates an approach that may be suitable for converting ordinal state data into cardinal utilities, and offering a number of advantages over previously described approaches. Ranking exercises for participants are considerably easier to structure from an initial TTO study, so the approach may be suitable for resource limited settings or for underrepresented populations.

PIH52
A UTILITY ALGORITHM FOR THE PRESSURE ULCER QUALITY OF LIFE-UTILITY INSTRUMENT (PUQL-Ul)
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OBJECTIVES: Pressure Ulcers are a important health care problem, recognized as ‘Never Events’ by the US Government. To date, there is no instrument to capture the effect of pressure ulcer quality of life on an individual’s health related quality of life and will allow calculation of QALYs necessary for cost-effectiveness analyses.

PIH53
TIME-TRADE-OFF MODELLING OF HEALTH UTILITY VALUES FOR MENOPAUSAL SYMPTOMS AND THEIR TREATMENT
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OBJECTIVES: Impaired Health-Related Quality of Life (HRQoL) of women due to various symptoms of menopause impairments has been given increased importance in the past years. The objective of the present study is to estimate utility values for symptoms relevant for menopause-specific disturbances and to convert them into women’s willingness to give away months of life (time-trade-off for relief of those symptoms). METHODS: A time-trade-off (TTO) model was applied to estimate the utilities of 7 symptoms caused by menopause impairments. A German version of the QuaPulase Inventory (QFI) was used for assessing the severity of the symptoms. A QoL-AQoL questionnaire was filled out by 465 women and 60 men, was interviewed. Health states were presented to participating women on a mobile computer screen, and they were asked to specify the willingness to give away months/years for the relief of the symptoms, using time-scaled graphic slide controls visible on the computer

PIH54
GEOGRAPHICAL VARIATIONS OF HEALTH PERCEPTION IN THE US, USING BRFSS DATA 2012
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OBJECTIVES: The BRFSS (Behavioral Risk Factor Surveillance System) is conducted by the US Government. To date, there is no instrument to capture the effect of a region’s health perception on the quality of life. We attempt to estimate the utilities of 7 symptoms caused by menopause impairments. A German version of the QuaPulase Inventory (QFI) was used for assessing the severity of the symptoms. A QoL-AQoL questionnaire was filled out by 465 women and 60 men, was interviewed. Health states were presented to participating women on a mobile computer screen, and they were asked to specify the willingness to give away months/years for the relief of the symptoms, using time-scaled graphic slide controls visible on the computer

REFERENCES
2014 A323–A686
2015 A513
2016 A513
2017 A513
we cannot affirm that occupational therapy has long-term effect. The aging population in Japan and UK. METHODS: A web survey was conducted asking respondents whether each health state is WTD before direct choice experi- enced any injuries. The mean number of out-patient visits reported

back pain (43%) for women and for men (27%). The number of out-patient visits reported by subjects completed a questionnaire of the Health Utilities Index Mark3 (HUI3). We used the EQ-5D-3L descriptive system. The 48 health states were blocked into 24 sets of 4 health states. The health states were described using the EQ-5D-3L descriptive system. The 48 health states were blocked into 24 sets of 4 health states. The health states were described using

was 1.35 (95% CI 1.20–1.51). The median score of EQ-5D was 0.75 (range 0.22–0.95). Both 15D and SF-6D were significantly correlated with each other (Pearson's correlation coefficient of 0.76 for 15D and 0.75 for SF-6D, p < 0.001). Gender and age were the most important differences (0.02–0.03 for 15D and 0.04 for SF-6D) were used to guide the clinical

patients undergoing four surgical procedures: groin hernia repair 11.9% for men and 13.2% for women (Figure 1). The difference was statistically significant (p = 0.04).

be value of WTD for health state 33332 and 33323, respectively (72.0% and 60.0% in UK). An internet survey was conducted for finding suggestions for the Japanese value of worse health states not to be low in comparison with UK's. On the other hand, it was thought that participants might not understand the tasks.

dysfunction (ED) affects millions of males worldwide. While it is obvious that ED affects individuals’ quality of life, the quantifiable data on disutility associated with ED is comparatively less. The study aimed to investigate the prevalence of antenatal depression and explore its risk factors among pregnant women in Chengdu, China. METHODS: Women at third trimester of pregnancy were screened for symptoms of antenatal depression using the Edinburgh Postnatal Depression Scale (EPDS) and a psychosocial risk factors checklist. RESULTS: A total of 2243 pregnant women aged 30±4 years participated in the survey. The median EPDS score was 8.43 (standard deviation: 3.97). With a threshold score of 13, 14.2% were screened as having symptoms of depression. Age (P < 0.007), education level (P < 0.001), occupation (P < 0.001), number of lifetime partners (P = 0.02), and history of miscarriage/abortion (P = 0.048), and age of first pregnancy (P < 0.001) were associated with antenatal depression in univariable analysis but not multivariable analysis (P > 0.05 for all). Women who were dissatisfied with living conditions (OR = 1.81, 95% CI: 1.38–2.38), had a poor relationship with mother-in-law relationship (OR = 2.20, 95% CI: 1.65–2.92), and had unplanned pregnancy (OR = 1.34, 95% CI: 1.02–1.76) were more likely to show antenatal depression symptoms. CONCLUSIONS: Our study shows antenatal depression might be prevalent among Chinese women in Chengdu. Early detection and intervention for antenatal depression may be necessary to improve maternal and neonatal health after more systematic studies and reliable data are available.
OBJECTIVES: No recent Italian norm EQ-5D data were available. Furthermore, norm data were not available for the descriptive system with 5 levels. The main objective of the present study was to assess an Italian general population reference data using both the standard EQ-5D-3L version and the recently introduced EQ-5D-5L. METHODS: Large-scale telephone survey was conducted in November 2013 on a random sample from the general population of the Lombardy region with 9.8 million residents. They were recruited to be representative of the Lombardy general adult population as regards age (from 18 years), gender and geographical distribution. Each participant underwent a telephone interview including the Italian version of the 3L and 5L descriptive system, then, to minimize memory effects, between the two descriptive systems the participants were asked to report their socio-demographic data, and finally they answered the question on the visual analogue scale (VAS). The data collected with the 3L and 5L descriptive system were converted into utilities. RESULTS: Participants were 48% male with a mean (SE) age of 51.9 (2.1). Around half (51.3%) of the participants specified they had visited a doctor in the past two years. 15.8% were hospital patients and 26.5% retired. Overall no problems were reported by 86.5% (3L) and 84.2% (5L) with mobility, by 96.1% (3L) and 94.2% (5L) with self-care, by 88.0% (3L) and 84.9% (5L) with usual activities, by 58.4% (3L) and 52.8% (5L) with pain/discomfort, and by 59.4% (3L) and 52.8% (5L) with anxiety/depression. The mean (standard error) and median VAS was 78.2 (0.2) and 80. Mean (SE) utility index obtained from both the 3L and the 5L versions was 0.915 (0.003). CONCLUSIONS: Reference EQ-5D-3L and EQ-5D-5L data on the Italian general adult population are now available. Although these data were collected in the Lombardy region we can consider our results a proxy of the full Country.

PIH64 FAMiLY PREFerEnCES IN THE VOLUME vERSUS OUTCOmE dBATE: IMplicAtIONS FOR THE DELiVERY OF COMPlEx PEdiATRIC Care

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OBJECTIVES: A Relationship between volume and outcome for complex medical procedures has been used as an argument for regionalization; however, this must be balanced against the need to have care delivered close to home. The objective of our study was to determine how families trade-off variations in risk against the ability to have complex pediatric care delivered locally.

METHODS: Twenty parents of children without serious medical problems seen in an outpatient clinic participated in a preference study involving two scenarios in which they were asked to imagine their child required a complex medical procedure (low-risk: 5% mortality, high-risk: 30% mortality) available locally or at an alternate larger hospital. A graphic depiction of mortality and non-fatal complications were reduced in a stepwise fashion for procedures performed at the alternate center. Thresholds at which participants chose to travel were identified.

Results: Participants’ decisions were then challenged by increasing the costs incurred by travelling to the alternate center. In the high-risk scenario, 2 of 8 parents with household income > $100,000/y changed their decision to travel when faced with additional costs; however 8 of 12 with lower income changed their decision (p=0.07). In the high-risk scenario, 1 of 8 reported their decision changed. In the low-risk scenario, participants chose not to travel until absolute risk was reduced by 2±0.2 (relative risk reduction of 39%±3%). In the high-risk scenario, a larger absolute risk reduction (5±3% or p=0.001) but smaller relative risk reduction (17.5±% or p=0.001) triggered a decision to travel.

CONCLUSIONS: Our study showed that trade-off variations in risk against the ability to have complex pediatric care are valued differently, with parents near the median VAS. In the high-risk scenario, 1 of 8 parents with household income > $100,000/y changed their decision to travel when faced with additional costs; however 8 of 12 with lower income changed their decision (p=0.07). In the high-risk scenario, 1 of 8 reported their decision changed. In the low-risk scenario, participants chose not to travel until absolute risk was reduced by 2±0.2 (relative risk reduction of 39%±3%). In the high-risk scenario, a larger absolute risk reduction (5±3% or p=0.001) but smaller relative risk reduction (17.5±% or p=0.001) triggered a decision to travel.

PIH65 EVALUATING PREVALENCE OF SELF-MEDICATION IN BAHALAWFUR

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OBJECTIVES: Aim of this study was to determine the prevalence and pattern of self-medication among different classes in Bahawalpur community. METHODS: It was a cross-sectional descriptive study targeting residents of Bahawalpur including the whole class of every age group and gender. Sample size was calculated and 10% was added to encounter non response, respondents were selected through convenience sampling method. The data was collected using a pre-tested self-administered questionnaire. The data collected were measured after and converted to percentages. The data was analyzed using SPSS version 15 and the results were tabulated. RESULTS: A total of 420 of the participants responded including literate 280 (66.7%) illiterate 140 (33%). Most of the respondents were motivated towards self-medication due to high cost of prescription medicines (n=312, 74.3%), weak trust on physicians (n=404, 96.2%) and drug sellers (n=217, 51.7%). Significantly high percentage of medical professionals (n=6, 0.1%) had lower self-medication (p<0.001) than the respondents (n=416, 100%). The respondents considered it easier and cost effective to buy medicines (n=177, 49.5%) in comparison to respondents with no-medical background (n=180, 65%). CONCLUSIONS: It was concluded that self-medication is common among the residents of Bahawalpur and results more among literate and medical health care professionals as compare to illiterate and those not with medical background.

PIH66 A SYSTEMATIC REVIEW TO IDENTIFY THE USE OF PREFERENCE ELICITATION METHODS IN HEALTH CARE DECISION MAKING

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OBJECTIVES: Preference elicitation methods (PEMs) offer the potential to increase patient-centered medical decision-making (MDM), by offering a measure of benefit which could deliver adequate information to inform HTA and BRA decisions.

METHOdS IN HEALTH CARE dECISION mAkING

Raisch DW1, Lockhart A1, Hancock Friesen C1, Masood I1, Lockhart A1, Mullenger R1, Warren A1

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**PHH71** HEALTH LITERACY AND SELF-REPORTED HEALTH STATUS USING THE EQ-5D-5L: AN EXPLORATORY ANALYSIS

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**OBJECTIVES:** To describe health literacy (HL) in Uruguayan general population and associated individual and socio-economic characteristics. ASSESSmENT Of HEALTH STATES ANd ERECTILE dySfUNCTION-ASSOCIATEd QUAliTy Of LIfE IN GERmANy, THE UNITEd kINGdOm ANd THE UNITEd STATES

**METHODS:** As part of an ongoing Uruguay EQ-5D-5L valuation study, we included the Short Assessment of Health Literacy-Spanish questionnaire (SAHL-S), a previously validated instrument that evaluates HL through 18 items combining word recognition and comprehension.

**RESULTS:** Of 773 participants 60.2% were women (mean age 42.02 years; SD: 15.51). VAS mean was 79.34 (DS: 16.39). 52.9% participants had at least one limitation in any of the EQ-5D domains, 75.9% had experience with illness and 51.5% in caring others. Educational attainment (EA) distribution was 17.2% up to primary, 52.3% up to secondary and 30.5% to tertiary or higher education. HL was present in 39.8% of the population.

In bivariate analysis aging and low HL were associated with poorer VAS scores (coef -0.276, p=0.000; coef -0.306, p=0.012). Higher VAS scores were observed with EA and low HL (coef 0.382, p=0.000). Multiplicative regression shows HL is related to VAS independently of age, but this association loses its statistical significance -becoming borderline- after adjusting for EA and experience in caring others (coef -1.93, p=0.05). This study confirms that HL is associated with formal education and acquired knowledge related to health. This is the first study that describes HL in Uruguay, and shows that is associated with self-reported health.

Further studies are needed to explore the potential value added to standard educational level measurement.

**PHH72** ASSESSING THE TRANSLATABILITY OF THE TERM “FRUSTRATED”

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**OBJECTIVES:** The objective of this study was to assess the translatability of “frustrated,” a term commonly used to describe a range of emotions in Clinical Outcomes Assessments (COA). “Frustrated” includes many constructs, such as “disagreement,” “anger” and “upset.” Previous studies have shown that terms including multiple constructs in English, such as “bother,” are not sufficiently translatable across all languages. METHODS: Back-translations of questionnaires containing the word “frustrated” were analyzed to assess the translatability of the term. The following related constructs were also included in analysis: “discouraged,” “angered,” “disappointed” and “upset.” Data collection forms resulting from cognitive debriefing were also translated and back-translated with limited success.

**RESULTS:** The following terms were translated with no issues in all 12 languages available for analysis. “Upset” was found to be equally problematic, and thus rejected as a recommended alternative. Conclusions: “Frustrated” is not recommended for use in EQ-5D intended for international data pooling. Similar to the findings of previous studies, more
PH73 MOBILE PHONE USE IN PATIENT REPORTED OUTCOMES – AN UPDATED LITERATURE SEARCH

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OBJECTIVES: To demonstrate the increasing use of mobile phones to collect patient reported outcomes in research as a valid method of data collection. METHODS: A literature search was conducted looking at articles published between 2009 and 2019 that referenced electronic diaries of some description. Articles were pulled out that specifically referenced mobile or cellular phones. RESULTS: 39 out of 191 articles found were mobile phone related. The articles were classified into 15 therapy areas including metabolic and genetic disorders, pain, weight management, sexual activity, respiratory, multiple sclerosis and gastroesophageal reflux disease. Mobile phones were specifically referenced from 2012 to 994 (mean 208.3, SD 269.9), and subjects reported for a minimum of 7 days (up to 6 reports per day) to a maximum of 2 years (mean 154.3 days; SD 170.6). Notably, 18 out of the 39 studies allowed the subjects to use their own mobile phone for the reporting and 19 articles referenced smartphone specifically. CONCLUSIONS: All concluded that mobile phones were suited to collect data from subjects. It was noted that the use of mobiles was acceptable as they are used in everyday life and found to be convenient; the technology was also acceptable to implement. The fact that 46.2% of the studies allowed the subjects to use their own mobile phones for the reporting emphasises the practicality of using mobile phones in patient reported outcomes. Although the mean age of all the studies was relatively low, the frequency of mobile use was very wide and ranges can be confident that older populations could use mobile phones to collect these data. The technical evolution of mobile technologies and ubiquitous nature show that this technology is a valid means to collect patient reported outcomes.

PH74 REGULATORY ISSUES IN PRO ADVERTISING: A REVIEW OF THE DDMAC/OPDF LETTERS FROM 1998 TO 2013 TO IDENTIFY PRO CLAIMS VIOLATIONS AND EXAMINE THEIR EVOLUTION OVER TIME

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OBJECTIVES: According to the Federal, Food, Drug and Cosmetic Act (FD&C Act), prescription drug promotion must not be false or misleading, have fair balance, be consistent with the approved product labeling, and only include claims substantiated by FDA-approved labeling. METHODS: DDMAC letters were identified on the Enforcement Activities by FDA webpage. Letters from 1998 to 2013 were all reviewed manually to identify violations in relation to PRO and HRQOL claims during the periods before and after the publication of the guidance of the draft FD&C act (2005 vs 2006-2013). RESULTS: 762 Drug Promotion (OPDF), formerly the Division of Drug Marketing, Advertising and Communications (DDMAC), was set up to protect the public health by assuring precise prescription drug information is truthful, balanced and accurately communicated. The objective of this study was to review the DDMAC/OPDF warning and notice of violations letters to find out 1) how many violations were in relation to PRO and HRQOL claims and 2) how those evolved after the publication of the FDA PRO draft guidance (2006). METHODS: DDMAC letters were identified on the “Enforcement Activities by FDA” webpage. Letters from 1998 to 2013 were all reviewed manually to identify violations in relation to PRO and HRQOL claims during the periods before and after the publication of the guidance of the draft FD&C act (2005 vs 2006-2013). RESULTS: 762 PRO violations were found specifically referenced mobile or cellular phones. The studies referenced were carried out on specific terms, such as “discouraged” and “angered,” translate with greater conceptual difficulty to patient experiences. Although the mean age of all the studies was relatively low, the frequency of mobile use was very wide and ranges can be confident that older populations could use mobile phones to collect these data. The technical evolution of mobile technologies and ubiquitous nature show that this technology is a valid means to collect patient reported outcomes.

PH75 THE USE OF PATIENT REPORTED OUTCOMES (PROS) BY THE PHARMACEUTICAL INDUSTRY IN JAPAN – A BRIEF REVIEW OF FDA DATA IN COMPARISON WITH FDA AND EMA-APPROVED LABEL CLAIMS

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OBJECTIVES: The use of patient-reported outcomes (PROs) in label claims in the US and Europe is regulated by the FDA and EMA, respectively. Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) does not have such regulations. This study was done to determine whether Japan-based pharmaceutical companies utilize PRO endpoints at all and in what way, by investigating their inclusion in Phase III clinical trials, pharmacological clinical trials and drug information materials. METHODS: We searched the websites of ClinicalTrials.gov and the FDA and EMA for information on 14 drugs which had received PRO claim approvals from both the US and EMA. We compared the FDA and EMA approved label claims. RESULTS: Search terms were 1985-2005 and included PRO in the title and for the target condition resulting in 870 hits. CONCLUSIONS: Of the 14 drugs, none had “symptoms” as a primary endpoint; a drug for rheumatoid arthritis (RA) had “functioning” as its lead secondary endpoint; the remaining six drugs (for concomitant arterial hypertension (PAH), Crohn’s Disease, smoking cessation, Myasthenia Gravis, asthma, and overactive bladder) had “HRQOL,” “symptoms,” and “functioning” as minor secondary endpoints. Three drugs –indicated for PAH, seizure, and RA– had PRO claims in their labels. Although not yet prominent in Japan, PROs are used in drug clinical trials and label claims. Symptoms, Quality of Life, and Functioning are the most common PROs used.

PH76 COMPARING THE EQUIVALENCE OF EQ-SD-SL ACROSS DIFFERENT MODES OF ADMINISTRATION

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OBJECTIVES: Interest in delivering Patient Reported Outcome Measures (PROs) using mobile phones specifically, e-PROMs, increased in recent years. However there is debate about the level of equivalence between the traditional pencil and paper and electronic modes of administration. The aim of this study is to compare the equivalence of delivering a widely used generic PRO (EQ-SD-SL) pencil and paper method to delivering the e-PROMs. METHODS: A mobile version of the EQ-SD-SL was developed with guidance from the EuroQol Group. Two hundred respondents from a research cohort of people in South Yorkshire were identified, and randomly allocated to one of the administration modes based on stratifications for age and gender (and across a range of self-reported health issues). The EQ-SD-SL was completed either using a mobile device or the standard paper version which was sent out to the respondent. Follow up usability questions were also included. EQ-SD-SL equivalence was compared at the dimension and utility and VAS score level using ANOVA. RESULTS: Response rates were comparable across the arms, with the majority of respondents owning a smartphone. The mean EQ-SD-SL utility and VAS scores of respondents entering the individual EQ-SD-SL categories across each of the dimensions did not differ across the administration modes. The majority of the mobile phone completion sample agreed that the mobile version was completed-SL was easy to complete, and that the journey was short, and that they would complete e-PROMs again. CONCLUSIONS: Completing e-PROMs using mobile phones produces equivalent results and response rates to pencil and paper methods, and respondents are positive towards completing questionnaires using these methods. This study provides evidence that e-PROMs are valid for use to collect data in a range of settings including clinical trials, routine care, and as, for example, health diaries.

PH77 ARE PATIENT REPORTED OUTCOMES RELEVANT TO PATIENTS? LEARNINGS FROM A PATIENT ADVOCATE SURVEY

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OBJECTIVES: Increasingly, patients become active participants in making decisions on their therapy. A survey was conducted to understand the experience and expectations of patient organizations (POs) with patient reported outcomes (PRO) as they are measured today. METHODS: An online survey was conducted in English language in April 2015 and was distributed to patient organisations from various countries including USA, European countries, Asia, Latin America, Middle East and Australia. RESULTS: Current PROs were perceived as useful but not optimal for informing patients in making their treatment and therapy decisions. All of typical PRO domains were considered important (between 3.9 and 4.7 on a 5-point scale). Increasingly, POs develop their own instruments to elicit PROs from the patient perspective and as patient based evidence. CONCLUSIONS: The concept of patient reported outcomes is good in principle but more is needed for integrating additional aspects which are relevant for the patients themselves to understand the full impact and consequences of the therapy. Patient reported outcomes are key endpoints from the patient perspective and should be elicited throughout the entire development and marketing cycle of products.

PH78 THE ENDOMETRIOSIS HEALTH PROFILE (EHP) – A CASE STUDY OF SUCCESSFUL EPRO COLLABORATION

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OBJECTIVES: To migrate the UK English Endometriosis Health Profile (EHP) from paper to ePRO format for completion by respondents on a touchscreen tablet device in order to extend, to produce translations of the UK English ePRO version in 25 languages. METHODS: The draft ePRO version of the EHP was reviewed by the questionnaire developer, the translation project manager and the sponsor. During the initial review the questionnaire was assessed for linguistic equivalence with the English version to ensure for the target languages. A number of factors were considered including layout, response input method and forced completion. Decisions were made based on the recommendations of the developer, translation vendor and ePRO vendor according to the specifications of each party, taking into consideration the capabilities of the software and the requirements of the
patient group. Following the initial review the tablet-based ePRO version was pilot tested in a group of patients with mild cognitive deficiency who use English. The translated versions of the EHP were adapted for ePRO administration and the resulting screenshots proofread for accuracy. RESULTS: Feedback from patients indicated that some amendments to the formatting and ordering of instructions would be beneficial. However, all responders indicated that the ePRO version of the EHP was easy to use and preferable to a paper-based questionnaire. The ePRO format posed some difficulties for specific languages which required an adjustment to the layout and wording structure. CONCLUSIONS: The use of a paper-based or electronic administration of the EHP was an accurate representation of the original paper version. This was achieved via cooperative input at the initial review stage to ensure that all aspects were considered and close collaboration throughout the project to find appropriate solutions to the challenges posed by the ePRO administration of the EHP.

Evaluating the translatability of physical assessment clinical outcomes assessment (COA) items

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OBJECTIVES: The objective of this study is to determine which physical assessment Clinical Outcomes Assessment (COA) questionnaire items are most translatable. METHODS: Eighteen (18) physical assessment items were analyzed, using back-translations to determine conceptual equivalence with the source text. Previous studies have regarded 80% source conceptually equivalent as a translatable item. Item content, cultural appropriateness and any cultural alterations, as well as conceptual equivalency were noted. RESULTS: After translation and back-translation, proportion of items rated as highly translatable, moderately translatable, and problematic were recorded. Highly translatable items, such as “taking a trip” may be misconstrued, as the distance implied may differ across cultures. Problematic items, such as “going out,” translated with conceptual equivalency may be misconstrued, as the distance implied may differ across cultures.

Quality of life in pregnant women attending anti-natal clinics in rural and urban areas of Delta state

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OBJECTIVES: Preventing problems for mothers and babies depends on an operational continuum of care with accessible, high quality care before and during pregnancy. The objective of this study is to evaluate the quality of life of pregnant women attending antenatal clinics in rural and urban areas of Delta State, Nigeria. METHODS: A descriptive cross sectional study design was used. Six hundred and ninety nine pregnant women attending antenatal clinics in selected hospitals were interviewed using a 31 item pretested, structured questionnaire developed using the World Health Organization Quality of Life (WHOQOL) on Pregnancy assessment brief template. Data assessed include socio-demographics characteristics. Costs were measured in 2013 Australian dollars. RESULTS: Mean cost difference for the largest participating hospital was $9132 (95%CI 5998, 12267; p<0.001). Final results of infant health service use to 24 months’ age corrected for prematurity. We also tested the sensitivity of results to the costing approach used. METHODS: ProPrems Neuro study assesses the 2-year outcomes of very preterm/VLBW infants from birth to 24 months’ age corrected for prematurity. We also tested the sensitivity of results to the costing approach used.

Health related quality of life in patients receiving home enteral nutrition in Spain assessed by a specific questionnaire: NutriQL®

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OBJECTIVES: To assess Health Related Quality of Life (HRQoL) in patients receiving Home Enteral Nutrition (HEN) using NutriQL® questionnaire in Spain. METHODS: NutriQL® is a fully-validated and validated questionnaire assessing the measurement of HRQoL of patients receiving HEN regardless of the underlying condition was administered to a prospective cohort from 9 Spanish hospitals. It includes 17 pairs of items measured in two dimensions: 1) physical and psychological well-being and activities of daily living, 2) social life aspects, scoring from -51 (worst HRQoL) to 51 (best HRQoL). Cluster analysis using k-means identified groups of patients with similar HRQoL. RESULTS: A total of 140 subjects (61.4% men, mean (SD) age: 62.7 ± 15.5 years, 65% with a Charlson index 3.41 ± 3.26; mean lifetime score was 14.3 ± 6.86). Dimension 1 and 2 scored 13.55 (11.71) and 1.20 (4.74). Cancer patients presented lower HRQoL, compared to neurological and malabsorption patients (12.76 ± 0.18 vs. 11.17 ± 0.17, p=0.018). Physical wellbeing, oral HEN and postpartum care were better predictors than their only nutrition route (19.54 ± 14.00 ± 7.02, p<0.001) for the social relationship domain (11.43±1.81). The overall QOL mean scores for the two other domains were: physical health (24.84±3.74), psychological health (21.84±3.03). Significant differences were observed in all domains except social relationship. CONCLUSIONS: The health related life (HRQoL) in pregnant women was found to be lower in those living in rural and their counterparts in the urban areas in all domains except social relationships.

The health related quality of life in patients receiving home enteral nutrition in Spain assessed by a specific questionnaire: NutriQL®

Apeztegua A1, Cuerda C2, Virgili N1, Iries JA1, Cuesta P3, Casanueva F4, Carrillo L1, Layola M5, Uinón L1

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OBJECTIVES: To assess Health Related Quality of Life (HRQoL) in patients receiving Home Enteral Nutrition (HEN) using NutriQL® questionnaire in Spain. METHODS: NutriQL® is a fully-validated and validated questionnaire assessing the measurement of HRQoL of patients receiving HEN regardless of the underlying condition was administered to a prospective cohort from 9 Spanish hospitals. It includes 17 pairs of items measured in two dimensions: 1) physical and psychological well-being and activities of daily living, 2) social life aspects, scoring from -51 (worst HRQoL) to 51 (best HRQoL). Cluster analysis using k-means identified groups of patients with similar HRQoL. RESULTS: A total of 140 subjects (61.4% men, mean (SD) age: 62.7 ± 15.5 years, 65% with a Charlson index 3.41 ± 3.26; mean lifetime score was 14.3 ± 6.86). Dimension 1 and 2 scored 13.55 (11.71) and 1.20 (4.74). Cancer patients presented lower HRQoL, compared to neurological and malabsorption patients (12.76 ± 0.18 vs. 11.17 ± 0.17, p=0.018). Physical wellbeing, oral HEN and postpartum care were better predictors than their only nutrition route (19.54 ± 14.00 ± 7.02, p<0.001) for the social relationship domain (11.43±1.81). The overall QOL mean scores for the two other domains were: physical health (24.84±3.74), psychological health (21.84±3.03). Significant differences were observed in all domains except social relationship. CONCLUSIONS: The health related life (HRQoL) in pregnant women was found to be lower in those living in rural and their counterparts in the urban areas in all domains except social relationships.

Individual’s health – Health Care use & Policy studies

HOSPITAL DRG COSTING AND HEALTH SERVICES USE OF VERY PRE-TERM INFANTS FROM THE PROPREMS Neuro STUDY CROSSOVER ACROSS 10 HOSPITALS IN AUSTRALIA AND NEW ZEALAND

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OBJECTIVES: Mortality and morbidity of very preterm (born <32 weeks’ gestation) and very-low-birth-weight (VLBW, <1500g) infants impose substantially on finite health resources. This study estimated costs of hospital and non-hospital services for a cohort enrolled in ProPrems Neuro, of very preterm/VLBW infants from birth to 24 months’ age corrected for prematurity. We also tested the sensitivity of results to the costing approach used. METHODS: ProPrems Neuro study assesses the 2-year outcomes of very preterm/VLBW infants from Australia and New Zealand from 2007-2011 in a prospective multicentre, double-blinded randomised controlled trial of probiotic administration. Infants’ health resource use was collected from medical assessment records and parent report. Health resource use was sourced from Medicare Australia (Government database) for resource use up to 24 months. Hospital costs were calculated separately by the Victorian (State) Casemix funding approach and the newly implemented national and territorial accounting (ABF) algorithm. AR-DRG diagnostic/procedural codes were used to classify inpatient episodes by prematurity/birth weight, complications, length of stay (LoS), hospital and patient characteristics. Costs were measured in 2013 Australian dollars. RESULTS: 1099 preterm infants across 10 hospitals were included. Average costs were highest for infants with birth weight <750g: $224,558 with mean LoS 105 days. Cost comparison between Casemix and ABF systems showed significantly lower costs using the national algorithm. Mean cost difference for the largest participating hospital was $9132 (95%CI 5998, 12267; p<0.001). Final results of infant health service use to 2
years corrected age will be presented in November 2014 with follow-up comple- 
tion and data release from Government database by August 2014. CONCLUSIONS: 
Preterm infants showed high services use including hospitalisation, with associated 
high costs. Costs vary by patient characteristics and costing approach. This study’s 
results should inform effective resource planning of neonatal health services and 
development of future prevention interventions aimed at preterm birth.

**PIH84**

**DAILY DOSE AND COSTS ASSOCIATED WITH MAINTENANCE THERAPY OF TOPICAL TESTOSTERONE AGENTS AMONG HYPOGONADAL MEN**

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**OBJECTIVES:** Topical testosterone agents (TTAs) are commonly used to raise low serum testosterone levels in men. After implementation of the Retail Drug Price Database (RDPD), patients may undergo dose titration to achieve an appropriate maintenance 
dose. The objective of this study was to compare daily maintenance doses and costs of treatment with TTAs from US payer perspective in adult men diagnosed with hypogonadism (HC).

**METHODS:** Adult men with a HC-associated diagnosis 

**PIH83**

**THE CHAMBER (CEMED) PROPOSED TO PUBLIC MEDICINES ACQUISITIONS IN THE EFFICIENCY EVALUATION OF THE RULE FROM DRUG MARKET REGULATION TO ADOPT THE USE OF THE COST COMPARISON RESULTS IN THE PREPARATION OF THE LIST OF INEXPENSIVE THERAPIES**

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**OBJECTIVES:** The aging of the population and the increase of chronic disease patients represent the current medical and socio-economic challenges. In 2008, facilitated the preparation of the list of inexpensive therapies in the canton of Vaud (Switzerland), professionals around the residents were invited to develop a collaborative pharmacy practice model derived from the successful experimentation in the canton of Fribourg. The intervention called Quality Circle promotes team based care and clinical guidelines. The model has shown sustainable 
evidence of the cost containment of medicines without affecting the quality of care. The objective of this study was to assess the first results of economic impact of the program in NH engaged between 2009 and 2012.

**METHODS:** Individual data by NH resident was derived from community pharmacists’ invoice and from resident admission data. The evolution of the daily mean drug cost per resident was compared with the total mean daily drug cost of the population over 65 years old in primary care from cantonal pharmacy invoice (Swiss Health Observatory, OBSAN). **RESULTS:** Between 2009 and 2012,13 NH were entered into the model. Mean dose of medicines decreased from 6.8 to 6.1 EUR, representing a reduction cost of 10.3% from 2009 to 2012. In 2012, the mean age of residents was 88 (SD 7.3) years old, 78% were women. From 2009 to 2012 the daily mean drug cost per resident of the program decreased to 10.3% from 2009 to 2012. **CONCLUSIONS:** The monitoring of the program shows first positive results due to the reduction of drug costs. Nevertheless, this model has an operating cost. The next step will be to determine the breakpoint of the intervention.

**PIH82**

**TOPICAL TESTOSTERONE AGENTS AMONG HYPOGONADAL MEN**

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**OBJECTIVES:** To assess the patterns and factors associated with prescription of FDA classified C, D and X category drugs (unsafe medications) during pregnancy. **METHODS:** Cross-sectional analysis was conducted of pregnant women aged 20 and 49 years using data from the Medical Expenditure Panel Survey (MEPS) for the years 2009 and 2011. Difference in the demographic variables, socioeconomic status, access to health care, and chronic conditions were tested for the use of safe medications. All analyses accounted for the complex survey design of MEPS. **RESULTS:** The study sample consisted of 1603 pregnant women (whites [595 (38.4%), married to a man [924 (66.3%)], employed [918 (64.5%), no chronic illness [1103 (68%)]), A total of 413 (28.3%) women utilized medication of FDA category CDX. The use of the category CDX among pregnant women was 1.12, 95% CI: 1.00, 1.25, P = 0.04, higher in age groups (69 [0.62, 95% CI: 0.40, 0.95, P = 0.05]), were less likely to receive unsafe medications. There were no differences rates of unsafe medications use by age, race, marital status, employment status, mental health, and smoking status. **CONCLUSIONS:** Nearly one-third of all pregnant women utilized a category CDX drugs. Further research should be carried out to reduce utilization of FDA CDX especially among the women with chronic conditions and poor health status.

**PIH81**

**FDA CDX CATEGORY MEDICATION USE DURING PREGNANCY IN THE UNITED STATES**

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**OBJECTIVES:** To assess the patterns and factors associated with prescription of FDA classified C, D and X category drugs (unsafe medications) during pregnancy.

**METHODS:** Cross-sectional analysis was conducted of pregnant women aged 20 and 49 years using data from the Medical Expenditure Panel Survey (MEPS) for the years 2009 and 2011. Difference in the demographic variables, socioeconomic status, access to health care, and chronic conditions were tested for the use of safe medications. All analyses accounted for the complex survey design of MEPS. **RESULTS:** The study sample consisted of 1603 pregnant women (whites [595 (38.4%), married to a man [924 (66.3%)]), employed [918 (64.5%), no chronic illness [1103 (68%)]), A total of 413 (28.3%) women utilized medication of FDA category CDX. The use of the category CDX among pregnant women was 1.12, 95% CI: 1.00, 1.25, P = 0.04, higher in age groups (69 [0.62, 95% CI: 0.40, 0.95, P = 0.05]), were less likely to receive unsafe medications. There were no differences rates of unsafe medications use by age, race, marital status, employment status, mental health, and smoking status. **CONCLUSIONS:** Nearly one-third of all pregnant women utilized a category CDX drugs. Further research should be carried out to reduce utilization of FDA CDX especially among the women with chronic conditions and poor health status.
perspective) for the standard fertility treatment strategy is about 50M USD compared to the fast-track fertility treatment strategy at an estimated 41M USD for a net budget impact of 9M USD. The average cost per patient per year (patient perspective) for the standard fertility treatment strategy is approximately 4,800 USD compared to the fast-track fertility treatment strategy at an estimated 4,200 USD for a net budget impact of 600 USD. Results vary upon user inputs. CONCLUSIONS: An Excel-based model was developed to assist managed care organizations and employers with the development of an optimal fertility benefit design. The model serves as an educational tool to evaluate various fertility benefit designs in terms of patient and financial outcomes.

PIH90
POtentially inAPPrOpRIAtE meDICines And POTentIAlly PreSCRIBIng OMISSIONS in OLder PeOPle And thEIR ASSOCIAtion WITh heAlth Care uTIlITy: A rETROspoChET COhORt sTudY
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OBJECTIVES: Older people are vulnerable to medicine-related adverse effects. In response to these concerns, prescribing indicators have been developed addressing Potentially Inappropriate Medicines (PIMs), medicines with unfavourable risk-benefit ratios and Potential Prescribing Omissions (PPOs), omission of indicated medicines with a clear benefit. Little is known about the impact of PIMs and PPOs on health care utilization. This study aims to determine the association between PIMs and PPOs and health care utilization. METHODS: This is a retrospective cohort study of 2,051 community-dwelling participants in The Irish Longitudinal Study on Ageing (TILDA) aged 65 years with linked health service and prescription data from the national pharmacy claims database. FIM and PPO exposure in the 12 months prior to participants’ TILDA interviews was determined using validated prescribing indicators (Screening Tool for Older Persons’ Prescriptions (STOPP), the Screening Tool to Alert doctors to Right Treatment (START), Beers’ criteria and Assessing Care of Vulnerable Elders (ACOVE) indicators). Outcome measures used were self-reported number of GP visits, number of hospital admissions (overall and general practitioner (GP) visits in the previous year). Poisson regression models were used to determine the associations between PIMs and PPOs and these outcomes, adjusting for age, sex, education, number of medications, chronic conditions, and health service use. RESULTS: Overall PIM exposure was 18.8-52.7% and PPO prevalence was 43.6-44.8% depending on the screening tool applied. Independent of screening tool used, PIMs and PPOs were significantly associated with hospital visits. For example, the adjusted incident Rate Ratio (IRR) for each additional STOPP FIM was 1.24 (95%CI: 1.15-1.35). With the exception of START FIMs, PIMs and PPO exposure were also significantly associated with GP visits (adjusted IRR vs additional bears’ FIM for example). CONCLUSIONS: FIMs and PPOs are independently associated with increased health care utilization, supporting application of FIM/PPO indicators as robust measures of health care expenditure.

PIH91
IMPACT oF ASSISTED REPRODUCTIVE THERAPY (ART) ON INFANT HEALTHe AND hEALTH CARe COST OutCOMES
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OBJECTIVES: Assisted reproductive therapy (ART) has increased dramatically in the last two decades, notably since 1999 to 2008. Prior research has evaluated multiple outcomes from ART including newborn survival and birth weight as well as cost analyses measuring cost per live birth; despite robust research, we still need information on the long-term health and cost outcomes. METHODS: We used frequency by age and gender for this specialized attention. Overall PIM exposure was 18.8-52.7% and PPO prevalence was 43.6-44.8% depending on the screening tool applied. Independent of screening tool used, PIMs and PPOs were significantly associated with hospital visits. For example, the adjusted incident Rate Ratio (IRR) for each additional STOPP FIM was 1.24 (95%CI: 1.15-1.35). With the exception of START FIMs, PIMs and PPO exposure were also significantly associated with GP visits (adjusted IRR: 1.10 (95%CI: 1.06-1.15) for each additional Beers’ FIM for example). CONCLUSIONS: FIMs and PPOs are independently associated with increased health care utilization, supporting application of FIM/PPO indicators as robust measures of health care quality and patient safety in relation to prescribed medications.

PIH92
AGING IMPACT ON THE NATIONAL HEALTH COST IN EXTREMADURA: PUBLIC HEALTH EXPENDITURE OF EXTREMADURA IN THE PERIOD 2011-21
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OBJECTIVES: To estimate the effect of demographic component in the evolution of public health expenditure of Extremadura in the period 2011-21. METHODS: We estimated health expenditure profiles by age and gender in 2011. Then, we used population projections to calculate future health expenditure. To obtain those profiles we used data obtained from the information systems of Extremadura. For the primary profile we used the data of frequency by age and gender for this specialized attention. The profile of the pharmaceutical expenditure by age and gender was obtained from the pharmacy invoice, once the public contribution was deducted. The estimated population in 10 years was obtained from the National Statistic Institute. INE (INE 2011) and INE (INE 2021) for public health expenditure growth of 5.34%. The aging effect implies a cumulative annual rate in the period 2011-2021 of 6.43% and a decrease of 0.69% due to the life expectancy growth (decrease in population). Of all the segments, the largest increase is in the pharmaceutical costs with an accumulated increase of 8.81%, of which 5.65% is in primary attention and 4.78% in specialised attention. CONCLUSIONS: According to our results, population growth or aging are determining aspects in public health expenditure increase. Using data directly from each region will explain the differences. In the case of Extremadura, the age factor is very important when increasing the pressure of the public health cost, having a special influence in the field of pharmaceutical expenditure and primary attention.

PIH93
KAZAKhSTAN vERSUs uZBEKISTAN: A REVieW OF THE DRUG PRoVIsION SYSTEMS
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OBJECTIVES: As is the case with many of the Commonwealth of Independent Countries (CIS), since the collapse of the Soviet Union, both Kazakhstan and Uzbekistan have been re-building health care provision, and improving access to medications for their populations. This study compares the two separate paths the two countries have taken in establishing the health care systems of the two countries as well as the direction of future reforms. METHODS: Secondary research focused on analysing the systems in place in the two countries, focusing on the systems in place in Uzbekistan and Kazakhstan. In Kazakhstan, the procurement of drugs that are provided for free as part of the guaranteed volume of free medical care. In both the cases these fall under an outpatient setting. Although the procurement of drugs is carried out mostly via tenders, Kazakhstan’s system involves establishing price ceilings. In Uzbekistan, retail and wholesale margins are controlled. Between 2002-2012, public health expenditure as a percentage of total health expenditure rose from 54% to 58% in Kazakhstan and from 45% to 53% in Uzbekistan. Life expectancy, however, increased from 65.9 to 68.6 years in Kazakhstan and from 67.1 to 68.1 years in Uzbekistan. CONCLUSIONS: With growing government health expenditure, reflecting the expansion of the health care systems, the countries are likely to increasingly look into containing costs. Given that some pricing mechanism is already in place in Kazakhstan, it may consider implementing tighter pricing regulations, moving closer to those seen in Europe. In Uzbekistan, the government may potentially consider expanding the beneficiary categories while ensuring cost-effectiveness within the tendering process.

PIH94
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OBJECTIVES: The Cervantes scale is a specific health-related-quality-of-life (HRQOL) questionnaire developed in Spanish women through and beyond menopause. The original 31-items version was reduced to a 16-item shorter form. METHODS: We compared the behaviourism properties of the Cervantes-SF in a routine clinical sample of perimenopausal and postmenopausal women. METHODS: Peri and postmenopause adult women were recruited in twelve outpatient clinics of Gynecology. All of the patients completed both the full and the abridged version, however, order of administration was balanced. The instrument was the abridged version to avoid administration bias. A sub-sample of 31 women answered the 16-item sort form within 1-2 weeks later (rete-test). Correlation between forms and test-retest reliability were used to test measurement stability. Item analysis, internal consistency reliability, item-total and item-domain correlations and item correlation with the generic 3-SD-3L questionnaire were also studied. RESULTS: A sample of 215 women [mean age 55 years (SD=5.3)] was enrolled. Internal consistency was good (Cronbach’s α=0.857) but slightly lower than that of the original scale [α=0.895]. Dimensional reliabilities ranged between α=0.636 (Health) and α=0.923 (Vasomotor). Correlations between extended and reduced subscales was high and significant in all cases (p<0.001), ranging from r=0.790 for Health to r=0.872 for Vasomotor. Correlation between total scores was also high (r=0.885), and no differences were found between mean scores (Effect size=0.353). Short-form total score correlation with EQ-5D utility score was negative and significant (r=0.478) and also with EQ-5D Health VAS (r=0.432). Test-retest correlation was r=0.865. Completion of Cervantes-SF required half of the time than the original scale. CONCLUSIONS: The abridged 16-items Cervantes scale (Cervantes-SF) maintained the original psychometric properties. This version extends 51% of the original length, being faster to apply and making it specially suitable for routine clinical practice.

PIH95
PREDICTIONS FOR MEDICAL SUBSIDY ENROLLMENT AMONG YOUNG CHILDREN FROM HIGH-RISK FAMILIES IN TAIPEI
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OBJECTIVES: The current study looks to explore young children from high-risk families in an area with high-risk social welfare intervention and to evaluate the effectiveness of these interventions. First, differences between enrollees and non-enrollees for medical subsidy program among high-risk family whose cases were started in 2009 or 2010 will be looked at. Second, the study will try to determine the social welfare intervention’s effectiveness in reducing the need for enrolment for medical subsidy program among children, which may have helped or harmed application for enrollment. METHODS: The study sample included under 6 year old children high-risk families (n=199). High-risk family database and medical subsidy database were linked. Differences between high-risk subsidy enrollees (n=87) and non-enrollees (n=112) and effectiveness of a social welfare intervention in increasing subsidy application was investigated in a pre-post analysis of high-risk social welfare intervention. Individual level as well as relative residential level characteristics were explored. RESULTS: A trend towards a reduced enrollment was correlated with younger age at time of a high-risk intervention and relative district level variables. Pre-post comparison suggests high-risk interventions significantly increased subsidy application by 74%. Logistic regression indicates older age at time of intervention was associated with 40% less chance of application. CONCLUSIONS: The study provides empirical evidence for potential effects of a high risk social welfare intervention on the accessibility to health care. Findings also show relevance in order to address the needs of children at-risk, especially for different age groups.

OBJECTIVES: To estimate the calcium levels in peri menopausal and postmenopausal women and to evaluate the need for calcium supplementation among them. METHODS: A prospective study was conducted at gynecology department of a tertiary care hospital for the period of six months to estimate the serum calcium levels among them. Study populations were divided in to peri menopausal and post menopausal women and data were collected. A total of 100 patients of age 44-65 years The mean calcium level of 47 peri menopausal women was found to be 9.3 ± 0.55 (reference level: 8.0 -11.0 mg/dl) and 8.5 ± 0.54 for 53 postmenopausal women. In post menopausal women there was significant difference in serum calcium level compared to peri menopausal women. (CI 95%, p<0.001, r = -0.81). CONCLUSIONS: The serum concentrations of calcium in majority of our study population were within the normal range. There was a good source of dietary intake of calcium in the levels of the patients. The levels of calcium in women lower in postmenopausal women compared to peri menopausal women. Since there is a negative effect of calcium on the bone mineral density in postmenopausal women, it can be recommended that calcium supplementation can be given as prophylaxis to prevent the long term bone loss and to decrease the risk of fracture and osteoporosis.

OBJECTIVES: To describe patient characteristics and medication treatment patterns among newly diagnosed cases of BPH-LUTS, ED, and co-occurring ED and BPH-LUTS. METHODS: We review cohort studies according to Gothenburg and lower (L), lower-middle (LM), upper-middle (UM) and upper (U) quartiles were identified. RESULTS: Income (GNI/capita) was not significantly associated with achieving high EPI coverage rates. Within the income groups the factors trended with improved EPI coverage included: 5-yr mortality and corruption index in L, sanitary facilities in LM, 5-yr mortality, sanitary facilities, birth-rate and life-expectancy in UM. In U all countries achieved >90% coverage. CONCLUSIONS: Identifying simple predictive factors which predict successful vaccination uptake may help reduce the risk of multicolinearity. However, by exploring within homogeneous income groups, it was possible to identify underlying factors related to vaccination programme success. As the core EPI vaccines were introduced 40yrs ago one would expect introduction to have been fully implemented thus reducing the likelihood of a relationship between country income and coverage today, however it could have been expected some time ago. To further explore the relationship between country income and vaccination program success we could expand the analysis to include the newer vaccines as soon as coverage information is available for a majority of the countries.

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D) CAT-Health scores of -1.2412 (1.6065) vs. -0.0119 (1.3495) (p = 0.001). Patients taking biologics also showed worse scores: -1.1005 (1.9348) vs. -0.3288 (1.4169) (p = 0.037). Differences on HRQoL according to antidepressant drugs were not statistically significant. Episodes of pain during dialysis were concentrated in 24 patients who had 6 or more painful sessions. These patients were taking analgesics more frequently (86% vs. 36%, p = 0.048), and showed worse CAT-Health score: -1.2412 (1.6065) vs. -0.3243 (1.4981) (p = 0.005).

**CONCLUSIONS:** Pain during haemodialysis sessions is very common and requires the frequent use of analgesics, having a negative impact on patients’ HRQoL.

**PSY2**

**CLINICAL UTILITY OF THE SCALE TO ASSESS COMORBIDITIES IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA**

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**OBJECTIVES:** COLLECT scale assesses comorbidities in patients with Chronic Lymphocytic Leukemia (CLL). Validation of COLLECT was a secondary objective of the MABERYC non-interventional study. The aim is to assess the clinical utility and the validity of COLLECT to guide treatment regimen prescribed to CLL patients.

**METHODS:** MABERYC study included patients with CLL, being or not previously treated, initiating treatment with Rituximab+chemotherapy. COLLECT was administered at baseline and 12 months following treatment finalization. Treatment response was also assessed at each visit. COLLECT was administered at baseline. PREMABERYC was included 218 patients, 179 completed COLLECT at baseline. Patients had a mean age of 67.5 years, 73% were male, 53% were naive, 37% had moderate comorbidity and 27% high comorbidity. At baseline, 42% of patients were in treatment with prednisone, 30% with rituximab, 18% with rituximab-Bendamustine (RB), 18% with rituximab-Chlorambucil (RC) and 10% other patterns. MEAN COLLECT score was higher in older patient, higher ECOG, previously treated (5.2 vs 4.2) and those receiving less aggressive treatment (5.8 vs 5.3). Changes in COLLECT were analysed in 194 patients. CK could be associated to improvement in comorbidity. Complete remission was reached by 53% of patients with COLLECT improvement, 47% without changes and, 32% worsening. Number of adverse events (AE) treatment related tended to be higher in patient with lower comorbidity (1.6 vs 0.9), using more aggressive treatments. Total number of AEs (related or not to treatment) trend to be higher in patients with higher comorbidity (7.8 vs 5.8).

**CONCLUSIONS:** COLLECT scale assesses comorbidity, which could be related with higher comorbidity and with different strategies of treatment (prednisone, rituximab, rituximab-Bendamustine, rituximab-Chlorambucil). RC could be associated to improvement in comorbidity. Complete remission was reached by 53% of patients with COLLECT improvement, 47% without changes and, 32% worsening.

**PSY3**

**IMPACT OF BIOLOGICS USE ON DEPRESSION AND ANXIETY FREQUENCY AND HEALTH CARE RESOURCE UTILIZATION IN PSORIASIS: AN ANALYSIS USING THE QUEBEc PROVINCIAL REIMBURSEMENTS DATABASE**

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**OBJECTIVES:** Psoriasis is a chronic inflammatory disease of the skin that cannot be cured. For patients with active moderate to severe psoriasis, biologics use is associated with improvements in quality of life especially by reducing psychological disorders. The objective of this study was to evaluate the impact of biologics use on depression and anxiety frequency and the number of medical visits. 

**METHODS:** A retrospective study of the Quebec provincial drug reimbursement program (RAMP) database was conducted using a randomly selected group of patients who have received at least one diagnosis of psoriasis between January 1st, 2007 and June 30th, 2012. To assess the impact of biologics use, time series analyses were performed. Time series analyses evaluate changes in the slope of a trend pre- and post-intervention, herein defined as biologics initiation. Trends in depression and anxiety frequency and medical visits frequency were compared for each year for a 5-year period before and after biologics initiation to assess the differences in slopes. RESULTS: A total of 43,400 patients with psoriasis were included in the study (mean age 54.6 [SD=21.9] years, 53.7% females), of which 1,108 (2.6%) used a biologic agent. For patients who needed to be treated with biologics, the rates of change in the depression and anxiety prevalence increased by 3.4% and by 4.2% per year prior to biologics initiation respectively. After biologics initiation, the trends were still increasing, but at a statistically lower rate of 2.5% (p=0.028) and of 2.4% (p=0.013) per year. Medical visits per patient increased during the 5-year period before biologics initiation. Visits frequency has reduced during the 5-year period after biologics initiation with a trend decreasing annually (p<0.002).

**CONCLUSIONS:** The present analysis illustrates that biologics use reduces the increase in depression and anxiety frequency and decreases the number of medical visits.

**PSY4**

**A REAL-WORLD CHARACTERIZATION OF PATIENTS WITH “MODERATE-TO-SEVERE” SYSTEMIC LUPUS ERYTHEMATOSUS**

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**OBJECTIVES:** To characterize the patient (pt) group classified by physicians as having “moderate-to-severe” systemic lupus erythematosus (SLE) disease severity, and assess disease burden. 

**METHODS:** Data were collected from the Adelphi 2013 Lupus Disease-Specific Program, a multinational evaluation of clinical practice. Physicians com-

\textbf{ImPACT Of BIOLOGICS USE ON dEPRESSION ANd ANxIETy fREQUENCy ANd} 

\textbf{the number of medical visits.}

\textbf{siation on HRQoL (EQ-5D: 0.72 vs 0.86; WPAI: 35.0 vs 16.3) than “mild” disease. Fewer}

\textbf{and outcomes of patients with ANxyloSPONDYLITIS (AS) receiving ADALIMUMAb OR ETANcePT} 

\textbf{Monotherapy in Europe}}

Narayanan S, Lu Y, Hutchings R, Raynton R

\textbf{OBJECTIVES:** To compare the disease status and outcomes of patients with AS receiving adalimumab and etanercept monotherapy in Europe. **METHODS:** A multi-
country multi-center medical chart-review study of AS patients was conducted among 14,000 people in 16 countries. Results: We included 1,211 patients in the analyses. Patients data on patients who were currently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30yrs) and patient volume (incl. >50 biologic patients/month) and recruited from a large panel to be geographically and professionally representative in each country. Eligible patient charts (N=231) were selected from a sample of prospective patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns and outcomes for each symptomatology/Germany/disease. Pain patients on adalimumab/etanercept therapy were monitored. RESULTS: 329 eligible AS patient charts were abstracted, 141 on adalimumab (male: 89%, age: 41.3yrs, average months on adalimumab: 29.5, 95% on first biologic) and 102 on etanercept (male: 78%, age: 42.7yrs, average months on etanercept: 12.3, 98% on first biologic). Top-3 comorbidities (adalimumab vs. etanercept) were dyslipidemia: 6% (range: 0% (Germany) -11% (Italy)) vs. 8% (range: 0% (UK/Germany) -15% (Spain)), obesity: 4% (range: 0% (Italy) -7% (UK/Germany)) vs. 6% (range: 0% (Italy) -11% (France)), depression: 6% (range: 0% (Spain)/Italy) -15% (UK)) vs. 5% (range: 0% (Germany/Spain) -7% (Italy/France). Among patients with available data, latest lab measures documented were (adalimumab vs. etanercept): ESR: 15.1mm/h (range: 11.6 (Germany) - 23.6 (Italy)) vs. 13.6mm/h (range: 8.0 (Germany) -19.2 (Italy)), CRP: 6.7mg/dL (range: 2.6 (Spain) -8.9 (France)) vs. 7.3mg/dl (range: 1.9 (Germany) -10.0 (Italy)), rheumatoid factor-positive: 6% (range: 0% (France) -10% (Germany)) vs. 10% (range: 0% (UK) -3% (Italy)). Latest disease severity measures documented were (adalimumab vs. etanercept): Swollen Joint Counts: 0.8 (range: 0.1 (France) - 1.4U (UK) vs. 0.3 (France) -0.9 (Italy)), Tender Joint Counts: 1.2 (range: 0.5 (Germany) -1.9 (Italy)) vs. 1.1 (range: 0.4 (France) -2.1 (Italy)), HAQ: 1.1 (range: 0.7 (Spain) -1.5 (UK) vs. 1.3 (France) -1.9 (Italy)). The average group of patients on adalimumab or etanercept therapy, disease severity differed within the EU5, with patients on adalimumab, and patients in Italy, having marginally higher burden and poorer outcomes. Factors influencing the observed patterns and the impact of specific biologic treatments on these observations warrant further scrutiny to optimize therapeutic interventions and improve outcomes.

PSY11
A PILOT STUDY OF THE EFFECTIVENESS OF TREATMENT PATIENTS WITH HEMOPHILIA IN UK
Zalika Q1, Mudrak V2, Mudrak V2
1Danylo Halytsky Lviv National Medical University, Lviv, Ukraine, 2Vinnitsa National Medical University, Vinnitsa, Ukraine
OBJECTIVES: The incidence is 87% of hemophilia and often leads to disability (90% of patients). WHO recommends annual demand of 1 patient of 30 000 IU of factor VIII, but in Ukraine with a national program funded an average 5768 IU per year (20% of the needs). The goal of the study is to determine the effectiveness of substitution treatment "BioKlot A" from 2012. The aim was to determine the effectiveness of substitution treatment "BioKlot A" native medicine in the treatment of patients with hemophilia A.

METHODS: A pilot clinical study examined 168 patients diagnosed with hemophilia A severe form of male, aged 18-52 years, who were hospitalized. Experimental group received "BioKlot A" control group – “Oktanat” in equal doses of 40 IU / kg / day - the next day. All patients were determined by the intensity of joint pain, joint circumference, blood count, and others criteria. RESULTS: Within 24 hours after "BioKlot A" (average dose rate of 10 000 IU) joint pain significantly decreased after 48 hours - the pain disappeared and patients returned to normal life. Physicians observed a significant decrease in anti-factor VIII total cholesterol, low-density lipoproteins (LDL), high-density lipoproteins (HDL) and triglycerides at 3 and 6 months. Amfepramone treatment showed a superior efficacy and safety in the long-term has been scarcely published data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30yrs) and patient volume (incl. >50 biologic patients/month) and recruited from a large panel to be geographically and professionally representative in each country. Eligible patient charts (N=231) were selected from a sample of prospective patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns and outcomes for each symptomatology/Germany/disease. Pain patients on adalimumab/etanercept therapy were monitored. RESULTS: 329 eligible AS patient charts were abstracted, 141 on adalimumab (male: 89%, age: 41.3yrs, average months on adalimumab: 29.5, 95% on first biologic) and 102 on etanercept (male: 78%, age: 42.7yrs, average months on etanercept: 12.3, 98% on first biologic). Top-3 comorbidities (adalimumab vs. etanercept) were dyslipidemia: 6% (range: 0% (Germany) -11% (Italy)) vs. 8% (range: 0% (UK/Germany) -15% (Spain)), obesity: 4% (range: 0% (Italy) -7% (UK/Germany)) vs. 6% (range: 0% (Italy) -11% (France)), depression: 6% (range: 0% (Spain/Italy) -15% (UK)) vs. 5% (range: 0% (Germany/Spain) -7% (Italy/France)). Among patients with available data, latest lab measures documented were (adalimumab vs. etanercept): ESR: 15.1mm/h (range: 11.6 (Germany) - 23.6 (Italy)) vs. 13.6mm/h (range: 8.0 (Germany) -19.2 (Italy)), CRP: 6.7mg/dL (range: 2.6 (Spain) -8.9 (France)) vs. 7.3mg/dl (range: 1.9 (Germany) -10.0 (Italy)), rheumatoid factor-positive: 6% (range: 0% (France) -10% (Germany)) vs. 10% (range: 0% (UK) -3% (Italy)). Latest disease severity measures documented were (adalimumab vs. etanercept): Swollen Joint Counts: 0.8 (range: 0.1 (France) - 1.4U (UK) vs. 0.3 (France) -0.9 (Italy)), Tender Joint Counts: 1.2 (range: 0.5 (Germany) -1.9 (Italy)) vs. 1.1 (range: 0.4 (France) -2.1 (Italy)), HAQ: 1.1 (range: 0.7 (Spain) -1.5 (UK) vs. 1.3 (France) -1.9 (Italy)). The average group of patients on adalimumab or etanercept therapy, disease severity differed within the EU5, with patients on adalimumab, and patients in Italy, having marginally higher burden and poorer outcomes. Factors influencing the observed patterns and the impact of specific biologic treatments on these observations warrant further scrutiny to optimize therapeutic interventions and improve outcomes.
6 years, would be 34% lower. CONCLUSIONS: Treatment with nilotinib is expected to result in better health outcomes, with more patients achieving TFR. This initial TKI investment should reflect itself in long term economic benefits.

PSY13 PRE-SYMPHOMATIC GENETIC TESTING IN FAMILIAL AMYLOID POLYNEUROPATHY: THE REPRODUCTIVE OPTIONS

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OBJECTIVES: Familial Amyloid Polyneuropathy (FAP) is a rare, rapidly progressive, debilitating and life-threatening neurodegenerative disease. Pre-symptomatic genetic testing (PST) can contribute to reduce FAP prevalence, informing carriers about risk of transmission to offspring and available reproductive options such as Pre NAT. The aim of this study was to analyse the impact of an intervention for Pre-implantation Genetic Diagnosis (PGD) on reproductive options. METHODS: Data from a cohort of 145 FAP carriers that underwent PST at Medical Genetics Unit (HP/CHUC – Portugal, 2000-2012) was used. The study was specified to identify determinants for natural reproduction option. RESULTS: The subjects were mainly women (55%) with mean age of 35 years (SD=15) at PST entry. Most participants were in a relationship (92.145 (52%) and mean number of years education was 9 years (SD=14). 75/145 (52%) of subjects were already parents, reporting a total of 144 children. 21/145 (14%) subjects decided not to have offspring following their positive test result. No child adoption was reported. 27/145 (19%) of subjects reported offspring post-PST: 19/27 (70%) subjects under- went natural reproduction and 8/27 (30%) reproduction with PND or PGD support. A total of 9 offspring non-FAP carriers (with PND/PGD) and 24 offspring from natural reproduction were included in the analysis. The logic on natural reproduction confirms statistical significance (p-value<0.05) for only two variables: being in relationship and having previous children. No statistical significance was observed for PST and number of reproduction years. CONCLUSIONS: There is evidence of a high proportion of carriers of offspring’s when initiate PST and high proportion of natural reproduction within FAP carriers after PST. An ethical physiological case-by-case approach is essential to learn more about the determinants for preventing FAP offspring transmission.

PSY14 TRENDS IN PRESCRIPTION OPIATE USE AMONG PATIENTS WITH COMMERCIAL OR GOVERNMENT SPONSORED HEALTH INSURANCE IN THE US FROM 2010-2013

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OBJECTIVES: To describe the prevalence of outpatient opiate prescription use among patients with Commercial, Medicare Supplemental, or Medicaid insurance in the US after 2010. METHODS: Patients were identified using the TruenHealth (TM) National and Multi-State databases from 2010-2013 and Medical Multi-State databases from 2010-2012. We estimated the proportion of patients with at least one outpatient opiate prescription for each calendar year among patients with continuous medical and pharmacy enrollment for the entire calendar year, stratifying by insurance and age (18-64 and age ≥65). Definitions included: lifetime age, 18-64 and ≥65. Medicare Supplemental adults (65.9 to 68.6 days); days supply per year was steady at 3.77 days. RESULTS: Monthly prevalence dropped by 15.3% among commercially-insured patients from 2010 to 2013 (p<0.001). Among Medicaid adults, opiate prescription prevalence dropped by 12.1% among Medicaid children from 2010 to 2012 (p<0.001) with a similar decrease among Medicare Supplemental adults (65.9 to 68.6 days). prevalence was lower prevalence in 2012 (38.9%) than in 2010 (44.1%) or 2011 (45.2%). CONCLUSIONS: The proportion with opiate prescriptions was modestly increased with the year of the procedure to reach 35% grafted in 2012, corresponding to mean annual mortality rate of around 20%. Among the 16,006 patients diagnosed AML or MDS who were alive during the year 2012. Patients with diagnosis of typical GvHD symptoms (eczematous dermatitis, xerosis, and keratitis) were identified. RESULTS: Since 2006 to 2012, 9,855 patients received allogeneic stem cell transplant in France of which 3,469 died during a hospitalization over the period, with an annual death rate stable around 20%. In 2012, 1,824 ASCT patients aged more than 15 were hospitalized at least once, and the proportion with GVHD was estimated to 40% (1,574). 75/145 (52%) of subjects were already parents, and by 12.1% among Medicaid children from 2010 to 2012 with a similar decrease among Medicare Supplemental adults (65.9 to 68.6 days). Among those patients, 55.2% were male, mean age was 60.4 years, 30% died during a hospital stay and 19% (664) were bone marrow grafted during the year 2012. These patients had 1.8 stays for chemotherapy per year with a mean hospitalization duration of 27 days. Two thirds of these patients (34%) were diagnosed in 2012 and 23% in 2011. CONCLUSIONS: Among the 16,006 patients diagnosed AML or MDS and hospitalized in France in 2012, 1,468 (21%) received intensive chemotherapy inducing neutropenia, putting them at high risk of invasive fungal infection.

PSY16 ACUTE MYELOID LEUKEMIA AND MYELOID-POLYMYELOID CYSTIC SYNDROME TREATED WITH INTENSIVE CHEMOTHERAPY IN FRANCE BASED ON NATIONAL HOSPITAL DATABASES (PMSI)

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OBJECTIVES: To estimate the number of patients with Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS) treated with intensive chemotherapy susceptible to induce neutropenia. METHODS: French hospital databases named PMSI record medical information about all the hospitalizations performed annually in France. From 2006 to 2012, databases allow linking the stays of a given patient with an anonymous number. In this study, PMSI databases were used to identify patient, aged more than 15, with diagnosis of AML or MDS and who were alive during the year 2012. Then, patients who underwent hospitalization more than 5 days were identified and considered as neutropenic according to experts opinions. RESULTS: Since 2006, 51,386 patients with at least one diagnosis of AML or MDS and aged more than 15 were identified. The proportion with GVHD was estimated to 40% (1,574). Treatment with nilotinib is expected to reduce the types of treatment being utilized and care settings using sickness funds of Germany: An Analysis of Sickness Funds (PST). The examination only in a serious illness. All element 149 heads. At the compilation of the questionnaire used Helena (Healthy Lifestyle in Europe by Nutrition in primary schools of Szekszárd, 13-14 year ones among students. Inclusion it was a primary school, that is not enough to identify patients aged more than 15, with diagnostic of AML or MDS and who were alive during the year 2012. Then, patients who underwent hospitalization more than 5 days were identified and considered as neutropenic according to experts opinions. RESULTS: Since 2006, 51,386 patients with at least one diagnosis of AML or MDS and aged more than 15 were identified. The proportion with GVHD was estimated to 40% (1,574). Treatment with nilotinib is expected to reduce the types of treatment being utilized and care settings using sickness funds of Germany: An Analysis of Sickness Funds (PST). The examination only in a serious illness. All element 149 heads. At the compilation of the questionnaire used Helena (Healthy Lifestyle in Europe by Nutrition in primary schools of Szekszárd, 13-14 year ones among students. Inclusion it was a primary school, that is not enough to identify patients aged more than 15, with diagnostic of AML or MDS and who were alive during the year 2012. Then, patients who underwent hospitalization more than 5 days were identified and considered as neutropenic according to experts opinions. RESULTS: Since 2006, 51,386 patients with at least one diagnosis of AML or MDS and aged more than 15 were identified. The proportion with GVHD was estimated to 40% (1,574).
so. RESULTS: Our 1 hypothesis, that the children with normal weight move much, than their obese counterparts, is not proven true (p = 0.078). It was the next supposition, that less are truth with a subject for the students with normal weight they have difficulties, than for the obese students. According to the examination, the normal one and the obese child with a subject truth in the look of difficulty, we found a significant difference (p = 0.002) (Yuva Center for the Study of Drug Development database). RESULTS: A total of 18 drugs under patent protection for non-oncological URDs were identified. Furthermore, 29 drugs for non-oncological URDs under development that have the potential to reach the market by 2021 were found. Total budget impact over 10 years was estimated to be €14,112 and €4,965 million for approved and pipeline URD drugs, respectively (total: €19,077 million). Relative to total pharmaceutical expenditures in Europe, spending on drugs for URDs is estimated to rise from 0.7% at present to 1.6% in 2021. Univariate sensitivity analyses and extreme scenario analyses suggest uncertainty of robustness of this projection will be presented. CONCLUSIONS: Our analysis does not support concerns regarding an uncontrolled growth in expenditures for drugs for URDs. Nevertheless, continuous monitoring of the budget impact as an input to rational policy making is recommended.

**PSY20**

CLINICAL AND COST-EFFECTIVENESS AND BUDGET IMPACT OF ROUTINE USE OF BISECTAL INDEX MONITORS IN THEATRES

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OBJECTIVES: Biseptical Index (BIS) monitoring systems monitor spontaneous electroencephalography, track sedative drug effects and help guide anaesthetic administration. Evidence shows such monitoring enables savings on anaesthesia and reduces adverse events compared with monitoring clinical signs only. However, the cost-effectiveness of monitors is uncertain. METHODS: A cost-effectiveness model and budget impact analysis were developed to compare the outcomes of monitoring the depth of anaesthesia with BIS monitors compared with standard clinical monitoring. Over a five-year period, the model estimated the incremental cost per quality-adjusted life year (QALY) and incremental number of adverse events avoided in theatres with anaesthetists using BIS monitors compared with standard care. Data values were obtained from peer-reviewed literature. Subgroup analysis was conducted for four patient groups. Sensitivity analysis was conducted to explore uncertainty in the model. A budget impact model examined the financial impact of adopting BIS monitors across the UK. RESULTS: The modelled results showed that using BIS monitors dominated clinical observation of signs and use of electrocardiograph and other monitors plus conventional devices only. The budget impact analysis showed a cumulative saving of over £136 million if theatres in the UK adopted a phased increase in monitor use such that 1.35 million surgical procedures were conducted in the first year. Savings of £32.8 million were estimated in the second year, £53.3 million for the 10%, 20% and 30% price discount scenarios, respectively. CONCLUSIONS: The introduction of biosimilar infliximab has been approved byEMA for the management of inflammatory autoimmune disorders including rheumatoid arthritis (RA), ankylosing spondylitis (AS), Crohn’s disease, ulcerative colitis (UC), psoriatic arthritis (PsA), and psoriasis based on quality, safety and efficacy profiles comparable to infliximab. The aim of this study was to evaluate the financial impact of introducing biosimilar infliximab in the management of RA, AS, Crohn’s disease, UC, PsA, and psoriasis from the health care system perspective. METHODS: An Excel-based budget impact model was developed. The numbers of patients eligible for infliximab were calculated based on disease prevalence rates in Germany, Italy, Belgium, the Netherlands and the United Kingdom. The price of biosimilar infliximab is not yet known therefore three discount scenarios versus infliximab (10%, 20%, and 30%) were applied. Market share was assumed to be 25% in the first year and 50% in the second year. Annual market share growth was varied in each of the scenarios at 20%, 30% and 40%, respectively. RESULTS: The total increment budget savings for Germany, Italy, Belgium, the Netherlands and the United Kingdom in the first year was €17.8 and €35.5 million per year. Over a five year period the net budget savings were €132.8, €322.8 and €532.8 million for the 10%, 20% and 30% price discount scenarios, respectively. CONCLUSIONS: The introduction of biosimilar infliximab as a treatment option for patients with RA, AS, Crohn’s disease, UC, PsA, and psoriasis could achieve substantial cost savings for health care systems. In the price discount scenarios tested, the total combined savings across Germany, Italy, Belgium, the Netherlands and the United Kingdom over a 5-year period ranged from €132.8 million to €532.8 million. The net budget impact was highly sensitive to market uptake rates and the price discount applied.

**PSY25**

BUDGET IMPACT ANALYSIS OF OUTDOOR BIFOCAL ILLUMINATOR FOR THE TREATMENT OF AUTO IMMUNE DISORDERS IN FIVE EUROPEAN COUNTRIES

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OBJECTIVES: To estimate the costs of drug supply for registered rare diseases (RD) patients in Russia in 2013. METHODS: The study included two steps: 1) the analysis of the state financing of RD patients in Russia in 2013 and 2) estimating the unmet needs - necessary weighted average costs (nWAC) for a pathogenetic pharmacotherapy of registered patients with RD in the same year. A budget impact model was developed. The numbers of patients eligible for infliximab were calculated based on disease prevalence rates in Germany, Italy, Belgium, the Netherlands and the United Kingdom. The price of biosimilar infliximab is not yet known therefore three discount scenarios versus infliximab (10%, 20%, and 30%) were applied. Market share was assumed to be 25% in the first year and 50% in the second year. Annual market share growth was varied in each of the scenarios at 20%, 30% and 40%, respectively. RESULTS: The combined total budget savings for Germany, Italy, Belgium, the Netherlands and the United Kingdom in the first year was €17.8 and €35.5 million per year. Over a five year period the net budget savings were €132.8, €322.8 and €532.8 million for the 10%, 20% and 30% price discount scenarios, respectively. CONCLUSIONS: The introduction of biosimilar infliximab as a treatment option for patients with RA, AS, Crohn’s disease, UC, PsA, and psoriasis could achieve substantial cost savings for health care systems. In the price discount scenarios tested, the total combined savings across Germany, Italy, Belgium, the Netherlands and the United Kingdom over a 5-year period ranged from €132.8 million to €532.8 million. The net budget impact was highly sensitive to market uptake rates and the price discount applied.

**PSY26**

BUDGET IMPACT ANALYSIS OF BILMBUMAB IN THE TREATMENT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS IN RUSSIAN FEDERATION

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OBJECTIVES: To estimate budget impact analysis (BIA) of belimumab plus standard and SoC alone in the treatment of SLE patients, comparing with current treatment from systemic lupus erythematosus (SLE). METHODS: BIA was conducted of the belimumab treatment plus SoC vs SoC alone. Costs of treatments in both groups contained following direct medical costs: costs of drugs and administration, costs of patient visits, costs of SLE complications and also adverse event costs. A five-year time horizon was used. All costs in both groups were estimated to their present value using a 5% discount rate. Results: The budget impact of belimumab therapy was €1,184,499 RUB/ 45,581 EUR for 5 years but the difference in the required budget funds between belimumab treatment groups and SoC alone treatment group amounted to 8,765,965 RUB/ 40,385 EUR for 5 years with a 5 % discount rate. The decrease of the difference in the required budget funds between these two groups was due to lower
frequency of inpatient visits and pulmonary, cardiovascular, renal and skin complications of SLE in group treated with belimumab. Therefore the use of belimumab led to a reduced difference in the required budget funds from 2,118,449 EUR/54,581 EUR to 1,876,965 RUB/40,385 EUR and the reduction ran as high as 241,484 RUB/5,196 EUR for 5 years. **CONCLUSIONS:** The use of belimumab in the treatment of patients with SLE resulted in budget spending. However, a good safety profile and efficacy of belimumab help to reduce the costs for 241,484 RUB/5,196 EUR for 5 years in belimumab treatment group.

**PSY27**
PUBLIC EXPENDITURE ON AUTHORISED ORPHAN DRUGS IN THE CZECH REPUBLIC BETWEEN 2008 AND 2013

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OBJECTIVES:** The purpose of this study was to determine public expenditure on medicines for rare diseases from the public health sector in the Czech Republic (CZ).

**METHODS:** We identified orphan medicinal products (OMPs) registered by the European Medicines Agency (EMA) until December 2013 in the public database of EMA. In the case of CZ, we considered only within the interval of marketing authorisation date and December 2013 or OMP designation withdrawal date or date of withdrawal of use. Reports on consumption and real expenditures of these OMPs came from all health insurance companies in the CZ. Exchange rate of 25.4 CZK € was used.

**RESULTS:** Overall, 86 OMPs were authorised within the European Union (EU) between 2008 and 2013. Of these, 50 OMPs (58.0%) were covered from the Czech public health insurance at some point within this period. The number of registered OMPs increased from 54 in 2008 to 84 in 2013, while the number of covered OMPs doubled from 24 to 41, respectively. The annual public expenditure on OMPs rose steadily from 43 to 72 million EUR, while the total expenditure on drugs increased from 1.7 to 2.0 billion EUR. The OMP share of total pharmaceutical sales grew steadily from 2.5% in 2008, reaching 3.4% in 2011 and plateaued at 3.6% in 2013. Twenty-one oncological OMPs (51.2%) generated up to 72.6% of the total expenditure on OMPs in 2013. **CONCLUSION:** The public expenditure on OMPs of 3.6% of all drugs seems to be relatively high. The major part of OMP costs is in oncological diagnoses. One of the limitations is the exclusion of designated OMPs not authorised by EMA since these OMPs still might be present on the market and reimbursed. This aspect needs further investigation.

**PSY28**
QUOTENZA® ESTIMATED COSTS PER PATIENT IN PRIMARY vERSUS SECONdARY CARE. A COMPARISON BETWEEN QUOTENZA®, PREGABALIN AND LIDOCAINE FOR THE TREATMENT OF PERIPHERAL NEUROPATHIC PAIN

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**OBJECTIVES:** The objective of this analysis was to estimate and compare the annual cost per patient treated with Quatenza® in Primary and Secondary Care for the treatment of adult patients with peripheral neuropathic pain (PNP). The annual cost per patient treated with Quatenza® was also compared with Pregabalin and Lidocaine in Primary Care. **METHODS:** The costs per patient for each treatment was estimated by analysing health care resources consumed associated with the use of pregabalin, lidocaine and Quatenza®for the treatment of PNP from the perspective of the Spanish National Health System. Healthcare resources associated with pharmacological treatments considered were administration time and health care personnel, complementary non-pharmacological treatment, hospitalisation, adverse effects and concomitant medication, EUR 2013. Total healthcare cost was estimated and compared for both inpatients and outpatients, associated with the three pharmacological treatments considered were administered. The overall treatment public expenditure on OMPs of 3.6% of all drugs seems to be relatively high. The major part of OMP costs is in oncological diagnoses. One of the limitations is the exclusion of designated OMPs not authorised by EMA since these OMPs still might be present on the market and reimbursed. This aspect needs further investigation.

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**PSY29**
QUOTENZA® ESTIMATED COSTS PER PATIENT IN PRIMARY vERSUS SECONdARY CARE. A COMPARISON BETWEEN QUOTENZA®, PREGABALIN AND LIDOCAINE FOR THE TREATMENT OF PERIPHERAL NEUROPATHIC PAIN

Darba J⁎, Egozcue L⁎, Villa G⁎
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**OBJECTIVES:** The objective of this analysis was to estimate and compare the annual cost per patient of the administration of capsaicin 8% patch, Quatenza®, in Primary Care. The costs per patient were estimated at €14,074.14 and €5,387.32 and €5,259.19 when administered in Primary Care.

**RESULTS:** The costs per patient of the administration of capsaicin 8% patch, Quatenza®, in Primary Care was estimated at €14,074.14 and €5,387.32 and €5,259.19 when administered in Primary Care.

**CONCLUSION:** Quatenza® also showed to be the less expensive option in comparison with pregabalin or lidocaine, associated with the three pharmacological treatments considered were administered. The overall treatment cost per patient was €1,876,965 RUB/40,385 EUR and the reduction ran as high as 241,484 RUB/5,196 EUR for 5 years in belimumab treatment group.

**CONCLUSION:** Quatenza® showed to be the less expensive option in comparison with pregabalin or lidocaine, associated with the three pharmacological treatments considered were administered. The overall treatment cost per patient was €1,876,965 RUB/40,385 EUR and the reduction ran as high as 241,484 RUB/5,196 EUR for 5 years in belimumab treatment group.

**CONCLUSION:** Quatenza® also showed to be the less expensive option in comparison with pregabalin or lidocaine, associated with the three pharmacological treatments considered were administered. The overall treatment cost per patient was €1,876,965 RUB/40,385 EUR and the reduction ran as high as 241,484 RUB/5,196 EUR for 5 years in belimumab treatment group.
OBJECTIVES: To assess pill burden, health care resource utilization (HRU), and costs among subpopulations of immediate release (IR) hydrocodone users.

METHODOLOGY: We performed a retrospective analysis of health care claims from 2011-2012 Truven MarketScan® Commercial, Medicare supplemental, and Medicaid Multistate databases. Patients with IR hydrocodone prescription for ≥ 90 days during 6 month baseline period (July 2011-December 2011) with continuous enrollment during baseline and 12 month follow-up periods were selected. The final population was sub-categorized by prescribed coverage days (PCD) of IR hydrocodone during baseline line into 90-119, 120-179, and ≥ 180 days. Claims data from IR hydrocodone users were used to test pill burden, HRU and costs (standardized to 2013 US dollars) during baseline and follow-up periods across subpopulations.

RESULTS: A total of 36,174 commercial, 52,699 Medicaid, and 8,873 Medicare IR hydrocodone users were selected. In the baseline period, subgroups of patients with longer PCD had greater increase in number of inpatient and outpatient HRU, emergency department visits, office visits, and emergency room visits. The subgroup of patients with PCD <120 days had lower annual all-cause medical costs during follow-up compared with baseline (decreasing by $2,624, $2,955, $4,200 per patient per year in Medicaid, Medicare and commercial patients, respectively), while patients with longer PCD during baseline had increased costs (p<0.05). For example, Medicaid patients with 120-179 PCD had an increase of $1,874 and those with ≥ 180 PCD had an increase of $4,348. These trends were similar for all insurance types.

CONCLUSIONS: Extended length of PCD, particularly after 120 days, corresponds with higher patient burden including elevated pill burden and rising HRU and costs in both commercial and public insurance patients with long-term IR hydrocodone use.

PSY34

OPIOID PRESCRIBING AND THE IMPACT OF BRANDED GENERICS

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OBJECTIVES: Opioids are the mainstay of therapy for patients with moderate to severe pain. Mandatory generic substitution exists in South Africa, unless otherwise indicated by the prescriber or if the patient refuses. Few studies have been conducted assessing the prescribing patterns and cost of opioid analogics. METHODS: A retrospective, cross-sectional drug utilisation study was conducted on prescription data of a medical insurance scheme administrator in South Africa for 2011. The database contained 2,298,312 records for medicine, medical devices and procedures. RESULTS: A total of 97,491 analgesics were dispensed to 31,854 patients during the year. Within ATC category N02, opioids (N02A) accounted for 26.55% of analgesic prescriptions at a cost of R1,071,230.14. A total of 9,793 patients were prescribed 25,888 opioid analgesics. The average age of patients was 41.50 (SD=16.61) years. Female patients were slightly younger (average age: 40.69 (SD=17.05) years) than male patients (average age: 42.32 (SD=16.09) years). Nine different active ingredients and two combination products were prescribed. Tramadol, an atypical opioid, was the most often prescribed (68.11%), followed by pethidine the lowest (R8.53). Overall, the average cost for an originator product was R41.38 (SD=1,020,000). A probabilistic sensitivity analysis was carried out to assess the influence of the uncertainty of the variables introduced into the model. All the costs and effects (quality-adjusted survival) have been discounted with an annual rate of 3%, following local recommendations. RESULTS: The observed greater efficacy of tramadol in the trial translates into a gain of 3.03 (unadjusted) and 1.33 (discounted) QALY’s and an additional cost of €102,000. The estimated budgetary impact of using tramadol in 10% to 100% of the potential population would cost €671,000 and €6.7 million respectively. CONCLUSIONS: The ICER of tramadol in South Africa is in the low band (<100) of the ICERs obtained for other orphan drugs and would have a limited, predictable and affordable cost in South Africa.

PSY37

RATES OF DIAGNOSED OPIOID ABUSE OR DEPENDENCE AND INCREMENTAL DIRECT HEALTH CARE COSTS AMONG PATIENTS WITH LONG-TERM USE OF IMMEDIATE RELEASE HYDROCODONE

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OBJECTIVES: To estimate rates of diagnosed abuse and incremental health care costs among long-term immediate release (IR) hydrocodone users.

METHODOLOGY: We performed a retrospective analysis of health care claims from 2011-2012 Truven MarketScan® Commercial and Medicaid Multistate databases. Patients with IR hydrocodone prescription ≥ 90 days during 6 month baseline period (July 2011-December 2011) with continuous enrollment during baseline and 12 month follow-up periods were selected. The final population was sub-categorized by prescribed coverage days (PCD) of IR hydrocodone during baseline line into 90-119, 120-179, and ≥ 180 days. Claims data from IR hydrocodone users were used to test pill burden, HRU and costs (standardized to 2013 US dollars) during baseline and follow-up periods.

RESULTS: A total of 36,174 commercial, 52,699 Medicaid, and 8,873 Medicare IR hydrocodone users were selected. In the baseline period, subgroups of patients with longer PCD had greater increase in number of inpatient and outpatient HRU, emergency department visits, office visits, and emergency room visits. The subgroup of patients with PCD <120 days had lower annual all-cause medical costs during follow-up compared with baseline (decreasing by $2,624, $2,955, $4,200 per patient per year in Medicaid, Medicare and commercial patients, respectively), while patients with longer PCD during baseline had increased costs (p<0.05). For example, Medicaid patients with 120-179 PCD had an increase of $1,874 and those with ≥ 180 PCD had an increase of $4,348. These trends were similar for all insurance types.

CONCLUSIONS: Extended length of PCD, particularly after 120 days, corresponds with higher patient burden including elevated pill burden and rising HRU and costs in both commercial and public insurance patients with long-term IR hydrocodone use.

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and costs (all p<0.05), the adjusted annual incremental costs in abusers versus non-abusers were $28,882 (95% Confidence Interval [CI]: 28,455-29,311) and $15,523 (95% CI: $15,389-$15,675) per patient among Medicaid and commercially insured patients, respectively, during the post-index period. The main cost driver was inpatient hospitalization which comprised 88% of unadjusted incremental costs during follow-up in Medicaid insured and 86% in commercially insured patients. 

CONCLUSIONS: Diagnostic opioid abusers among long-term IR hydrocodone users impose significantly higher financial burden in both Medicaid and commercially insured patients. Uncontrolled patients present at diagnosis with opioid addiction and complications. Costs are those that weigh more on the total expenditure of the NHS with €474.634.836 (95%CI: €300.028.168 - €698.695.090) per year, while the direct health care costs are €745.596 (95%CI: €514.369.29 - €1.263.785) and nonmedical costs are €12,946,879 (95% CI: €7,925,699 - €19,175,331). Patients with more than 16 years spend more than those between 0 and 7 years old, and even more than those between 8 and 15. For what concern the private expenditure, the model estimated per person €2.910.506 (95% CI: €2.454.281 - €3.366.722) for ADD. Direct non medical costs and indirect costs represent the main component of social cost in patients with hypertension and ADD. CONCLUSIONS: Bariatric surgery led to reductions of obesity-related comorbidities. One year after, the economic burden is mainly sustained by patients, their families and the productivity system.

PSY41

COST OF ILLNESS ANALYSIS OF DUCHENNE MUSCLAR DYSTROPHY IN ITALY

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OBJECTIVES: The objective of this study is to estimate the average annual direct and indirect costs associated with Duchenne muscular dystrophy (DMD) in Italy considering both National Health System (NHS) societal perspective. METHODS: A probabilistic prevalence-based cost of illness model was used to estimate the economic burden of DMD. All the costs were determined through a survey that families registered with the Muscular Dystrophy Association “Parent Project onlus” completed on-line. NHS and family prospective has been analyzed separately. RESULTS: The economic burden was higher for ADD. Direct non medical costs and indirect costs represent the main component of social cost in patients with hypertension and ADD. CONCLUSIONS: Bariatric surgery led to reductions of obesity-related comorbidities. One year after, the economic burden is mainly sustained by patients, their families and the productivity system.
OBJECTIVES: The aim of this study was to assess the indirect costs associated with multiple sclerosis from the perspective of Social Insurance Institution (ZUS) in Poland. METHODS: The estimates were based on data from the Social Insurance Institution (ZUS) referring to year 2012 and focused on absenteeism due to the illness: costs of sick leave as well as the short-term disability due to rehabilitation benefit. The number of absence episodes was divided by the number of working days in Poland. Cost analysis was performed based on the Human Capital Approach, taking into account Gross Domestic Product (GDP) per capita equalled 99 697 PLN. Costs were represented in Polish zloty (PLN). RESULTS: Total indirect costs of multiple sclerosis associated with absenteeism in the year 2012 in Poland were 39 870 385 PLN calculated using GDP per capita and 96 018 323 PLN as a GVA per worker. The predominant component of absenteeism of MS was sick leave, which accounted for 69%. Long and short term disability costs constituted 21% and 9% of total indirect costs of multiple sclerosis associated with absenteeism, respectively. One sick leave of person was provided for a period of 15 days generated from the first quarter of year PLN and 4 490 PLN calculated using GDP per capita and GVA per worker, respectively. Indirect cost of short-term disability for one entitlement to the benefit of rehabilitation was 17 077 PLN and 41 125 PLN, respectively. Cost of one long term benefit was estimated at 238 040 PLN and 559 409 PLN, respectively. CONCLUSIONS: Multiple sclerosis in Poland generated very high indirect costs. The main component was sick leave; disability pension and rehabilitation benefit generated lower costs of lost productivity.

PSY44 COSTS OF ABSENTEEISM IN ANKYLOSING SPONDYLITIS BASED ON REAL-LIFE DATA FROM POLAND'S SOCIAL INSURANCE INSTITUTION DATABASE IN 2012 Malinowski K1, Kowalew P2
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OBJECTIVES: The aim of this study was to assess the indirect costs caused by absenteeism associated with ankylosing spondylitis (AS) from the perspective of the Social Insurance Institution (ZUS) in Poland. METHODS: The estimates were based on data provided by ZUS referring to year 2012 and concerning absence from work due to the illness (sick leave), the amount of short term disability, the sufferers of which claimed rehabilitation benefit, and the amount of permanent (or long term) disability, the sufferer of which was characterized by periods of remissions and flares, with significant clinical and economic burden. The primary study objective was to estimate the 1-year direct medical cost for adult patients with active, autoantibody-positive SLE in Greece. Laboratory and imaging tests, medicines, physicians’ visits, and hospitalization costs represented 10.5%, 51.7%, 1.2%, 36.5% of mean cost respectively. Costs were statistically significantly higher for severe SLE patients. The total number of patients visiting health care facilities during 3-month period was 318 (19% with severe SLE). The weighted mean annual direct medical cost of SLE in Greece was estimated at €1,703. CONCLUSIONS: Direct medical cost of SLE in Greece is significant, especially for patients with severe disease. An estimation of indirect costs could provide a comprehensive picture of the societal burden of the disease.

PSY46 DIRECT AND INDIRECT COSTS ASSOCIATED WITH INCREASING BODY MASS INDEX (BMI) IN THE EU Richard L1, Gupta S2, Pomerantz D3, Forsythe A4
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OBJECTIVES: This study evaluated the impact of BMI category on health utilities, health care resource utilization, productivity, activity impairment, and associated costs. METHODS: Data were from the 2013 EUS National Health and Wellness Survey (N=62,000), a nationally representative, online survey of respondents aged ≥ 18 years. This analysis focused on normal weight (BMI<18.5 kg/m2), overweight (BMI=18.5 & <30 kg/m2), obese class (1) (BMI=30 & <35 kg/m2), and (2) (BMI≥35 kg/m2). Overweight and obesity are associated with an increased risk of morbidity and mortality. OBJS: The costs of treatment with romiplostim showed an annual saving of €8,724 for etrombopag in the Brazilian setting. The objective was to perform an economic analysis evaluating the cost per response of romiplostim and eltrombopag. Since these medications have different mode of administration, safety and efficacy profiles, it was of interest to study whether one drug would be more cost-effective than the other. The outcome of these trials was the global response to treatment. The cost of each drug presentation were based on ex-factory price (VAT 18%) and obtained from the official price list (CMED, April, 2014). CONCLUSIONS: Romiplostim was more cost-effective than eltrombopag for the treatment of chronic refractory ITP in adult patients. The average body weight adopted was 74.6 kg. Efficacy data were obtained from the product insert, as well as from scientific publications. In cost per response, it was considered a 6-month analysis, which corresponds to the overall platelet response duration. The outcome of these trials was the global response to treatment. The cost of each drug presentation were based on ex-factory price (VAT 18%) and obtained from the official price list (CMED, April, 2014). CONCLUSIONS: Romiplostim was more cost-effective than eltrombopag for the treatment of chronic refractory ITP in adult patients and may represent a better option in the Brazilian health system.

PSY47 ROmIPLOSTIM COST PER RESPONSE IN ITP TREATMENT IN THE BRAZILIAN HEALTH CARE SYSTEM Pepe C1, Tisch V2, Cassimato-MB3, Almeida S3
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OBJECTIVES: ITP, characterized by isolated thrombocytopenia with or without bleeding, is a manifestation of autoimmune thrombocytopenia caused by antibody-mediated destruction of platelets. Recently, two thrombopoietin receptor agonists have emerged as an important therapeutic options: romiplostim and eltrombopag. The direct costs per response of romiplostim was 26% lower than with eltrombopag. The analysis was performed based on ex-factory price (VAT 18%) and obtained from the official price list (CMED, April, 2014). CONCLUSIONS: Romiplostim was more cost-effective than eltrombopag for the treatment of chronic refractory ITP in adult patients and may represent a better option in the Brazilian health system.
PYS49 CROSS COUNTRY COMPARISON OF MEDICAL RESOURCE UTILISATION IN PATIENTS WITH AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE IN EUROPE
OBJECTIVES: Autosomal dominant polycystic kidney disease (ADPKD) is the most common genetic kidney disease. Currently there is little published information on medical resource utilisation (MRU) in European ADPKD patients. This study aimed to evaluate MRU in patients with ADPKD across six European countries.
METHODS: A retrospective review of medical charts was conducted via an online physician survey in France, Germany, Italy, Spain and the United Kingdom (UK). A total of 353 physicians were recruited to review MRU over the previous 24 month period from the records of 1,055 patients, with each clinician selecting the last three patients representing three different chronic kidney disease stages. Data collected included patient characteristics and MRU such as tests, visits, hospitalisations and medications.
RESULTS: The mean (SD) age of the sample was 47.4 (15.3) years. A total of 80.3% of patients had a known PKD genotype, of which 83% had PKD-1 and 17% had PKD-2.
A total of 1,055 ADPKD patients were enrolled. The mean (SD) age of the sample was 48.6 (12.8) years. A total of 80.3% of patients had a known PKD genotype, of which 83% had PKD-1 and 17% had PKD-2.
OBJECTIVES: To estimate the health care resource use of ADPKD patients across six European countries.
METHODS: An online physician survey in France, Germany, Italy, Spain, Sweden and the United Kingdom (UK) was conducted to collect information on medical resource utilisation (MRU) in patients with ADPKD in Europe. The survey was administered to 20 physicians in France, 20 in Germany, 20 in Italy, 20 in Spain, 20 in Sweden and 20 in the UK. Participating physicians abstracted data for the last three eligible ADPKD patients from their medical records. The survey included questions on visits to specialists and more disease-related hospitalisations, annual health care costs and indirect costs avoided were €94,684 and €7,334, respectively.
RESULTS: The results showed a reduction of the number of bleedings when treating with VWF concentrate almost devoid of FVIII (30 vs 0), minimizing the cost per bleeding episode (€79,957 vs €0), hospitalisations (3.35 vs 2.04), and remaining at 37.5% (30%). Costs for romiplostim were based on vials used, considering a representative Mexican patient (65kg); for eltrombopag, it was based on milligrams needed. Cost assessment included cost of medication, cost of administration and in case of eltrombopag, cost of liver monitoring, expressed in Mexican pesos. Crude Overall Response Rate (ORR) for romiplostim was 83%. Placebo adjusted OR for eltrombopag was 42% calculated by applying the OR estimated from the Bayesian indirect comparison performed by the NICE Evidence Review Group to the Mexican data. RESULTS: Romiplostim generates a cost per overall platelet response of $219,690.80, while eltrombopag yields $374,137.72. CONCLUSIONS: Within the TPO-RAs, romiplostim generates a lower cost per response than eltrombopag, in adult patients with chronic ITP in Mexico.

PYS53 COST-EFFECTIVENESS ANALYSIS OF BELIMUMAB IN THE TREATMENT OF ADULT SYSTEMIC LYMPHOPROLIFERATIVE DISORDERS IN MEXICO
OBJECTIVES: Belimumab is a novel biological treatment specifically developed for the treatment of active, autoantibody positive SLE patients. The purpose of this study is to evaluate the cost-effectiveness of belimumab compared to placebo in adult patients with chronic ITP in Mexico.
METHODS: A cost-effectiveness analysis from the societal perspective was performed using a Markov model. The model was adapted to the Spanish setting. The analysis compared standard of care (SoC) vs. belimumab plus SoC. Costs and outcomes were obtained from the Mexican Institute of Social Security (IMSS) data. RESULTS: The cost per response was $38,799.51. CONCLUSIONS: The model provides results that fall within an acceptable threshold considering the prevalence and the severity of the disease. These results highlight the importance of adopting a societal perspective, especially in pathologies such as SLE which affect young people of working age.

PYS54 COST-EFFECTIVENESS ANALYSIS OF MAINTENANCE TREATMENT WITH RITUXIMAB IN PATIENTS WITH FOLLICULAR LYMPHOMA RESPONDING TO FIRST LINE INDUCTION THERAPY IN PORTUGAL
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OBJECTIVES: Rituximab (RITUXAN®, Biogen Idec/Behringer-Crusell) is a monoclonal antibody that has been approved for use in the maintenance of patients with follicular lymphoma (FL) who achieved a complete response to first-line chemotherapy. The objective of this analysis was to assess the economic impact of rituximab in the long-term follow-up of patients with follicular lymphoma, who achieved a complete response to first-line chemotherapy. RESULTS: The cost per response was 719€. CONCLUSIONS: The results show that rituximab is cost-effective from the Portuguese perspective. From the NHS perspective, the model provides results that fall within an acceptable threshold considering the prevalence and the severity of the disease. These results highlight the importance of adopting a societal perspective, especially in pathologies such as SLE which affect young people of working age.
Years Gained - LYC and cost-utility analysis (Quality-Adjusted Life years - QALYs) were performed for 10 years according to a Markov model with four health states - "progression-free survival (PFS) in first and second lines", "progression" and "death" - and monthly cycles. Health state transition probabilities were obtained from two randomized controlled clinical trials: PRIMA (Salle et al. 2007) and DART (CORRIGED 2008; van Gent et al. 2010). Health state utilities were obtained from literature (Pettengell R. et al. 2008). Resource consumption was estimated by a Portuguese expert's panel. Costs were calculated considering the Portuguese Health System perspective through official data (unit costs: € in 2014). Costs and consequences were discounted at 5% per annum. Deterministic and probabilistic (Monte Carlo simulation) sensitivity analyses were performed for several assumptions namely time horizon, PFS supportive care and progression costs; adverse events costs; health state utilities values and costs and benefits annual discount. RESULTS: For a 10-years time horizon, the cost per LYC and QALY gained was €10,630 and €10,674 respectively. Sensitivity analyses confirmed the base case results. QALYs of 20.39 and 17.15 per QALY gained, respectively. Probabilistic sensitivity analysis confirmed the robustness of the model with a cost per QALY gained of €10,657. The incremental cost-effectiveness acceptability curve shows that rituximab maintenance therapy is highly likely to pay €12,000 per QALY gained. CONCLUSIONS: According to the present model rituximab maintenance treatment of FL patients who respond to first-line induction therapy compared with observation is a cost-effective strategy in Portugal.

PSY55

THE COST-EFFECTIVENESS OF EXPANDING THE NHS NEWBORN BLOODSPOT SCREENING PROGRAMME TO INCLUDE HOMOCYSTINURIA (HCY), MAPLE SYRUP URINE DISEASE (MSUD), GLUTARIC ACIDURIA TYPE 1 (GA1), ISOOVALERIC ACIDEMIA (IVA), AND LONG-CHAIN HYDROXYACYL-COA DEHYDROGENASE DEFICIENCY (LCHADD) in the UK

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OBJECTIVES: To describe the burden of newborn bloodspot screening currently screens all babies in England for five rare conditions. The objective of this study was to assess the cost-effectiveness of expanding the screening programme to include five new rare conditions all inborn errors of the metabolism; HCY, MSUD, GA1, IVA, and LCHADD. METHODS: A decision tree model was estimated to evaluate the cost-effec- tiveness of the expanded newborn screening programme. Estimates of the prevalence of the five conditions and the test characteristics of screening were taken from the literature. Survival and morbidity estimates for the screened and unscreened populations were estimated from published case series. Quality adjusted life years (QALYs) were estimated from the expanded DX-SD+ (C) which includes a cognitive dimension in order to capture the impact of neurological impairment and develop- mental delay measured on the DQ-SD. Known sequelae and known condition treatments were added to the marginal cost of the expanded screening programme, management costs of the conditions, and costs associated with the sequelae of the conditions were estimated from the pilot study of the expanded screening, case reports from the pilot, expert elicitation, published guidelines and estimates from the literature. Costs and QALYs were multiplied by survival and morbidity estimates to give lifetime estimates for the screened and unscreened populations. A probabilistic sensitivity analysis (PSA) was conducted. RESULTS: The results from the deterministic analysis suggest that screening adds costs and QALYs gained. The PSA suggests that screening for all five conditions is cost-saving with screening associated with £0.46 for IVA and £5.94 for GA1. CONCLUSIONS: Screening for HCY, MSUD, GA1, IVA, and LCHADD are each estimated to be potentially cost saving and result in increased quality of life compared to no screening.

PSY56

COST-EFFECTIVENESS OF CAPSAICIN 8% PATCH (QULENZATm) COMPARED WITH PREGABALIN FOR THE TREATMENT OF PATIENTS WITH PERIPHERAL NEUROPATHIC PAIN (PNP) in SCOTLAND

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OBJECTIVES: NPS is a high-burden disease exacerbated by poor tolerability of conven- tional oral therapies. Capsaicin 8% patch versus pregabalin in patients with PNP from the perspective of NHS Scotland. METHODS: A decision tree model was developed considering patients with PNP who had neither achieved pain relief nor tolerated conventional first-/second-line treatments. After 8 weeks' treatment with capsaicin 8% patch or pregabalin, patients remained on therapy or discontinued due to intolerable adverse events. Patients continuing on therapy were classified as either responders (≥30% decrease in pain from baseline) or non-responders. Last-line therapy was given to non-responders and those who discontinued treatment. The base-case time horizon was 2 years. Effectiveness, discontinuations and quality of life utilities were estimated from a recent head-to-head randomized controlled trial comparing both treatments. Costs and outcomes beyond the time horizon of the available trial data and to allow for the cost of managing complications were extrapolated. Cost-effectiveness was measured as cost per QALY gained. A total of 15,000 patients were simulated with 1% of the population being non-responders. RESULTS: Compared with pregabalin, capsaicin 8% patch was dominant versus pregabalin (total cost difference, -£11 and total QALY gains, +0.049). Using a 1-year time horizon, the ICER increased to £1,240/QALY. The model was most sensitive to variations in time to capsaicin 8% patch retreatment (worst case ICER, £7,951/QALY). Capsaicin 8% patch was dominant in six/seven scenario analyses. At a willingness-to-pay threshold of £20,000/QALY gained, the probability of cost-effectiveness for capsaicin 8% patch versus pregabalin was 97%. CONCLUSIONS: Capsaicin 8% patch is cost-effective compared to pregabalin for patients who have failed one or more previous systemic treatments for PNP.

PSY57

COST-EFFECTIVENESS ANALYSIS EVALUATING FACTOR VIII AS PRIMARY PROPHYLAXIS TREATMENT FOR PATIENTS WITH SEVERE HAEMOPHILIA IN THE NETHERLANDS

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COST EFFECTIVENESS ANALYSIS EVALUATING FACTOR VIII AS PRIMARY PROPHYLAXIS TREATMENT FOR PATIENTS WITH SEVERE HAEMOPHILIA A IN THE NETHERLANDS

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OBJECTIVES: Multiple regimens are used in the treatment of severe haemophilia A in the Netherlands. Most patients receive clotting factors intravenously 2-3 times weekly to prevent bleedings: intermediate dose prophylaxis. Given the high utili- zation of prophylaxis treatment, reimbursement restrictions might hinder the availability of prophylaxis for patients in the nearby future. Other treatment regimens are on-demand (OD) treatment, administering clotting factors in case of bleedings, and prophylaxis treatment with a switch to OD at 18 years. This analysis estimates the marginal cost of the expanded screening programme, management costs of the conditions, and costs associated with the sequelae of the conditions were estimated from the literature. Survival and morbidity estimates for the screened and unscreened populations were estimated from published case series. Quality adjusted life-years (QALYs gained). Model assumptions were tested with scenario analyses. RESULTS: Compared with pregabalin, capsaicin 8% patch was cost-effective at a threshold of €25,000 per QALY gained. CONCLUSIONS: Capsaicin 8% patch is cost-effective compared to pregabalin for patients who have failed one or more previous systemic treatments for PNP.

PSY58

COST-EFFECTIVENESS OF THE LIDOCAINE 5% MEDICATED PLASTER VERSUS PREGABALIN AND AMITRIPTYLINE FOR THE TREATMENT OF POST-HERPETIC NEURALGIA IN THE NETHERLANDS

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OBJECTIVES: The object of the analysis was to evaluate costs and outcomes of treating post-herpetic neuralgia (PHN), a chronic disease with severe burden for patients, in the Netherlands with lidoceaine 5% medicated plaster compared to pregabalin and amitriptyline. METHODS: A Markov model was used to extrapolate outcomes beyond the time horizon of the available trial data and to allow for the fact that patients may discontinue treatment at any point during treatment. Costs and effects, expressed in terms of the quality-adjusted life-year (QALY) gained, were estimated for each treatment over a period of up to 2 years. The study included direct costs related to PHN. Indirect costs were not included as most patients with PHN are older and retired. Transition probabilities were based on the comparative and long-term clinical trials. Utilities were derived through a stated preference exercise. Resource utilization was based on the results from a two-step Delphi study with pain specialists. Cost data were obtained from the official price tariffs/lists. Extensive sensitivity and scenario analyses were performed to explore robustness of the results. RESULTS: In 6-month time horizon, treatment with the lidocaine plaster yielded 0.4283 QALY’s. For pregabalin and amitriptyline the total effect was 0.3390 QALYs. The mean costs per patient treated with lidoceaine plaster (1.71 plasters/day) was 1,082 €. For pregabalin (488 mg/day) and amitriptyline (25 mg/day) the mean costs were 912 € and 346 €, respectively. Therefore, the lidoceaine plaster compared to pregabalin and amitriptyline had an incremental cost-effectiveness ratio of 1,907 €/QALY and 8,246 €/QALY, respectively. Probability of the lidoceaine plaster being cost-effective versus pregabalin and amitriptyline exceeded 99% when considering a threshold of 30,000 € per QALY gained. Extensive scenario and one-way sensitivity analyses confirmed robustness of the results. CONCLUSIONS: The lidoceaine 5% plaster is a highly cost-effective treatment for PHN in the Netherlands.
strength of the analysis, deterministic and probabilistic sensitivity tests were performed, which were expressed in the Spanish Health Systems Model (SHSM). Both groups lose weight and reduce their BMI. However, these changes were earlier and more pronounced in the DeP+Da group. DeP+Da presented a significantly higher percentage of patients reducing 10% of their initial weight (3% vs 17%, p = 0.05). In general, cost was $1,655.09, and incremental cost-effectiveness ratio (ICER) of DeP+Da compared to a treatment for obesity in Mexico. CONCLUSIONS: The combination of DeP+Da provides a cost-effective improvement to the treatment of patients with a risk profile for obesity in Mexico.

PSYS6
COST-EFFECTIVENESS ANALYSIS OF OXYCODONE LP AN OPIOID ANALGESIC FOR PATIENTS WITH MODERATE TO SEVERE PAIN SECONDARY TO CANCER IN MEXICO
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OBJECTIVES: To perform a complete economic evaluation type using oxycodone (Endocodi XR®) versus morphine, buprenorphine (transdermal patches) and fentanyl (transdermal patches) on moderate to severe pain secondary to cancer type in Mexico, from the point of view of public health. METHODS: A cost-effectiveness analysis was made, a decision tree model was developed to simulate the costs and benefits of health outcomes of each opioid analgesic, the probabilities were obtained through external evidence. The model has 13 cycles of 28 days under a time horizon of 364 days, the main measure of effectiveness was determined as days without severe adverse events and pain controlled, only measured direct medical costs and the ratio was obtained incremental cost-effectiveness ratio (ICER) further a deterministic sensitivity analysis, probabilistic sensitivity analysis and budget impact was performed. RESULTS: The results demonstrate that oxycodone (Endocodi XR®) versus morphine, buprenorphine (transdermal patches) and fentanyl (transdermal patches) show a higher percentage of patients reducing 10% of their initial weight (37% vs 17%, p = 0.001). Transition probabilities for each 1-month cycle, utilities and direct health care costs were used to recreate patient events during INF-treatment. When eltrombopag was used to recreate patient events during INF-treatment with eltrombopag, 75% to 125 %, the ICER for a one LYG do not exceed the threshold of willingness to pay in the Russian Federation equal 38390 USD. One-way sensitivity analysis showed that the model was most sensitive to variations in the drug doses/ percentage of utilization and costs (romiplostim, eltrombopag and intravenous immunoglobulin) and to the utility of patients responding to ITP treatments. In the combined population the probabilistic sensitivity analysis showed that romiplostim is likely to be cost-effective in 66% and 84% of samples versus eltrombopag and SoC at a willingness-to-pay threshold of 50,000 QALY and 80,000 QALY respectively. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment.

PSYS5
COMPARATIVE PHARMACOECONOMIC ANALYSIS OF THE APPLICATION OF POSACONAZOLE, FLUCONAZOLE AND ITRACONAZOLE IN PATIENTS WITH NEUTOPENIA DURING CHEMOTHERAPY FOR ACUTE MYELOGENOUS LEUKAEMIA OR MYELODYSPLASTIC SYNDROME
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OBJECTIVES: To perform a comparative pharmacoeconomic analysis of alternative schemes of prophylactic and preemptive invasive mycosis treatment for patients with neutropenia in patients with neutropenia, after chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome. METHODS: We reviewed research on the clinical effectiveness and safety of use of posaconazole. Assess of the quality of research and level of evidence obtained in these results was performed. The model is constructed on the basis of the results of a multicenter randomized trial Cornelj O. A. et al., 2007. The model calculated the differences in direct medical costs for the use of drugs, as well as the costs of medical treatment cases invasive mycosis the ineffectiveness of primary prevention. The duration of preventive treatment, the probability of various outcomes correspond to the data of specified clinical study. RESULTS: Analysis of the evidence has shown that on patients with neutropenia antifungal prophylaxis with posaconazole is more effective than fluconazole/itraconazole, and significantly reduces the risk of developing invasive mycosis, and associated mortality. Total costs for the use of posaconazole was $3169 USD, that by 24.6 % higher than the use of fluconazole (total costs $992 USD) and 24.3 % higher than iraconazole (total costs $966 USD). Also use of posaconazole has increased the total number of LGY by 6%. The ICER was $21339 USD and 21171 USD compared to fluconazole and iraconazole, and lower than the existing threshold of willingness to pay in the Russian Federation equal 38390 USD. One-way sensitivity analysis showed that in case of changes in the cost of posaconazole from 75% to 125 %, the ICER remains constant and a one LGY do not exceed the threshold of willingness to pay. CONCLUSIONS: Use of posaconazole for prevention of invasive mycosis in patients with neutropenia is economically justified.

PSYS4
BELIMUMAB FOR THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN GREECE: A COST-EFFECTIVENESS AND COST-UTILITY ANALYSIS
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OBJECTIVES: Systemic Lupus Erythematosus (SLE) is a chronic autoimmune inflammatory disease, associated with significant health and socioeconomic burden. Current treatment of SLE involves glucocorticoids, antimalarials, non-steroid anti-inflammatory drugs, and immunosuppressive agents. Belimumab, a human IgG monoclonal antibody specific for soluble human B lymphocyte stimulator protein, is a novel pharmaceutical treatment approved as an add-on therapy in adult SLE patients with highly active disease (autoantibody-positive and low complement levels) despite treatment. The study objective was to estimate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of adding belimumab to the Standard-of-Care (SoC) treatment of SLE patients with high disease activity in the Greek health care setting. METHODS: The analysis is based on the local adaptation of a micro-simulation model. The model follows individual patients over a lifetime period. Data on short-term outcomes were sourced from two randomized controlled trials (BLISS 72/7614). Long-term outcomes were estimated via natural history models developed on the basis of data from the John Hopkins cohort of SLE patients. Direct medical costs of both the study and comparator arms were identified through a literature review. Results were discounted at 3.5% for both costs and effects. The study was performed from the perspective of the health care payer. RESULTS: Treatment with belimumab +SoC resulted in 0.81 added life years (LYG) and 377 QALYs at a cost of 30,000 €/LYG (Life-Year Gained) and 27,254/ QALY. CONCLUSIONS: Cost-effectiveness and cost-utility ratios of belimumab compared to SoC treatment are below internationally applied thresholds. Belimumab can be considered as an add-on therapy to SoC for the treatment of SLE patients with highly active disease in Greece.
COST-UTILITY ANALYSIS OF BOSUTINIB FOR PREVIOUSLY TREATED CHRONIC MYELOID LEUKAEMIA (CML) IN PORTUGAL

OBJECTIVES: To assess the incremental cost-utility ratio (ICU) of bosutinib for CML as a third-line (3L) treatment for chronic phase (CP) Philadelphia chromosome-positive (Ph) patients in Portugal compared to hydroxyurea, in the societal perspective. METHODS: A survival analysis model was adapted to the Portuguese setting. Bosutinib overall survival was based on Study 200, an open-label phase II/IIi single-arm study of Ph+ CML patients. Overall survival with hydroxyurea was described inpersonal observations. Costs were based on Portuguese official sources. Utility values were adapted from the IRIS study. A 5% discount rate was applied to both costs and consequences on a 50-year time horizon. RESULTS: The use of bosutinib allows an increase of 4.1 life years (LY) and 3.5 quality adjusted life years (QALY), being associated to an additional cost of 88,319€. Consequently, cost per LY is 21,465€ and cost per QALY is 25,252€. Sensitivity analysis shows that results are mainly driven by survival time gained with bosutinib. CONCLUSIONS: Bosutinib for CML 3L treatment for CP patients in Portugal represents a substantial added benefit relative to hydroxyurea although with added costs per LY and per QALY. These ratios are generally accepted in Portugal, both below 30,000€ willingness to pay threshold.

COST EFFECTIVENESS OF PROTHROMBIN COMPLEX CONCENTRATE (APCC) VS. RECOMBINANT FACTOR VIIA (rFVIIa) FOR HEMOPHILIA PATIENTS WITH INHIBITORS

OBJECTIVES: To assess the cost-effectiveness of romiplostim in the treatment of adult patients with ITP in the Czech Republic, in comparison with the medical standard of care (SoC) and etrombopag. METHODS: A lifetime treatment sequel in a cost-utility model was developed from the health care payer perspective. The model was based on the treatment sequel that reflects current practice for ITP management and was driven by platelet response (platelet count >50x10^9/L), which determined effectiveness and progression along the treatment pathway, need for rescue therapy and risk of bleeding. Costs were derived from reimbursement lists available in January 2013. Four scenarios were conducted: where concomitant was compared with SoC with rituximab, SoC without rituximab, and with etrombopag and with rituximab and mycophenolate mofetil (MMF), and etrombopag. Patients were evaluated by splenectomy status and for the combined population (CP). RESULTS: Compared to SoC with rituximab, romiplostim was dominant in splenectomised patients and CP, and with cost savings of 2,203,662CZK and 1,078,899CZK and gains of 1.58 and 1.81 quality-adjusted life-years (QALYs), respectively, and was cost-effective in non-splenectomised patients with an ICER of 44,107CZK/QALY. Compared to etrombopag, romiplostim was dominant in splenectomised patients and CP, with cost savings of 1,626,409CZK and 741,613CZK and gains of 1.12 and 1.21 QALYs, respectively, and was cost-effective in non-splenectomised patients with an ICER of 74,266CZK/QALY. Similar results were shown for the other two scenarios: romiplostim was dominant in splenectomised patients and CP compared to SoC without rituximab and SoC without both rituximab and MMF, and was cost-effective in non-splenectomised patients with ICERs of 51,920CZK/QALY without rituximab and 149,216CZK/QALY (SoC without rituximab and MMF). CONCLUSIONS: Romiplostim was cost-effective compared with higher costs gain compared to SoC and etrombopag in splenectomised patients and CP. Romiplostim was cost-effective with ICERS between 41,000 and 74,000CZK/QALY in all non-splenectomised populations in all four scenarios.
PSY71 REAL-WORLD COST-UTILITY EVALUATION OF MULTIPLE MYELOMA TREATMENTS IN STEM CELL TRANSPLANTED PATIENTS
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OBJECTIVES: multiple myeloma (MM) is an incurable disease with an incidence of 4-7 new cases by 100,000 people. In the setting of the study, 28% of the yearly 25 new cases of MM are candidates to autologous stem cell transplant (ASCT). In this context, economic evaluations are needed to assess the cost per quality-adjusted-life-year (QALY) of the MM treatment in a group of transplanted patients. METHODS: an observational retrospective study was performed and included detailed clinical cohort of patients with MM. All patients received bortezomib based treatments. Costs were evaluated from the payer’s perspective and included total drug costs and hospital admission costs. QALY’s values were obtained from the CEA Registry of Tufts University. Four health states were considered: complete response (CR), partial response, stability and progressive disease. Time between state transitions were used to calculate QALY’s for each patient. RESULTS: the study included 17 patients with a mean age of 61,2±7.9 years. All patients received ASCT. A global complete response rate one year after ASCT was 8/17 (47.0%) and dropped to 5/12 (41.6%) at two years. For the whole cohort the median of QALY’s cost was 48.5±12.3. Using ASCET the median of QALY’s cost was 46.358 (IQR range 39.697-57.3). For all other patients the median of QALY’s cost was 56.676 (IQR range 39.114-73.613). For Group 1 patients, the median of QALY’S cost was 51.278 (IQR range 36.345-73.613). CONCLUSIONS: these results mean that the actual costs of MM treatment using an analysis that include bortezomib are above the 30.000-50.000 threshold generally admitted in cost-effectiveness studies.

PSY72 ORPHAN DRUG PRICING IN FRANCE: INFLUENCE OF MAIN FACTORS
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OBJECTIVES: Orphan drugs (OD) require considerable expenditures, which causes difficulties in their market access. For several years, the price of these new therapies has often been underestimated and considered as too high. However few studies about OD pricing mechanisms are available. The aim of the paper is to highlight the main factors that influence OD pricing in France. METHODS: We collected public prices of 37 products designated as OD and approved by the European Medicines Agency until January 2014. Given that an OD can have several indications, our database contains 49 observations. For each observation, we calculated the ex-factory price without tax (defined per daily dose) defined by summary products characteristics. We also determined the characteristics of OD products: indications, price, clinical benefit (CAB), clinical actual benefit (ACB), number of OD indications, number of comparators drugs, number of competing orphan drugs, therapeutic use, target population, inclusion on the list of medicines reimbursed by National Health Insurance, at least 3 months of treatment. We studied the relationships of OD prices. RESULTS: The distribution of OD prices is very heterogeneous, with a minimum of 2.34 euros and a maximum of 2882.08 euros. The average (SD) price is 380.67 euros per year. Our main results are that OD prices are 2.64 times lower for OD that do not improve actual clinical benefit (p=0.01), for OD with only one orphan indication (p=0.047), and for OD with a high target population (p=0.000). CONCLUSIONS: There is a need to understand OD pricing mechanisms. Our study shows that innovation and research efforts are more effective in improving adherence than either informational or behavioral strategies alone. This in turn may improve patient outcomes.

PSY73 EVALUATION OF USE OF BELIMUMAB IN CLINICAL PRACTICE SETTINGS
(OBSERVE STUDY) IN SPAIN: HEALTH RESOURCE UTILIZATION AND LABOUR ABSENTEEISM
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OBJECTIVES: to analyze the health resource utilization (HERU) and labor absenteeism (LA) in Systemic Lupus Erythematosus (SLE) patients treated with belimumab in their daily practice. METHODS: OBSERVE (Observatorio Español de Realización de Estudios de Eficacia) is a Spanish naturalistic observational medical chart-review study. Twenty-five rheumatologists from Spanish hospitals with >10 SLE patients annually and >5 years of practice experience identified adult SLE patients who had received 6-months of belimumab treatment in the 6-months pre- and 6-months post-index periods physicians assessed: demographics, comorbidities, SLE disease characteristics, treatment clinical outcomes, HERU and LA data. Index-date is the date of the first infusion. OBSERVE primary endpoint was overall clinical response per rheumatologist judgment. Statistical analyses included: tests for paired-samples (parametric/ non-parametric). Two-way P-values 0.05 were considered statistically significant. RESULTS: A total of 64 patients were eligible for analysis (mean age 47±12 years, female 96%, hypertension 70% and high anti-dsDNA 69%. After receiving 6-months therapy, 72%, 52% & 27% of patients presented an overall clinical improvement of >20%, >50% and >80%. These improvements were observed in advanced patients with a history of SLE exacerbations. The percentage of 75% of patients on steroids at belimumab-initiation decreased mean dose from 14.8 to 6.8mg/day; p<0.001 and HRU between the pre/post index periods: emergency-room visits 1.65 to 0.41; p<0.001, unscheduled visits to treating physician 1.02 to 0.03; p<0.001, visits to other specialists (1.64 to 1.06; p=0.017) and antibody tests (7.7 to 7.53; p=0.47). An increase in HRU was observed for hematological and renal tests (3.14 to 5.52; p=0.045) and (5.9 to 6.59; p=0.024), respectively. Working patients (39%) showed improvement in the LA days between the pre/post index periods (25.6 to 5.7 days; p=0.025). CONCLUSIONS: Belimumab treatment yielded improved clinical outcomes and a reduction in HRU directly related with SLE management, as corticoid use. Mean number of LA days also showed a substantial reduction, especially important in SLE, mostly affecting young patients.

PSY74 IMPACT OF PATIENT PROGRAMS ON ADHERENCE IN INFLAMMATION AND IMMUNOLOGY: A GLOBAL SYSTEMATIC REVIEW AND META-ANALYSIS OF PUBLISHED EVIDENCE
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OBJECTIVES: Patient adherence is important for successful treatment in chronic conditions, including inflammation and immunology (I&I) diseases, to improve patient’s outcomes and reduce treatment costs. Fragmented and inconsistent adherence strategies (ES) may be impeding the optimal use of ES. CONCLUSIONS: adherence strategy (OR 1.33, 95% CI = 1.23 - 1.44, P < 0.0001) or only an informational strategy (OR 2.16, 95% CI = 1.36 - 3.44, P = 0.001). CONCLUSIONS: Patient programs and interventions can significantly improve adherence in I&I diseases as compared to standard of care or no intervention. Programs employing a multimodal approach are more effective in improving adherence than either informational or behavioral strategies alone. This in turn may improve patient outcomes.

PSY75 ADHERENCE TO ANTICOAGULANT THERAPY IN CHILDREN HOSPITALIZED FOR PULMONARY EMBOLISM AND DEEP VEIN THROMBOSIS
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OBJECTIVES: The American College of Chest Physicians Guideline recommends anticoagulants for at least three months in children with venous thromboembolism. The objectives of the study were to evaluate the medication utilization patterns, and the predictors of adherence to anticoagulant therapy in the pediatric population. METHODS: Texas Medicaid medical and prescription claims from June 01, 2007 to September 31, 2012 were extracted for children (<18 years) hospitalized for Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT). The index date was defined as the date of the first prescription of an anticoagulant warfarin (oral) and/ or enoxaparin (injectable) given within 14 days after discharge from hospitalization. Patients hospitalized for atrial fibrillation, air/fat embolism, bleeding/coagulation disorder within 90 days of discharge were excluded. Proportion of days covered (PDC);80% vs. <80% was used to assess adherence to anticoagulants while controlling for demographics, cause of hospitalization, history of NSAID use, anticoagulant use, malignancy, drug type, and Charlson comorbidity index (CCI). A multivariate logistic regression analysis was used. RESULTS: For warfarin (n=57), we had a mean (SD) age of 14.1 (±4.9) years, were primarily female (54.4%), African American (61.4%), enoxaparin users (54.4%), and had a mean (SD) CCI of 19.7 (±9.4). The mean (SD) adherence rates for warfarin and enoxaparin were 85.6% (±23% and 78.2% (±22%), respectively. 66.6% were adherent (PDC≥80%) to anticoagulant therapy. The median (MeansD) persistence with anticoagulant therapy was 84.6 (71.9x±3.3) days. Logistic regression showed that increasing age was significantly associated with adherence to anticoagulant therapy (Odds Ratio=1.3, 95% CI 1.05-1.62) after controlling for covariates. CONCLUSIONS: Nearly one third of the pediatric patients on anticoagulant therapy after discharge from hospitalization were non-adherent. Further research is needed to underline the factors responsible for non-adherence in pediatric patients.

PSY76 NEW OBSERVER-REPORTED OUTCOMES TO MEASURE TREATMENT SATISFACTION, COMPLIANCE, PALTABILITY, AND GI SYMPTOMS FOR PATIENTS NEEDING IRON-CHELATION THERAPY
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OBJECTIVES: Adherence to iron chelation therapy (ICT) is essential for patients with transfusion-dependent anemia (TDA) (e.g., sickle cell disease [SCD] and thalassemia) for transfusion prevention and minimize related sequelae. Adherence has been noted as especially problematic for children and adolescents. In order to measure compliance and treatment satisfaction in young children, the Satisfaction with Iron Chelation (SIC) (instrument initially developed for use by caregivers of adolescents) was modified to be an observer-reported outcome (ObsRO) measure to be administered electronically to caregivers. In addition, three other ObsROs were developed measuring compliance, palatability, and gastrointestinal (GI) symptoms related to treatment benefit of a new ICT formulation.

METHODS: Subjects included 10 caregivers of children with TDA. Informed consent was obtained. ‘Two sets of face-to-face cognitive interviews were conducted iteratively with modifications to items and further debriefing of modifications. Interviews began with an open-ended question to elicit caregivers’ and their reports of their child’s experiences with ICT. Interviews were audio recorded and transcribed. Data were analyzed using ATLAS.ti software.

RESULTS: Three interviewers conducted 10 caregiver interviews in 6 US cities. Caregivers were 90% female aged 35–65 (mean = 48). Children of caregivers included those with SCD (80%) and thalassemia (20%) and were 60% female, aged 2–17 (mean = 9). Responses to the open-ended question confirmed several concepts in the modified SICt, and the need for new questions and antinuclear antibodies included those with SCD (80%) and thalassemia (20%) and were 60% female, aged 2–17 (mean = 9). Responses to the open-ended question confirmed several concepts in the modified SICt and the need for new questions and appropriateness options. CONCLUSIONS: Evidence supports the content validation of the modified SICt; Compliance, Palatability, and GI Symptom Diary questionnaires. Use in clinical research awaits tests of validity, reliability, and responsiveness.

PV77 IMPACT OF PULMONARY EXACERBATIONS ON EQ-SD MEASURES IN PATIENTS WITH CYSTIC FIBROSIS

Background: The impact of pulmonary exacerbations (PEs) in patients with cystic fibrosis (CF) have not previously been assessed using validated health-related quality of life (HRQoL) measures. This study aimed to examine the impact of PEs on EQ-SD measures in CF using trial-based data.

Methods: In a 48-week randomized, placebo-controlled study of ivacaftor in patients with advanced CF (NCT01177812), the EQ-5D (45) was collected in the 8-week post-PE exacerbation periods after pooling observations across study treatments and visits. RESULTS: A total of 146 PE were examined by 72 (44.7% of total 161) patients, including 59 (35.6%) PEs that required hospitalization. Mean ±SD 30.9 ±2.2 days for PE days PE requiring hospitalization (n=48) and 20.6 ±11.6 days for those not requiring hospitalization (n=89) (P=0.001). For PE requiring hospitalization, mean (SD) EQ-5D index/VAS scores within 1-8 weeks prior to PE start, and 0.90 ±0.13 (p =0.039). Correlation of MCD-SS total score with conceptual model variables (r =0.48) was a value that explained, with graphically or narrative form, the main things to be studied - the key factors, concepts and variables – and the presumed relationships between them. This research aimed to develop a qualitatively-derived, patient-centred, conceptual model of SSc. METHODS: To identify patient-reported SSc symptoms and impacts, we reviewed qualitative literature (published since 2000 to limit the search) in which experiences of living/coping with SSc are described. We also reviewed social media blogs/forums to identify additional concepts and provide supporting quotes. Concepts were identified by independent researchers who collaboratively developed the model. RESULTS: Twelve qualitative studies and 150 social media posts were reviewed. The review identified 56 symptom concepts, which were categorised into 13 domains (peripheral, cognitive, pain, neurological, cardiorespiratory, ophthalmological, gastrointestinal, fatigue, nausea, weight, cardiovascular, depression, and impact aspects). One key concept was identified with high morbid and a significant effect on patients’ health-related quality of life. Quantitative insights can enrich context to the patients’ experience of a symptom so that it is more meaningful. We developed a conceptual model that explains, with graphically or narrative form, the main things to be studied - the key factors, concepts and variables – and the presumed relationships between them. A conceptual model of SSc exists. The conceptual model of SSc exists. This research aimed to develop a qualitatively-derived, patient-centred, conceptual model of SSc. METHODS: To identify patient-reported SSc symptoms and impacts, we reviewed qualitative literature (published since 2000 to limit the search) in which experiences of living/coping with SSc are described. We also reviewed social media blogs/forums to identify additional concepts and provide supporting quotes. Concepts were identified by independent researchers who collaboratively developed the model. RESULTS: Twelve qualitative studies and 150 social media posts were reviewed. The review identified 56 symptom concepts, which were categorised into 13 domains (peripheral, cognitive, pain, neurological, cardiorespiratory, ophthalmological, gastrointestinal, fatigue, nausea, weight, cardiovascular, depression, and impact aspects). One key concept was identified with high morbid and a significant effect on patients’ health-related quality of life. Quantitative insights can enrich context to the patients’ experience of a symptom so that it is more meaningful. We developed a conceptual model that explains, with graphically or narrative form, the main things to be studied - the key factors, concepts and variables – and the presumed relationships between them. A conceptual model of SSc exists. The conceptual model of SSc exists.
observational study. It was conducted from September 2011 to December 2012 and included a total of 1,109 patients who were scheduled for lumbar spinal surgery from 44 spinal centers (both orthopaedic surgery and neurosurgeons). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANS5) pain scale criteria were ≥12 points. The patients were investigated to assess their pain using the pressure pain threshold (PPT) of life using EuroQol (EQ)-5D at baseline, after 1 week and 3 months of the surgery.

RESULTS: Among 1,109 patients, at baseline, NP was identified in 404 (36%) patients. At week 1 and 3 months of surgery, NP was found in 8.6% and 4.0% patients respectively. Among the 705 patients without NP preoperatively, the prevalence of de novo NP occurred in the 1 week and 3 months of post-surgery was 3.1% and 2.3% respectively. At baseline, NP patients showed lower Qol compared with the NP patients (0.49 vs 0.53 p<0.01). However, NP patients improved more their Qol compared to non-NP patients after 3 months (0.86 vs 0.84 p=0.029). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved significantly on the EMQ. Conclusions: The study showed that NP was not observed in female 880 (88%) as compared to female 120 (12%). A rapid fall in white blood cells count (WBC) was observed in initial CBC reports at start of disease then in 3 months. The percentage of PRO claims was 3% in total, 55 patients (306 individuals, ages 9-45 years; 253 parents, ages 24-66 years) were included in the analysis. Return rate and quality of completion of the questionnaires were good, indicating good acceptability. Scores were defined to assess all relevant aspects of patients' experiences: FKU symptoms, impact of FKU, dietary protein restriction and supplementation. Reliability and validity were satisfactory overall for the adolescent, adult and parent FKU-QoL questionnaires, and slightly weaker but acceptable for the child version. Conclusions: The four FKU-QOL questionnaires are valid and reliable instruments for assessing the specific quality of life aspects that are affected in individuals with FKU of different age groups (children, adolescents and adults) and their parents, and are available in seven languages. They are very promising tools for focused evaluation of FKU impact on individuals and parents in different countries, and for monitoring the efficacy of therapeutic strategies.

PSY83 IMPACTS OF LOWER BACK PAIN: REFINE THE PAIN ASSESSMENT FOR LOWER BACK-IMPAISSERTS QUESTIONNAIRE (PAL-I) USING A MIXED METHODS APPROACH Buschell DM2, McCarron KP1, Ramasamy A4, Liedgren H3, Blum St4, Cano S5, Martin ML, Patrick DL1
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OBJECTIVES: The Pain Assessment for Lower Back Symptoms (PAL-S) is a Patient Reported Outcome (PRO) instrument being developed to assess the key symptoms of chronic low back pain (cLBP). Qualitative development included both concept elicitation and cognitive interviewing. As part of the mixed-methods instrument, we further evaluated and refined the PAL-S using a mixed methods approach.

METHODS: Adults self-reporting a clinical diagnosis of cLBP were recruited from an existing US-based commercial survey panel to participate in a pilot PREL-I qualitative study. Qualifying participants completed a web-based survey consisting of the 14-item PAL-S and items assessing clinical, treatment, and demographic characteristics. Data was analyzed to assess item- and scale-level performance of the PAL-S using Rasch Measurement Theory analyses. Following analysis and modification, two waves of cognitive interviews were conducted to evaluate respondent understanding of the revised PAL-S.

RESULTS: The dataset included 598 respondents (mean age: 55±12.6, 67% female, 88.0% white, and 54.0% married) who had cLBP for mean of 15.2±11.5 years. The Rasch analyses item performance of the revised instrument, we further evaluated and refined the PAL-S using a mixed methods approach. The Pain Assessment for Lower Back Symptoms (PAL-S) is a Patient Reported Outcome (PRO) instrument being developed to assess the key symptoms of chronic low back pain (cLBP). Qualitative development included both concept elicitation and cognitive interviewing. As part of the mixed-methods instrument, we further evaluated and refined the PAL-S using a mixed methods approach. The revised instrument, we further evaluated and refined the PAL-S using a mixed methods approach. The mixed-methods approach proved valuable in the development of the PAL-S using Rasch Measurement Theory analyses. Following analysis and modification, two waves of cognitive interviews were conducted to evaluate respondent understanding of the revised PAL-S.

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in platelet count. During recovery phase WBC count increased first followed by platelet count after 3-4 days. Among 1000 confirmed confirmed deaths, 812 were considered dengue hemorrhagic fever cases on the basis of clinical finding. In most of these cases (n=812), directly proportional relation was observed between WBC and platelet count. CONCLUSIONS: It was wrongly perceived in common practice that dengue hemorrhagic infection is still present because of low WBC.

In normal even the white blood cells counts is getting better during recovery phase. White blood cells production during recovery phase is a good indicator about recovery of disease rather than focused on platelets counts production.

PSY78 PHYSICIANS’ AND PATIENTS’ PREFERENCES OVER THE ATTRIBUTES OF BIOLOGICAL AGENTS USED IN THE TREATMENT OF RHEUMATIC DISEASES IN SPAIN: A CONJOINT ANALYSIS

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OBJECTIVES: To define the importance values assigned to the attributes of biological agents used in the treatment of rheumatic diseases and patients with rheumatic diseases: rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PA).

METHODOLOGY: Observational, cross-sectional design based on conjoint analysis. RA, AS and PA patients diagnosed at least 2 years prior and currently or previously (≤1 year ago) receiving RA for a minimum of 1 year were consecutively recruited. Rheumatologists with at least 3 year experience on RA patients participated. A literature review and 4 focus groups were undertaken to identify attributes and levels. Scenarios were selected using orthogonal design. Participants ranked 8 scenarios from 1 (most preferred) to 8 (least preferred). Relative importance (RI) of attributes was calculated. Multivariate regression analysis was performed for each attribute. The ideal was: for patients and physicians, respectively, ‘pain relief and improvement of the functional capacity’ (RI=49.1% and 48.9%), ‘risk of adverse events’ (RI=31.8% and 31.5%), ‘administration method’ (RI=10.2% and 11.4%) and ‘time to perceive the need for a new dose’ (RI=19.2%). The ideal attribute to treat rheumatoid arthritis patients should allow pain relief and an improvement of the functional capacity, with a low risk of adverse events, a short time to perceive the need for a new dose and self-administration at home, when possible.

CONCLUSIONS: Although efficacy and safety are key for patients with rheumatic diseases and rheumatologists to make a choice over a BA, the need for a low frequency of administration and the administration method also play an important role as preference attributes for BAs in Spain.

PSY85 PREFERENCES OF SPANISH PATIENTS OVER THE ATTRIBUTES OF BIOLOGICAL AGENTS FOR THE TREATMENT OF RHEUMATIC DISEASES DEPENDING ON THE ADMINISTRATION ROUTE

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OBJECTIVES: To determine the relative importance of attributes assigned to biological agents (BA) to treat rheumatic diseases in RA, AS and PA patients diagnosed at least 2 years prior and currently or previously (≤1 year ago) receiving RA for a minimum of 1 year were consecutively recruited. Rheumatologists with at least 3 year experience on RA patients participated. A literature review and 4 focus groups were undertaken to identify attributes and levels. Scenarios were selected using orthogonal design. Participants ranked 8 scenarios from 1 (most preferred) to 8 (least preferred). Relative importance (RI) of attributes was calculated. Multivariate regression analysis was performed for each attribute. The ideal was: for patients and physicians, respectively, ‘pain relief and improvement of the functional capacity’ (RI=49.1% and 48.9%), ‘risk of adverse events’ (RI=31.8% and 31.5%), ‘administration method’ (RI=10.2% and 11.4%) and ‘time to perceive the need for a new dose’ (RI=19.2%). The ideal attribute to treat rheumatoid arthritis patients should allow pain relief and an improvement of the functional capacity, with a low risk of adverse events, a short time to perceive the need for a new dose and self-administration at home, when possible.

CONCLUSIONS: Although efficacy and safety are key for patients with rheumatic diseases and rheumatologists to make a choice over a BA, the need for a low frequency of administration and the administration method also play an important role as preference attributes for BAs in Spain.

PSY91 PATIENT-REPORTED OUTCOMES IN MODERATE TO SEVERE HEMOPHILIA PATIENTS: FINDING FROM A CROSS-SECTIONAL STUDY IN KOREA

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OBJECTIVE: There are approximately 2,000 hemophilia patients in Korea, but patient-reported outcome (PRO) studies involving a large number of hemophilia patients have been rarely studied. The aim of this study was to assess PROs in moderate to severe hemophilia patients in Korea. METHODS: It was a cross-sectional, multi-centered and observational study. Moderate to severe male hemophilia patients aged 8 to 65 were recruited at 2 of Korea Hemophilia Foundations and 3 other pediatrics from November 2012 to September 2013. All subjects completed several questionnaires. The PROs compared to those with reversible conditions, joint bleedings (0.68 vs. 0.73, p<0.001),
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hemophilic joint health (0.67vs. 0.73, p< .001) or disability (0.65 vs. 0.70, p< .001) as
similar as in the results of Haemo-QoL. With patients who were either on a job or
students (n= 467, 77.2%), LPT was estimated at 127.81 hours per month on average.
Of 467, patients with inhibitor or disability showed higher LPT compared to those
without inhibitor (130.61 vs. 126.61 hours per month, p= 0.486) or disability. (132.27
vs. 124.95 hours per month p=.087). Conclusions: The study findings suggest that
patients’ clinical characteristics should take into account for the management of
hemophilia given patient-reported outcomes differed by clinical manifestations.
PSY92
Burden of Lupus Nephritis (Ln) Among Patients Managed In Routine
Clinical Practices In Europe (Eu)
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Objectives: To assess the burden of LN in comparison to SLE patients without
Nephritis (Non-LN) in routine clinical practices in EU. Methods: A multi-center
medical chart-review of adult (16-89yrs) SLE patients was conducted among rheumatologists and internal medicine physicians in UK/France/Germany/Italy/Spain
(5EU). Physicians were recruited from a geographically representative sample in
each country. Approx. 5 consecutive eligible persistent active or relapse remitting
SLE patients currently managed as part of usual care were identified. Physicians
abstracted de-identified patient data on disease characteristics, lab values and
treatment patterns. LN and Non-LN cohorts were compared using descriptive
statistics. Results: 168 LN patients and 569 non-LN patients with SLE were analyzed. Patient characteristics included (LN/Non-LN): age (yrs): 40.2/42.7; % Female:
82.7/79.4; % Caucasian: 82.7%/88.8%; % full-time employment: 32.1/36.0; % part-time
employment: 19.0%/22.0%. Among LN/Non-LN cohorts, frequency of clinic visits was:
9.5wks/10.6wks, % currently receiving care in in-patient setting was: 14.9/8.8, % hospitalized >=1 in the past-year was: 49.4/29.7; mean # of organ manifestations was:
3.9/3.0. Top-5 organ manifestations were (% LN/Non-LN): musculoskeletal: 85.1/90.8,
mucocutaneous: 85.1/84.8, haematologic: 51.8/52.2, renal: 100.0/5.9, pulmonary:
16.7/16.2; % experiencing a flare was (LN/Non-LN): 23.2/16.6. Renal biopsy was performed in 87.5% (LN) and 4.0% (Non-LN) of patients. Steroids were used by 82.1%
(LN) and 69.4% (Non-LN). % patients with low C3 and C4 was LN: 66.3/48.1/Non-LN:
60.2/50.0; mean ESR scores were 40.2 (LN) and 36.8 (Non-LN). Among patients with
available data, SELENA-SLEDAI scores were 11.5 (LN) and 8.5 (Non-LN). Humanistic
burden (reported via physician ratings, on a scale of 0 (most impact) to 7 (least impact))
was (LN/Non-LN, mean scores): ability to perform every-day tasks: 5.0/5.3, ability to
interact fully with family and friends: 5.4/5.6, and ability to work/keep employment:
4.5/5.0. Conclusions: LN cohorts had higher clinical and humanistic burden in 5EU
in comparison to their non-LN SLE counterparts. Factors influencing the observed
burden, including the therapeutic strategies used in these geographies warrant further investigation to manage SLE, and LN in particular, optimally.
PSY93
Quality of Life (Qol) With Psoriasis: Ethnography Study Evaluating
the Impact of Psoriasis On Moderate To Severe Patients In Europe
(Eu), From A Patient’s Perspective
Narayanan S 1, Franceschetti A 2
Healthcare, Columbia, MD, USA, 2Ipsos Healthcare, London, UK
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1Ipsos

Objectives: To qualitatively assess the impact of Psoriasis on patient
QoL. Methods: An ethnographic study with moderate/severe Psoriasis patients
was conducted in 4EU (UK/France/Spain/Italy) and the US to explore patients’ views
on treatment options and Psoriasis impact on QoL. Anthropologists and ethnographers spent several-hours with consented patients and filmed their behaviours
inside and outside their homes in everyday situations. 175 hours of recordings/notes
were analysed to identify QoL-related themes: self-image, psychological effects of
psoriasis (e. g., anxiety/depression), life-style changes due to Psoriasis, relationship
with family, friends and colleagues. Results: Study included 35 adult patients (4EU:
20, US: 15; mean age: 39 yrs; female: 65%). Patients described their appearance with
a sense of disgust and self-loathing. Feelings of frustration were often expressed due
to a perceived lack of control of their lives. Prior to biologic initiation, daily rituals
absorbed good part of their day, including waking up earlier to apply creams, going
to work earlier to check their appearance and cover patches of dead skin. Due to
lack of cultural discourse and patient’s difficulty in articulating Psoriasis’ impact,
partners and family did not know how to react nor did they realize the full extent
of the problem. Difficulty in getting appropriate psychological support needed left
them with a feeling of resignation. As a result, majority dealt with their issues in
isolation. Most patients experienced social discriminations due to Psoriasis which
led some to lie about their disease, keeping it a secret. Biologic experienced patients
noticed a significant improvement physically, but psychological scarring remained.
Despite their regained confidence owing to the effectiveness of biologics, they still
did not discuss their condition with family and friends. Conclusions: Patients
with Psoriasis experienced significantly lower quality of life and high psychological
scarring. Ethnographic study design vividly depicted the unarticulated and emotional impact of Psoriasis on patients’ everyday lives.
PSY94
Health Related Quality of Life of Patients and Their Caregivers In
Rare Diseases Results of the Burqol-Rd Project In Hungary
Péntek M 1, Baji P 1, Pogány G 2, Brodszky V 1, Boncz I 3, Gulácsi L 1
University of Budapest, Budapest, Hungary, 2Hungarian Federation of People with Rare
and Congenital Diseases, Budapest, Hungary, 3Faculty of Health Sciences, University of Pécs, Pécs,
Hungary
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1Corvinus

Objectives: The Social Economic Burden and Health-Related Quality of Life in
Patients with Rare Diseases in Europe (BURQOL-RD, http://www.burqol-rd.com/)
project aimed to investigate disease burden and self-percieved health outcomes of
patients and their caregivers in rare diseases in eight EU countries (Bulgaria, France,
Germany, Hungary, Italy, Sweden, Spain, UK). Methods: An online questionnaire

survey was developed for patients (adults/children) and caregivers. Patients were
recruited by patient organisations in cystic fibrosis (CF), Prader–Willi syndrome
(PWS), haemophilia (HEMO), Duchenne muscular dystrophy (DMD), epidermolysis
bullosa (EB), fragile X syndrome (FXS), scleroderma (SCL), mucopolysaccharidosis
(MPS), juvenile idiopathic arthritis (JIA) and histiocytosis (HIS). Demography amd
main characteristics were recorded. Patients’ and caregivers’ health state was
assessed by the EQ-5D-5L, disability and caregivers’ burden by the Barthel Index
and Zarit Burden Interview questionnaires. Results: In Hungary, 296 Hungarian
patients (children: 161, 54%) participated in the study (CF 110, PWS 5, HEMO 58,
DMD 57, EB 6, FXS 12, SCL 38 and MPS 10 patients), no data were obtained in JIA and
HIS. Mean age among adults/children was 37.0 (SD 16.1) / 9.6 (SD= 4.5) years, and
disease duration was 18.5 (SD= 14.4) / 7.1 (SD= 4.5) years, respectively. The lowest
average EQ-5D-5L score was found in MPS (0.134 / 0.070) and DMD (0.310 / 0.198)
just alike with the Barthel Index (MPS: 35.6; DMD 58.0). Caregivers’ (N=95) mean
age was 39.2 (SD= 8.0) years and their EQ-5D-5L score (0.797, SD= 0.251) was not significantly different from the general populations’ average. Satisfaction with health
care (1-10 Likert scale) was the lowest in MPS, DMD and EB (mean 4.1, 5.2 and
4.3). Conclusions: Rare diseases induce substantial deterioration of patients’
quality of life and impose burden on caregivers. Taking an integrated approach our
results can serve for international comparisons and facilitate further investigations
in other orphan diseases.
PSY95
Is the Disease-Specific Lupusqol Sensitive To Changes of Disease
Activity In Systemic Lupus Erythematosus Patients After Treatment
of A Flare?
McElhone K 1, Burnell J 2, Sutton C 2, Abbott J 3, Lanyon P 4, Rahman A 5, Yee C S 6, Akil M 7,
Ahmad Y 8, Bruce I N 9, Gordon C 10, Teh L S 1
Blackburn Hospital, Blackburn, UK, 2UCLAN, Preston, UK, 3University of Central
Lancashire, Preston, UK, 4Queen’s Medical Centre, Nottingham, UK, 5University College London,
London, UK, 6Doncaster Royal Infirmary, Doncaster, UK, 7Royal Hallamshire Hospital, Sheffield,
UK, 8Betsi Cadwaldr University Health Board, Llandudno, UK, 9University of Manchester,
Manchester, UK, 10University of Birmingham, Birmingham, UK
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1Royal

Objectives: The aim of the UK multi-centre LupusQoL Sensitivity Study is to
assess whether the LupusQoL, a systemic lupus erythematosus (SLE) specific,
health-related quality of life measure is sensitive to change when disease activity improves or deteriorates. Methods: Patients with SLE experiencing a flare
(baseline) & requiring an increase in treatment were recruited. Assessments were
undertaken at baseline & monthly for 9 months & included BILAG-2004 disease
activity index & the LupusQoL with 8 domains and scores ranging from 0 (worst)
to 100 (best HRQoL). LupusQoL domain scores when disease activity improved or
deteriorated between consecutive time-points are reported as mean changes, with
95% CI constructed using robust standard errors to account for repeated patient
assessments. Results: Mean (SD) age was 40.9 (12.8) & duration since diagnosis was 9.3 (8.1) years for the 101 patients recruited; 94% females, 62.6% white
Caucasians. At baseline all mean LupusQoL domain scores were < 52. Scores for
LupusQoL physical health (+4.0, 95%CI 1.9 to 6.1), pain (+7.7, 95%CI 4.8 to 10.5) &
fatigue (+4.1, 95%CI 1.7 to 6.5) increased when BILAG improved. Scores for physical health (-4.9, 95% -9.4 to -0.4) and pain (-6.9, 95%CI -12.9 to -0.8) decreased with
a major BILAG deterioration but changes with a minor deterioration were small
and non-significant. The effects of improvements & deterioration in BILAG on
the other LupusQoL domain scores were smaller. Conclusions: Improvement
and deterioration of LupusQoL domain scores for physical health, pain & fatigue
domain scores was seen in patients with significant changes in disease activity
over 1 month. Sensitivity to change of other LupusQoL domains in relation to
changes in disease activity may need to be evaluated over a longer interval as the
more emotive type of response to the disease & its consequences may be latent
and therefore not evident at monthly intervals.
PSY96
The Quality of Life of Patients Treated With Robotic Versus
Traditional Surgery Results From An Italian Observational
Multicenter Study
Turchetti G , Pierotti F , Palla I , Manetti S , Cuschieri A
Scuola Superiore Sant’Anna, Pisa, Italy
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Objectives: To assess the Quality of Life (QoL), focusing on level of pain, of patients
submitted to surgical interventions with robotic technique in comparison with
traditional approach in the Italian setting. Methods: The prospective multicentre study analysed the QoL of 699 patients submitted to surgical interventions,
enrolled in 8 Italian Hospitals for the period February 2011-May 2014. The specialties
were general, thoracic, gynecological surgery performed with open, manual laparoscopic or robotic technique. Patients completed two questionnaires: one related
to pain intensity during the hospitalization and one fulfilled at home related to
pain intensity and its impact on daily activities, mood, relationship, sleep. Pain was
measured using the scale of facial expressions corresponding to the Visual Analog
Scale. For each intervention and specialty, linear regression for repeated measure,
corrected by length of stay and use of analgesics, were performed to explain level
of pain during hospitalization and at home, respectively. Results: Level of pain
during hospitalization is significantly (p= 0.05) lower in general and gynecological
robotic surgery versus the open technique, but not versus laparoscopic, while robotic
thoracic surgery presents significant differences with laparoscopic but not with
open surgery (p= 0.059). Level of pain at home is significantly different for robotic
interventions versus open both in general and gynecological surgery; moreover,
with respect to laparoscopic interventions, the differences are significant both in
gynecological and in thoracic but not in general surgery. Conclusions: The study
gives us insightful knowledge about QoL, focusing on pain, of patients submitted to
surgical interventions with robotic technique vs traditional surgery. Further analysis
are in progress to combine results on QoL, not only referred to level of pain, with
clinical severity and other indicators of clinical efficacy as length of stay, operating


time, medical/surgical complications to refine a robust measure of effectiveness in order to be compared accurately. RESULTS: Overall consumption of opioids was grown during the period of investigation. Putting six selected opioids into two groups (non-synthetic, the growth rate of synthetic analgesics, % anti-ds-DNA positive value and treatment patterns. Patient disease status and humanistic burden was assessed by physician per clinical judgment & patient interaction. The ranking and prioritization of rare diseases are crucial in order to determine priority financing. METHODS: 85 experts were interviewed to estimate the importance of each criterion in the decision-making on financing MT for rare diseases. We used a 10-point scale, where 10 points mean major importance to the priority indicator, and 1 point means minor importance. Mean estimates were calculated using descriptive statistics, then means were normalized. RESULTS: Respondents were 11-71 years old, varying from 30 to 90 years old. The most important criteria were characteristics of the treatment - "Effect of treatment on quality of life" and "effect of treatment in life expectancy" with 1 point each. The least important criteria were both characteristics of the disease - "Cognitive disorders as manifestations of the disease" and "Additional burden on the daily lives of caregivers" with 0.28 and 0.1 respectively. CONCLUSIONS: Characteristics of the treatment turned out to be more important for respondents than characteristics of treatment, therefore characteristics of treatment should be given consideration when evaluating rare diseases to determine priority financing.

OBJECTIVES: Opioid analgesics are proven to be safe and effective in malignant or nonmalignant pains. The consumption trend of six opioids (Morphine, Codeine, Oxycodone, Fentanyl, Methadone, and Pethidine) in Islamic Republic of Iran was given, which is different from the partial reimbursements observed in certain countries or under the coverage of rare disease regulations, full reimbursement was given, which is different from the partial reimbursements observed in certain countries. In some cases, the application of drug treatment can be approved prior to or without market authorisation. The availability of opioid drugs to patients was not inferior to that of the EU. CONCLUSIONS: While access in Japan, South Korea and Taiwan was stricter than in the EU.

SYSTEMIC DISORDERS/CONDITIONS - Health Care Use & Policy Studies

PSY98 ORPHAN DRUG POLICY: APPROACHES TO MARKET ACCESS IN MULTIPLE COUNTRIES Shih DY, Jarrett E

METHODS: A targeted literature review was conducted to identify papers pertaining to approval, while extensions of indication for the same condition were not considered. Information on drug status, indications, therapeutic area, and authorization date was extracted. RESULTS: 77 orphan molecules were identified as an indicator for prescription pattern and is evaluated during five year period (2007-2011) as the aim of this study. METHODS: The data of opioid analgesic consumption were collected from FIO (Food and Drug Organization) of Iran. The collected data were converted to DDD (Define Daily Dose) for each of six selected opioids in order to be compared accurately. RESULTS: Overall consumption of opioids was grown during the period of investigation. Putting six selected opioids into two groups (non-synthetic, the growth rate of synthetic analgesics, % anti-ds-DNA positive value and treatment patterns. Patient disease status and humanistic burden was assessed by physician per clinical judgment & patient interaction. The ranking and prioritization of rare diseases are crucial in order to determine priority financing. METHODS: 85 experts were interviewed to estimate the importance of each criterion in the decision-making on financing MT for rare diseases. We used a 10-point scale, where 10 points mean major importance to the priority indicator, and 1 point means minor importance. Mean estimates were calculated using descriptive statistics, then means were normalized. RESULTS: Respondents were 11-71 years old, varying from 30 to 90 years old. The most important criteria were characteristics of the treatment - "Effect of treatment on quality of life" and "effect of treatment in life expectancy" with 1 point each. The least important criteria were both characteristics of the disease - "Cognitive disorders as manifestations of the disease" and "Additional burden on the daily lives of caregivers" with 0.28 and 0.1 respectively. CONCLUSIONS: Characteristics of the treatment turned out to be more important for respondents than characteristics of treatment, therefore characteristics of treatment should be given consideration when evaluating rare diseases to determine priority financing.

PSY101 ORPHAN DRUG APPROVALS IN EUROPE: HISTORICAL REVIEW AND TRENDS Rodon L1,2, Korchagina D1,3, Rémuazut C1, Brunet J1, Tavella F1, Cournel A1, Tourny M4
OBJECTIVES: In Europe, orphan designation has been granted by European Medicines Agency since 2000. Molecules with orphan designation can benefit from a number of incentives to guarantee return on investment for manufacturers. Since introduction of orphan legislation, the number of Orphan Drugs (OD) has significantly increased. In 2012, total OD sales reached 13% of the whole pharmaceutical market. This study aims to analyse current situation and trends in OD approvals. METHODS: All ODs approved gaining marketing authorization was identified through the number of ODs, and the growth rate of non-synthetic. Opioid analgesics consumption in 2011 was shown to be 4 times more than the opioid consumption in 2007. The CAGR (Compound Annual Growth Rate) 2007-2011 was increased from 13.91% to 33.11%. 16.46%, 3.91%, 3.76%, and -41.63% for Oxycodone, Methadone, Fentanyl, Morphine, Pethidine and Codeine respectively. The growth rate of mentioned above opioids for the last year of investigation was reported 41.12%, 16.54%, 29.99%, -0.38%, 7.66%, 6.20%, -5.76%, for Methadone, Fentanyl, Pethidine, and Codeine respectively. The most important criteria were characteristics of treatment - "Effect of treatment on quality of life" and "effect of treatment in life expectancy" with 1 point each. The least important criteria were both characteristics of the disease - "Cognitive disorders as manifestations of the disease" and "Additional burden on the daily lives of caregivers" with 0.28 and 0.1 respectively. CONCLUSIONS: Characteristics of the treatment turned out to be more important for respondents than characteristics of treatment, therefore characteristics of treatment should be given consideration when evaluating rare diseases to determine priority financing.

PSY102 COLLABORATIVE ANALYSIS OF HTA DECISIONS, PRICE AND REIMBURSEMENT LEVEL OF ORPHAN DRUGS IN FRANCE AND ITALY Korchagina D1, Tavella F1, Rémuazut C1, Cournel A1, Tourny M4
OBJECTIVES: While there exist a number of incentives to stimulate research and development of orphan drugs (OD), the Health Technology Assessment (HTA) agencies do not use a specific path for OD in most countries where it is considered a different type of value judgement. This leads to a high inequity in patient access to OD. The study aims at comparing the HTA decisions, price and reimbursement level of OD in France and Italy. RESULTS: Among 74 OD approved in France during 2004 and 2014, 25 ODs approved in France and 22 ODs approved in Italy. All available ODs in France are officially available in Italy. The average delay between the market authorization and the price and reimbursement decision was about 16 and 17 months in France and Italy respectively. In France all available drugs are 70% reimbursed through hospital, 36 molecules are available in retail pharmacy with reimbursement from...
15% to 100%. In Italy only 9 molecules are reimbursed in retail pharmacy and other 10 are not reimbursed at all. In 63% cases ex-factory prices in Italy are higher than in France. The average price difference in price is 12% with 50% of products sharing almost same price (less than 5% difference). No information is available in France on managed entry agreement, while it is publicly available in Italy This prevents fair price comparison. CONCLUSIONS: OD are more available in Italy but reimbursement is poorer than in France. Prices are slightly higher in Italy but France displays multiple confidential rebates making it impossible to compare net prices. In Italy the actual accessibility depends a lot on regional level unlike France.

PSY103
HEALTH TECHNOLOGY ASSESSMENT, PRICE AND REIMBURSEMENT REVIEW FOR ORPHAN DRUGS IN ITALY
Tavella F.1, Korchinaga D.2, Rodrigues J.2, Remuzat C.2
1Crestiv-Ceutical, London, UK, 2Crestiv-Ceutical, Paris, France
OBJECTIVES: In France Health Technology Assessment (HTA) is conducted by the Scientific Technical Commission of Italian Medicines Agency (AIFA) with further negotiation between the manufacturers and the AIFA’s Pricing & Reimbursement Committee on price and reimbursement. After the decision is taken it is published in the official journal (Gazetta officiale), the assessed drug is formally available for Italian patients next day. There does not exist a specific procedure for orphan drugs (OD), they are evaluated under the same conditions as drugs for common diseases. Pharmaco-economic studies are recommended for innovative drugs. The objective of the study is to review HTA decisions, prices and reimbursement of OD in Italy. METHODS: All OD assessed in Italy since 2000 were identified. Prices, reimbursement rates and decision details were extracted for each drug using Farmadati Italia database. RESULTS: Among 74 OD approved in Europe 66 molecules are officially available in Italy. It took 5-10 months from granting market authorization to final decision on pricing and reimbursement and publication in ‘Gazetta officiale’. The remaining 9 are either not or under considered and grouped into 15 clusters based on the information provided. The most common related to the nature of the disease, and considerations based on rarity or unmet need. 52% were one of the main reasons for the reimbursement rate. There was also a substantial variation in interpreting and uncertain ICER. Categorizing these as social or scientific value judgments was done to identify areas where further elicitation of societal preferences, and where more consistency and transparency in their use are needed, respectively. Each of these was then compared to the actual situation, and compared to the reimbursement decision: drug’s medical benefit (SMR) and improvement in quality of life (ASMR). CONCLUSIONS: A540

PSY104
HEALTH TECHNOLOGY ASSESSMENT, PRICE AND REIMBURSEMENT REVIEW FOR ORPHAN DRUGS IN FRANCE
Korchinaga D.1, Remuzat C.2, Rodrigues J.1, Kornfeld A.2, Toumi M.2
2500 to almost 1,500 to 8,000. CONCLUSIONS: Among 74 OD approved in Europe 66 molecules are officially available in Italy. This prevents fair price comparison. CONCLUSIONS: OD are more available in Italy but reimbursement is poorer than in France. Prices are slightly higher in Italy but France displays multiple confidential rebates making it impossible to compare net prices. In Italy the actual accessibility depends a lot on regional level unlike France.

PSY106
TO WHAT EXTENT DO DISEASE AND TREATMENT CHARACTERISTICS INFLUENCE HTA-BASED RECOMMENDATIONS FOR A SAMPLE OF ORPHAN DRUGS IN THREE COUNTRIES, AND COULD THESE INDICATE WHETHER ORPHAN DRUGS HAVE A “SPECIAL STATUS”?1
Nicolò F.
London School of Economics and Political Science, London, UK
Routine HTA methods may not adequately capture all the important considerations of a treatment’s value and the impact of the condition on the patient given that evidence is often incomplete. This study aims to explore the influence of broader considerations of scientific and social value judgments on reimbursement decisions for a sample of orphan drugs OBJECTIVES: To identify and compare the extent to which these broader considerations not captured by the incremental cost-effectiveness ratio (ICER) influenced HTA decision-making process in three countries; and, on this basis, explore whether orphan drugs have a “special status”. METHODS: Countries included were England, Scotland and Sweden. Ten drug-indication pairs with DMA orphan designations were selected. A series ofletal reports were coded using thematic analysis to systematically identify and compare these broader considerations across countries using an existing analytical framework. RESULTS: ICER very rarely considered and appraised in 10% cases. At the drug level, in some cases, ICERs were considered but with varying levels of detail in reporting the clinical outcomes, explaining some of the reasons for differing HTA recommendations. Agency-specific risk preferences were identified through correspondence analysis as drivers of decision-making processes; and, on this basis, further explaining some of these differences. Poor to moderate agreement in the interpretation of the evidence was measured using Cohen’s kappa scores. This reflected situations where the countries interpreted the same evidence differently and situations where differences in the handling of the same uncertainties were seen, including differences in the extent to which stakeholder input influenced a decision. CONCLUSIONS: This research systematically compared HTA processes in different countries, facilitating the understanding of these complex processes including how different HTA bodies conduct value assessments. It enabled to raise awareness among the reasons for differences across countries, and highlight areas for potential methodological improvements in HTA. Further application of this framework to other disease areas and countries is a way forward to improving the drivers of coverage decisions but while better understanding the settings and limitations of HTA.

PSY110
WHY ARE THERE DIFFERENCES IN HTA RECOMMENDATIONS ACROSS COUNTRIES? A SYSTEMATIC COMPARISON OF HTA DECISION PROCESSES FOR A SAMPLE OF ORPHAN DRUGS IN FOUR COUNTRIES
Nicolò F.
London School of Economics and Political Science, London, UK
HTA reimbursement recommendations often result in different outcomes across countries despite the same evidence being appraised for a same technology. There is a need to understand the reasons for these differences. OBJECTIVES: To systematically compare HTA processes for a sample of orphan drugs across four countries (England, Scotland, Sweden and France) to identify the use and interpretation of evidence appraised, and highlight differences across countries. METHODS: Ten orphan drug-indication pairs were selected and systematically compared using a previously validated framework. An exploratory sequential mixed methods design divided the research into two stages: (1) qualitative in-depth analysis of the decision-making processes; and (2) quantitative identification of agency-specific risk preferences and agreement levels across countries. RESULTS: Differences at each step of the decision-making process were identified. The same pivotal trials were appraised but with varying levels of detail in reporting the clinical outcomes, explaining some of the reasons for differing HTA recommendations. Agency-specific risk preferences were identified through correspondence analysis as drivers of these decisions, further explaining some of these differences. Poor to moderate agreement in the interpretation of the evidence was measured using Cohen’s kappa scores. This reflected situations where the countries interpreted the same evidence differently and situations where differences in the handling of the same uncertainties were seen, including differences in the extent to which stakeholder input influenced a decision. CONCLUSIONS: This research systematically compared HTA processes in different countries, facilitating the understanding of these complex processes including how different HTA bodies conduct value assessments. It enabled to raise awareness among the reasons for differences across countries, and highlight areas for potential methodological improvements in HTA. Further application of this framework to other disease areas and countries is a way forward to improving the drivers of coverage decisions but while better understanding the settings and limitations of HTA.

PSY118
TOP 20 ORPHAN DRUGS AVAILABLE, PRICING AND REIMBURSEMENT IN THE CZECH REPUBLIC 2005–2012
Babelova O.1, Orav V.2, Babelova O.2, Slezkova Z.2
1St. Elizabeth University, Bratislava, Slovak Republic, 2St. Elizabeth University, Bratislava, Slovak Republic
OBJECTIVES: Orphan drugs are highly priced and top 20 orphan drugs create almost 75% of total drug expenditure in Slovakia. We conducted 8 years review of government and literature sources to provide insight into pricing, reimbursement and availability situation surrounding top 20 orphan drugs in Slovakia from the health care payer perspective. METHODS: We provide analysis of official prices, reim-

A540

VALUE IN HEALTH 17 (2014) A323–A686
bureusment status and availability of top 20 orphan drugs in Slovakia from 2005 till 2012. Data were obtained from government sources. RESULTS: We considered orphan drugs list (Cote and Kesting, 2012) that exceeded 1 billion $ sales in 2008 (globally) and compared molecules’ availability in Slovakia. Same molecules are among best selling 20 orphan drugs in Slovakia, with highest sale of 95 million EUR (Brevariaam, 2005–2012) compared to lowest sale of 15 million EUR (Ticruxolin, 2005–2012). It took from 1 (matinib) to 19 years (Gliracetamide) to be launched in Slovakia after orphan designation. Top 20 orphan drugs had average DOT 472 EUR or 472% higher than market DOT. From the selected orphan drugs 60% had full reimbursement status and 40% were fully covered by hospital budgets. Only 4 of them were launched in Slovakia since 2005 (included), 16 of them were launched from 1990 till 2004. Prices ranged from 330 EUR to 5800 EUR (ex-factory one package, 2012). CONCLUSIONS: There are highly valuable incentives for industry to invest to development of orphan drugs in EU. Current context of economic constraints in EU however justifies the need to pay close attention to the reduction to 26 and an increase in Secondary Targets from 25 to 28.

To describe the health care resource utilization associated with the treatment of neuroblastoma (NB) in England is challenging especially during the economic crisis. Financial constraints to an algorithm (EPA) that determined final recommendations (Core conditions, Non-patient benefits from consideration, 3 conditions would have changed from a Core recommendation for screening to only a Secondary Target. non-patient benefits (NPB). Such attributes have historically not been considered for mandatory newborn screening (NBS). Scores of 19 different surveyed conditions (19%) whose initial total scores were capable of changing by enough to an algorithm (EPA) that determined final recommendations, had no changes made to the algorithm consequent to dropping of those, 10 (67%) conditions (19%) whose initial total scores were capable of changing by enough to an algorithm (EPA) that determined final recommendations (Core conditions, Non-patient benefits from consideration, 3 conditions would have changed from a Core recommendation for screening to only a Secondary Target.

Obstacles to patients’ access to ODs. There are two main channels through which the patient can have access to ODs. First via doctors’ prescription and “rare diseases” in Greek. Web-based documents and transcribed interviews were analyzed. RESULTS: Delays in pricing and reimbursement of ODs in the Greek pharmaceutical market, budget cuts in hospitals and absence of patient registries constitute according to the analysis the greatest barriers in patients’ access to ODs. There are two main channels through which the patient can have access to an OD and it depends whether it is licensed in Greece or not. In the first case the patient can take the drug through the hospital or the pharmacy of EOPYY if it is not available at the hospital pharmacy and in the second case through a public sector organization (GEPF). All cases are characterized by extensive bureaucracy and involvement of up to three organizations in order to receive the approval, a procedure creating delays in patients’ access and risking their health. Also, the absence of a well-described procedure and lack of cooperation between the organizations and committees create further delays.

CONCLUSIONS: Ensuring patients’ access to ODs in Greece is challenging especially during the economic crisis. Financial constraints to an algorithm (EPA) that determined final recommendations (Core conditions, Non-patient benefits from consideration, 3 conditions would have changed from a Core recommendation for screening to only a Secondary Target). The ACMG report provided scores for individual attribute survey responses. We deleted the attribute score for NF1 (0 to 100 points) and rescored the totals for each condition. We then assessed whether score changes were sufficient to alter the EPA and whether a different EPA would result in changes to the recommendations. RESULTS: Six conditions had missing data. Of the 78 remaining, there were 15 conditions (19%) whose initial total scores were capable of changing by enough to an exercise (maximum 100 point reduction) to change the EPA. Of those, 10 (67%) did change EPA and, of those, 3 (30%) changed final category (in all cases from Core to ST). Of the initial 29 recommended Core conditions, there would be a 10 percent reduction in risk associated with the disease in Secondary Targets.

CONCLUSIONS: Inclusion of screening benefits to non-patients (family or society) is controversial and has not been standard in the past. We have shown that in the ACMG recommendations, had no changes been made to the algorithm consequent to dropping of those, 10 (67%) conditions (19%) whose initial total scores were capable of changing by enough to an algorithm (EPA) that determined final recommendations (Core conditions, Non-patient benefits from consideration, 3 conditions would have changed from a Core recommendation for screening to only a Secondary Target.

Increased length of stay was 6 days for both sets of patients. CONCLUSIONS: To our knowledge this is the first retrospective analysis of NB cost and utilization using encounter data from England. While it does not capture the entire costs to the England health care system, it indicates the level of resource intensity and costs at the CCG level.

To our knowledge this is the first retrospective analysis of NB cost and utilization using encounter data from England. While it does not capture the entire costs to the England health care system, it indicates the level of resource intensity and costs at the CCG level.

A qualitative study took place over a 6-month period between December 2012 and January 2014. Data were retrieved through semi-structured interviews with six representatives of key stakeholders in Greece and policy documents identified through web searches using keywords “orphan drugs” and “rare diseases” in Greek. Web-based documents and transcribed interviews were content analyzed. RESULTS: Delays in pricing and reimbursement of ODs in the Greek pharmaceutical market, budget cuts in hospitals and absence of patient registries constitute according to the analysis the greatest barriers in patients’ access to ODs. There are two main channels through which the patient can have access to an OD and it depends whether it is licensed in Greece or not. In the first case the patient can take the drug through the hospital or the pharmacy of EOPYY if it is not available at the hospital pharmacy and in the second case through a public sector organization (GEPF). All cases are characterized by extensive bureaucracy and involvement of up to three organizations in order to receive the approval, a procedure creating delays in patients’ access and risking their health. Also, the absence of a well-described procedure and lack of cooperation between the organizations and committees create further delays.

CONCLUSIONS: Ensuring patients’ access to ODs in Greece is challenging especially during the economic crisis. Financial constraints to an algorithm (EPA) that determined final recommendations (Core conditions, Non-patient benefits from consideration, 3 conditions would have changed from a Core recommendation for screening to only a Secondary Target).

We observed 336 patients as newly diagnosed and an additional 13 patients were identified as HRNB. Newly diagnosed population with previously treated, 1 year old patients were added to this analysis. In total, 338 patients were included in this analysis. Total costs associated with the 33 HRNB patients were £6.3m. Costs per HRNB patient (£130,303) were almost double the costs per newly diagnosed patient (£72,321). The average length of stay was 6 days for both sets of patients. CONCLUSIONS: To our knowledge this is the first retrospective analysis of NB cost and utilization using encounter data from England. While it does not capture the entire costs to the England health care system, it indicates the level of resource intensity and costs at the CCG level.

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Patients with medically uncomplicated chronic pain with an average duration of chronic pain and opioid medication use of 10 and 6 years respectively. 27% of patients were currently employed. 18% of patients used at least one prescription laxative, 70% reported using at least one over-the-counter (OTC) laxative, and patients reported taking OIC, with the most common being stimulant laxatives (20%), omeprazole laxatives (15%) and stool softeners (7%). 63% of patients reported consuming OIC with a health care provider, 3% reported a visit to the emergency room and 2% reported being referred to a hospital or other health care provider because of their OIC.

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9% of employed patients reported missing an average of 4.6 hours per week because of problems associated with constipation and 32% reported impaired work while working due to constipation.

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OBJECTIVES: Reimbursement decisions are often unanalytical and lack transparency, for orphan drugs. The objective of this study was to demonstrate whether multi-criteria decision analysis (MCDA) can support rational and explicit reimbursement decision process for orphan drugs in the Netherlands. METHODS: An Analytic Hierarchy Process (AHP) framework was used in which Health Economics students served as expert panels and provided input for score combinations to create semi-quantitative scores for a web-based survey. Criteria were identified by a systematic literature review. Three different orphan drugs (alglucosidase alfa in infantile Pompe disease, canakinumab in cryopyrin-associated periodic syndromes and investigational product in rare diseases) were also assessed by the students on their performance on these criteria. Criteria weights and performance scores were aggregated to an overall score for each orphan drug. Rank-ordering on overall scores prioritized the reimbursement of the three drugs. RESULTS: A systematic literature review was used to assess five criteria: clinical impact, social impact, financial aspects (annual costs of the drug per patient, budget impact, cost-effectiveness) and quality of evidence. The criterion 'life-threatening nature of the disease' was given the highest importance weight and budget impact the least. Alglucosidase alfa for infantile Pompe disease ranked highest of the three orphan drugs examined, particularly due to its performance in the disease and drug domains. The AHP survey was perceived as difficult by the respondents, which was confirmed by poor values for consistency ratios. CONCLUSIONS: Performing MCDA can enable explicit, transparent and auditable reimbursement decision-making for orphan drugs. However, its feasibility and applicability needs further investigation.

PSY115

ORPHAN AND RARE DISEASES - THE PAYER PERSPECTIVE

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OBJECTIVES: To look at the affordability of orphan medications across Europe and whether payer attitudes to high-price medications are changing in the face of rising health care costs and tighter budgets. METHODS: We conducted an online, semi-quantitative survey of 10 European markets and the USA to understand how payers view orphan drug treatments in general and whether they consider orphan drug treatments to be cost-effective. RESULTS: Nine criteria were identified and categorized in four domains, disease burden, illness without treatment, life-threatening nature of the disease, drug availability. The criteria were scored on a scale from 1 (lowest weight) to 5 (highest weight). Results were aggregated to a total score for each drug. The overall scores ranged from 3.4 to 4.6 out of 5. With overall scores close to 5, orphan drug treatments were perceived as affordable. CONCLUSIONS: The payers that we surveyed are being increasingly sceptical about the prices charged in relation to the clinical benefit of orphan drugs in comparison to other treatments. Payers are becoming more cost-conscious and require better justification for drug expenditure. However, orphan drugs are likely to be viewed more favourably if they are considered cost-effective.

PSY117

SOURCE OF INFORMATION AND PHARMACISTS’ KNOWLEDGE REGARDING RARE DISEASES AND ORPHAN DRUGS: CROSS-SECTIONAL STUDY IN SERBIA

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OBJECTIVES: The lack of information and scientific knowledge of rare diseases (RDs) and orphan drug (ODs) could affect the quality of health care delivered to patients suffering from rare diseases. The aim of this study was to evaluate the level of general epidemiological knowledge among pharmacists regarding RDs and ODs as well as how that knowledge is influenced by information sources, education level and years of experience. METHODS: The research design was based on a descriptive cross-sectional study. A questionnaire previously used in a pilot KAP study in Serbia in 2012 was applied. The respondents were 182 pharmacists from public pharmacies in seven of 29 districts in Serbia. Individual level of knowledge was assessed by total number of correct answers from a maximum of 9, and overall knowledge was an average of the individual level of knowledge. RESULTS: In total, 155 pharmacists were included in the full analysis set (response rate was 86.3%). Overall, the mean age was 43.4 years, and 94% were women. The average number of information sources regarding RDs and ODs was 1.7, and mostly one source of five was used (56.1%). Pharmacists who were engaged in post-graduate programmes or completed such programmes tended to use more sources of information (p = 0.017). The average level of knowledge among pharmacists was 5.3 out of 10. A study of the value of correct answers on pharmacists’ knowledge regarding RD and OD was 4 ± 1.77. Most pharmacists (n = 30, 19.35%) replied correctly to 6 questions. CONCLUSIONS: The respondents revealed that years of experience and age among pharmacists do not have an influence to the overall knowledge about RD. The positive impact of education was evident, and for the better pharmaceutical care of RD patients the training of pharmacists to proper use of professional sources of information should be useful.

PSY118

BEHAVIOR THERAPY FOR OBESITY TREATMENT CONSIDERING APPROVED DRUG TREATMENT: AN UPDATE

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OBJECTIVES: Many obesity-associated diseases require intensive medical treatment and are cause of a large proportion of health-related expenditures in Germany. Treatment of obesity includes nutritional, exercise and behavior therapy. The objective of this study was to conduct a systematic literature review about a long-term alteration in eating and exercise habits of overweight and obese individuals. Depending of the severity of obesity, drug treatment may be indicated. To evaluate the effectiveness of behavior therapy for obesity considering approved drugs reducing weight, a Health Technology Assessment was carried out in the year 2008. This HTA was updated with publications up to 12/2013, along with new developments in behavior therapies and drugs. The objective of this review was to carry out an updated review of the scientific literature databases. Publications chosen according to predefined criteria were evaluated by two authors to assess the effectiveness of behavior therapy. Most of the studies showed moderate but statistically significant reduction of weight in the intervention groups compared to control groups between 1.1 kg (at month 4) and 6.6 kg (at month 9). Studies with several examination time points resulted in statistically significant differences in the first evaluation time point (month 6) but not in the subsequent time points (month 12, 18, 24). The most frequent approach used for behavior therapy was, per phone or Email, two studies offered behavior therapy as an internet-based intervention. Two studies evaluated cost-effectiveness of behavior therapy per phone or email showed cost-effectiveness for this kind of intervention but the results are biased due to a high rate of drop-outs. CONCLUSIONS: Behavior therapy considering new approaches is an effective method to reduce weight.

PSY119

COMPARISON OF TREATMENT PATTERNS AND DISEASE SEVERITY AMONG PATIENTS WITH PISORIASIS RECEIVING THEIR FIRST BIOLOGIC THERAPY (FAB) TREATED FOR PSORIASIS/PSORIATIC ARTHRITIS (PsA) RECEIVING THEIR FIRST BIOLOGIC THERAPY (FAB) TREATED FOR PSORIASIS/PSORIATIC ARTHRITIS (PsA) TREATED WITH RHEUMATOLOGISTS AND DERMATOLOGISTS IN EUROPE (EU)

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OBJECTIVES: To compare rheumatologists and dermatologists in terms of treatment patterns and disease severity among PsA patients receiving their first biologic in the EU (UK/Germany/France/Italy/Spain). METHODS: A medical chart-review study of psoriasis and PsA patients attending rheumatologists and dermatologists in hospitals and private practices to collect de-identified data on disease and treatment characteristics. Physicians were screened for duration of practice (≥3yrs) and patient volume (≥2 Psoriasis/PsA biologic patients/month) and included from a large geographic spread across their own country. Physicians abstracted charts of the next 5 consecutive Psoriasis/PsA patients in their respective sites. Treatment patterns and disease severity among PsA patients on their first line of biologic therapy treated by rheumatologists and dermatologists respectively were compared using descriptive statistics. RESULTS: In Q4/2012, 337 rheumatologists abstracted 527 PsA patient-charts (mean=age: 47 yrs, male = 44%) while dermatologists abstracted charts of 109 psoriasis patients with PsA (mean=age: 49 yrs, male: 56%; 55.1% were managed in conjunction with a rheumatologist; 67% were referred by GP/another dermatologist). Time to first biologic since diagnosis was 41.0mo/20.8mo for the rheumatologist/dermatologist-treated cohort and 41.0mo/19.0mo for the treatment-naive group (patients in moderate/severe) rheumatologist-treated cohort: 27.6%/30.72%, dermatologist-treated cohort: 19.6%/46.08%/51.96%. In rheumatologist-treated cohort: treatment naive: 65.5%, 37.5% in conjunction with another provider in moderate/severe; 75%/32.7% patients had moderate/severe disease-status among rheumatologist- and dermatologist-treated cohort respectively. Average number of systemic-treatment-experienced prior to their first biologic initiation: 69.5%. 38.7%/61.3% and 27.5%/72.5% had moderate-severe disease-status among rheumatologist- and dermatologist-treated cohort respectively. CONCLUSIONS: Across the EUS, FAB treatment patterns and disease severity among PsA patients on their first line of biologic therapy treated by rheumatologists and dermatologists respectively were compared using descriptive statistics. Values start from the year 2013 onwards and are available at a large geographic spread across their own country. Rheumatologists are more likely to prescribe PSORIASIS/PsA biologic patients in conjunction with a rheumatologist or another dermatologist and to refer patients more often to another specialist (75% vs. 33%). Rheumatologists are more likely to prescribe and offer biologic therapy to moderate/severe disease-status PsA patients more often than dermatologists. CONCLUSIONS: Across the EUS, FAB treatment patterns and disease severity among PsA patients on their first line of biologic therapy treated by rheumatologists and dermatologists respectively were compared using descriptive statistics. Values start from the year 2013 onwards and are available at a large geographic spread across their own country. Rheumatologists are more likely to prescribe PSORIASIS/PsA biologic patients in conjunction with a rheumatologist or another dermatologist and to refer patients more often to another specialist (75% vs. 33%). Rheumatologists are more likely to prescribe and offer biologic therapy to moderate/severe disease-status PsA patients more often than dermatologists.

PSY210

VARIATIONS IN TREATMENT PATTERNS AND DISEASE SEVERITY AMONG PATIENTS WITH PISORIASIS RECEIVING THEIR FIRST BIOLOGIC THERAPY IN EUROPE (EU)

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OBJECTIVES: To assess treatment patterns and disease severity of psoriasis patients receiving their first biological treatment in EU. METHODS: A medical chart-review study of psoriasis patients was conducted in Q4/2013 in 5 EU countries (UK/Germany/France/Italy/Spain) among dermatologists to collect de-identified data on disease on treatment patterns and patient-volume (≥2psoriasis biologic patients/month). The research design was based on a descriptive cross-sectional study. The sample was recruited using the existing patient database and was comprised of 1, 877 patient charts, 702 (80.0%) were from EU5-averages. RESULTS: 877 patient-charts were abstracted, 702 (80.0%) were on their first biologic (mean age: 47 yrs, male: 64.1%). Prior to initiating biologic therapy, immunomodulators/phototherapy were more widely used in UK than in other countries (90.3%/43.1% vs. 76.6%/60.4% overall, respectively). In Germany, fumarates/
corticosteroids were more widely used (46.5%/26.8% vs. 12.3%/11.0%), and retinoids were less (5%/1.8% vs. 14.2%/11.0%). Patients were less likely to receive a biologic treatment before trying -> other systemic treatment (18.8% vs. 8.5%), and to wait longer after diagnosis to initiate biologic-therapy (25.8mo. 21.0mo); in Germany, patients were more likely to have tried 3-5 other systemic-treatments before initiating biologic-treatment (28.0% vs. 14.2%); patients in France were the most likely to initiate a biologic without trying another systemic treatment first (11.2% vs. 8.5%). Patients in Germany were started on biologics later on average (25.8mo after diagnosis vs. 14.0mo). The average flares in past-year was highest in Germany (1.4 vs. 0.9). Average current PASI-score (26.4 vs. 16.0) and BSA-score (22.8 vs. 19.5) were highest in Germany. In France, 41.2% of patients had not had a PASI score done past year (vs. 23.3%). In Germany, 56.0% of patients had severe/terminal disease severity at biologic-treatment initiation (vs. 47.8%). CONCLUSIONS: Among psoriasis patients, receiving their first biologic-treatment, treatment patterns and disease severity varied across the EU5. Factors influencing the observed variations in treatment patterns and outcomes warrant further scrutiny to decrease patient disease burden.

PSY121
APOTOPSIS AND OXIDATIVE STRESS INDUCED BY EXPOSURE TO MICROWAVE RADIATION INDUCED IN RAT THYMUS: MODULATORY EFFECT OF METALIN
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OBJECTIVES: To exposition to microwave radiation (MW), from mobile phones, satellite communications, radio relays, radars and microwave devices in medicine induce disturbances in thymus. The pineal secretory product, melatonin (Mel), exerts a variety of biological effects, and induces the immune response. The objective of the present study was to evaluate the modulatory effect of metalin on apoptosis and oxidative stress parameters in thymus tissue of rats after 40 days long exposure to MWs. METHODS: Wister rats were divided in 4 experimental groups: I (control group) - rats treated with Mel every day (2 mg/kg b.w, i.p), II (Mel group) - rats treated with Mel every day (2 mg/kg b.w, i.p) exposed to MW and IV (MW+Mel) - rats treated with Mel every day (2 mg/kg b.w, i.p) and exposed to MW radiations. Results: Significant increase of thymocytes apoptosis (p<0.001) was registered during exposure. Metalin was found to be effective on rat thymocytes: (1) decreased apoptotic rate of thymocytes (p<0.001), (2) effect on terminal apoptotic reaction, because of the decrease Dnase I and Dnase II activity (p<0.01), (3) decreased the MDA and catalase activity in (p<0.05), compared with control group. Conclusions: Having in the mind obtained results we can conclude that melatonin exerts protective effects on rat thymocyte by preventing apoptosis and oxidative stress disturbances in rats’ thymus under exposure of MW.

RESEARCH POSTER PRESENTATIONS - SESSION IV
RESEARCH ON METHODS STUDIES - Research on Methods – Clinical Outcomes Methods
PRM1 SYMPTOMATIC FACTORS IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD): RESULTS FROM AN OBSERVATIONAL STUDY
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OBJECTIVES: To explore the existence and clinical implications of symptomatic factors in patients with major depressive episodes. METHODS: Data are from a 6-month prospective, non-interventional, observational study that included 1,549 MDD patients without sexual dysfunction in twelve countries. Depression severity was measured using the Clinical Global Impression (CGI) and the 16-item Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR). Pain and quality of life were measured using the pain related items of the Somatic Symptom Inventory (SSI) and the EuroQol-5D, respectively. The QIDS-SR, and the SSI items were jointly included in a factor analysis. Exploratory factor analysis (EFA) was conducted in a randomly selected half of the sample and confirmatory factor analysis (CFA) in the remaining half. RESULTS: The EFA showed that a four factor model explained the data appropriately (RMSEA 0.041, 90% CI 0.034 - 0.048, CFI 0.979). The four factors were mood (feeling sad, concentration/discrimination making, self-criticism, suicidal thoughts, interest in people or activities, energy/fatigability, psycho-motor retardation and agitation), sleep (insomnia, middle insomnia, early awakening and sleeping too much), appetite and weight, and pain (muscle soreness, cramps in abdomen, pain in lower back, pain in heart or chest, pain in joints, neck pain, headache). The four factors could be used in clinical practice to make differential diagnosis. The CFA showed that the four factor model (RMSEA 0.054, 90% CI 0.049 - 0.059, CFI 0.954) was well-fitted. There was a highly statistically significant correlation (Spearman) between each of the four factors and CGI severity score and quality of life at each of the visits, with higher scores in the factors (higher severity) and corresponding higher CGI and lower quality of life (p<0.001, all comparisons). CONCLUSIONS: Considering the results presented, the data reasonably support that pain symptoms be included in the evaluation of patients with major depression. Based on these pain symptoms are associated to higher severity of depression and lower quality of life.

PM2 MFC-INDUCED FACTORS OF FUNCTIONAL DISABILITY IN PATIENTS WITH CHRONIC LUMBOSACRAL RADIULAR PAIN
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OBJECTIVES: Chronic lumbosacral radiular pain has significant morbidity and burden to the society. The objective of this study was to assess the functional disability and factors affecting it in patients with chronic lumbosacral radiular pain. METHODS: We performed an observational cross sectional study in a public tertiary care hospital in north India. Adult patients (18 and 75 years), with > 12 weeks of low back pain, without any systemic conditions were included in this study. Data regarding socio-demographic, employment, duration of low back pain, prescribing pattern and depression collected at baseline. Pain assessed using visual analogue scale (VAS), functional disability using modified Oswestry disability questionnaire (ODI). Patients also asked for the multicollinearity at the end of study. Predictors of high disability were analysed using multivariate regression analysis. RESULTS: A total of 246 patients (51% males and 49% females) with mean age of 44.9 (12.25) years were included for final analysis. Mean VAS and MODQ scores at baseline were 72.3 +12.5 and 48.3+11.2 respectively based on disability scores. 62% of patients found to be crippled whereas 62% and 24% of patients fall in severe and moderate disability category respectively VAS and MODQ scores were positively correlated (r = 0.84, p<0.05). Multi factorial analysis reveals that severe pain (higher VAS scores), high duration of pain, older age, over-weight, patients from urban region and depression were significantly associated with high disability. CONCLUSIONS: Our study results suggest that chronic lumbosacral radiular pain patients suffer with severe disability. Severity of pain was significantly correlated with levels of disability.

PM3 HIERARCHICAL NETWORK META-ANALYSIS INCORPORATING ORDERING CONSTRAINTS ON INCREASING DOSES OF INTERVENTIONS - APPLICATION TO OVERACTIVE BLADDER SYNDROME
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BACKGROUND: For the conservative treatment of Overactive Bladder (OAB) symptoms, the National Institute for Health and Care Excellence (NICE) in the UK currently recommends a course of supervised pelvic floor muscle training, followed by behavioural therapy, anticholinergic medication, sacral nerve stimulation, and more recently, botulinum toxin type A (BoNTA) and Mirabegron. Given the large number of interventions and relatively few primary trials network meta-analyses (NMAs) produce considerable uncertainty in the estimated treatment effects and consequently, there is little evidence of the most clinically effective intervention. OBJECTIVES: To evaluate the use of hierarchical NMAs incorporating ordering constraints in order to identify the most effective intervention for the treatment of OAB symptoms. METHODS: Using Bayesian Markov Chain Monte Carlo methods, we apply a 3-level hierarchical NMA that accounts for both the correlation between treatments within the same class, as well as the residual between-study heterogeneity. We further extend this model to incorporate ordering constraints on increasing doses of the same intervention. We apply the methods to a dataset obtained from a systematic literature review on bladder training interventions for OAB symptoms. The primary outcomes of interest were mean change from baseline for voiding, urgency, and incontinence episodes. RESULTS: The dataset includes 78 trials comparing 39 interventions that can be further categorized into 10 classes of interventions, including placebo. For voiding, and urgency episodes, BoNTA 200u was the most effective intervention with estimated mean reduction of -2.24 (95% CI: -3.46, -1.01), and -2.6 (95% CI: -3.46, -1.7) episodes relative to placebo, respectively. BoNTA 300u was the most effective intervention for reducing incontinence episodes with an estimated mean reduction of -1.81 (95% CI: -2.39, -1.33) episodes relative to placebo. CONCLUSIONS: Use of hierarchical NMAs, incorporating ordering constraints, increase in the potential for inferences that account for the the interplay of individual interventions. BoNTA was found to be the most effective intervention for reducing symptoms of OAB.

PM4 TREATMENT EFFECT HETEROGENEITY IN CLINICAL TRIALS: AN EVALUATION OF 13 LARGE CLINICAL TRIALS USING INDIVIDUAL PATIENT DATA
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OBJECTIVES: Using randomized clinical trials (RCTs) for clinical decision-making necessitates making decisions for individuals based on average treatment effects. While many assume important patient variation in treatment effects, identifying patients most likely to benefit is problematic. Stratifying patients by their risk of the primary outcome was proposed as a method to identify high versus low benefit patients. METHODS: From publically available sources, we identified 13 large RCTs with greater than ~1000 enrollees and overall statistically significant results for the chosen endpoint (cure or remission). The number and range of factors blinded to treatment assignment and stratified the patient population into quartiles of risk for the outcome. Treatment effect within each risk quartile was assessed. Treatment effect within each risk quartile was assessed. Treatment effect in the extreme risk quartile was statistically evaluated statistically by testing for an interaction between treatment and the linear predictor of risk, and by comparing hazard (or odds) ratios and absolute risk reduction in the extreme risk quartiles. RESULTS: Among 19 unique treatment comparisons analyzed, there was no apparent relationship between baseline risk and the hazard (or odds) ratios across trials, only 1 of 19 analyses had a significant interaction between treatment and baseline risk on the proportional scale. The difference in the log hazard ratio between the extreme risk quartiles ranged from -0.89 to 0.60 (median=0.03, inter-quartile range (IQR) = 0.4-
0.2). However, absolute risk reduction was generally higher in high risk strata, ranging from 1.4 to 18.3% (median=4.6%, IQR=0.8-6.2%) in quartile one and from 0.8 to 35.0% (median=11.5%, IQR=3.3-19.8%) in quartile four. The difference in the absolute risk reduction between the extreme risk quartile ranged from -3.2 to 28.3% (median=7.7%, IQR=0-11.3%). CONCLUSIONS: Clinically significant HTB is commonly seen in our patient population. A panel of experts agreed that the methodological approach to subgroup analysis is feasible and often clinically informative when assessing treatment efficacy.

PRM3: NON-TREATMENT SPECIFIC PARAMETER VALUE ESTIMATES: RELATIONSHIP BETWEEN BMI AND UTILITY

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OBJECTIVES: Cost-effectiveness models are an important component of health economics evaluations. In addition to estimates of treatment effects (typically estimated for RCTs), cost-effectiveness estimates may be sensitive to estimates of non-treatment specific parameters that describe the relationship between model variables. These may be estimated from epidemiological studies that themselves are likely to benefit from the estimated relationship between BMI and utility. We illustrate methods for the review meta-analysis of parameter estimates arising from multiple studies and issues around the selection of appropriate estimates. METHODS: A targeted search was carried out in MEDLINE and EMBASE for studies with utility data on BMI. The outcome was utility change per unit increase in BMI. Study characteristics included the utility instrument used, study location, diabetes status and number of covariates. Fixed and random effects models as well as graphical methods were used to investigate the influence of study characteristics. RESULTS: Several utility scales were used throughout with some using multiple utility scales within the study. A range of utilities was included within studies. The relationship between BMI and utility could be measured across studies. Using a random effects model we observed a change in utility per unit increase in BMI of -0.0054 [-0.0077, -0.0031]. However there was significant heterogeneity between studies. Even if these parameter estimates are consistent, the differences between the studies and the appeared predictive of the magnitude of effect of BMI on utility. CONCLUSIONS: We illustrate methods for meta-analysing multiple parameter estimates and discuss the selection of appropriate parameter estimates for the inclusion in cost-effectiveness models. In future work we will demonstrate the relationship between the selection of appropriate parameter estimates in terms of which covariables were included in the originating studies and the cost-effectiveness model structure in terms of which independent causal effects are modelled.

PRM4: COMPARISON OF IQWIG AND G-BA BENEFIT RATINGS IN ONCOLOGY

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OBJECTIVES: This research was conducted to understand key reasons why the G-BA came to a different benefit rating than IQWIG during oncology HTAs. METHODS: Searching the G-BA and IQWIG homepages, oncology HTAs between 1st of January 2011 and 31st of December 2013 have been identified. Assessments for which the G-BA and IQWIG disagreed were identified and the disagreement was analyzed to reveal the key reasons for difference. RESULTS: In the observed time frame, 18 HTAs of oncology products have been conducted by IQWIG and G-BA in Germany. IQWIG and G-BA were aligned in their benefit ratings in 14 reports (78%). During four assessments (22%) the G-BA came to a different conclusion than IQWIG. These are the assessments of crizotinib, eribulin, pertuzumab and the resubmission of the monoclonal antibody rituximab. The reason for the disagreement is that the G-BA looked at time-adjusted analyses to correct for different lengths of treatment in the trial arms. The extent of benefit that is extracted from the same data also potentially differs. This is exemplified by the case of vandetanib, where the G-BA was more convinced by data on “time to worsening of pain” than IQWIG and attested a “minor benefit” (as compared to “no added benefit”). In the case of eribulin, G-BA and IQWIG agreed on benefit based on survival data. Due to the potential side effects however, G-BA observed in “three while IQWIG initially denoted to “no added benefit”. CONCLUSIONS: The translation of clinical evidence into a benefit rating and weighing of positive versus negative effects is highly complex. We see that G-BA and IQWIG can come to different conclusions. In all cases it is important that the manufacturer shows evidence against the specific comparator. The benefit rating plays an important role in the reimbursement amount negotiations.

PRM7: SURVIVAL STATUS IN (PHARMA)EPIDEMIOLOGICAL STUDIES CAN BE SUCCESSFULLY INVESTIGATED USING ADMINISTRATIVE RESIDENTIAL REGISTRIES

Pothoff F, Richman D, Klamer A

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OBJECTIVES: Study subject survival is a key outcome and endpoint in pharmacoepidemiological studies. When participants in long-term studies drop out, administrate residential registries can be a valuable source for investigating the survival status and the causes of death of study subjects in pharmaco- and general epidemiological studies.

PRM8: RECRUITING MYEOLOBLASTIC PATIENTS FOR CLINICAL AND HEALTH OUTCOME STUDIES USING MANAGED PHYSICIAN PANELS

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OBJECTIVE: Myeloblastic (MF) is a chronic blood cancer with an estimated prevalence in the US population of 4-5 patients per 100,000 inhabitants. Among the sources to recruit MF patients for post approval studies in a real life environment, oncological or cardiological sites are of primary importance. The objective of the present contribution is to assess the number of MF patients in these specialties and the willingness of the physicians to enroll MF patients for clinical and health outcome studies. METHODS: A feasibility survey assessing the incidence of MF patients in the sites of 94 oncologists, 72 hematologists and 65 cardiologists in 5 EU countries (UK, GER, FR, IT, ES) was run, using the All Global managed physician panel. Physicians groups to participate in health outcomes studies and to recruit patients for these studies was estimated among 335 oncologists/hematologists and 208 cardiologists. RESULTS: 88% of the oncologists/hematologists and 90% of the cardiologists are involved in MF treatment to a smaller degree (75%). In 25% of all practices, less than 10 patients are treated per year, in 36%, 11 to 50 patients, and in 38%, more than 50. Approximately 90% of the oncologists/ hematologists and 88% of the cardiologists are experienced in clinical and health outcomes studies; 80% of the oncologists/hematologists and 60% of the cardiologists are willing to participate in future studies and 92% resp. 94% in this group are willing to enroll patients for clinical and health outcome studies, including management of informed consent and ethics procedures as required for the study type. CONCLUSIONS: Myeloblastic patients can be successfully recruited for clinical and health outcomes studies using managed panels.

PRM9: CAN GASTRIC CANCER PATIENTS BE SUCCESSFULLY RECRUITED FOR CLINICAL PHASE III/IV AND HEALTH OUTCOME STUDIES USING MANAGED PHYSICIAN PANELS

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OBJECTIVE: Gastric cancer (GC) is a cancer arising from parts of the stomach. To recruit GC patients for post-approval studies in a real world environment, oncological, hematological, and internist sites might be of primary importance. The present contribution compared the incidence of the gastrointestinal tract, Myeloblastic proliferation patients, and the willingness of physicians to enroll GC patients for health outcome or clinical phase II/III/IV studies. METHODS: In 2011 a feasibility study about the number of GC patients was run in the sites of 63 oncologists, 23 hematono-oncologists and 26 internists in UK (16), GER (18), FR (4), IT (27), ES (27), and US (12). Physicians reported about the number of “new patients with unresectable, locally advanced or metastatic gastric or gas troesophageal junction (GEJ) adenocarcinoma”. The willingness of these specialist groups to participate in clinical phase II/IV or health outcome studies was also assessed in a different survey. RESULTS: In total these 132 specialists have seen approximately 3,200 new gastric cancer patients in the last 6 months. In average (median values) oncologists have seen 30 new gastric cancer patients in 6 months, hematologists 20 patients and internists 6 patients. Most of the patients (9,600) have been treated with chemotherapy. Approximately 90% of the oncologists/hematologists and 88% of the cardiologists are experienced in clinical phase II/III/IV or health outcome studies; 80% of the oncologists/hematologists and 60% of the cardiologists are willing to participate in future studies and 92% resp. 94% in this group are willing to enroll patients for clinical phase II/IV or health outcome studies and ask them for written informed consent. CONCLUSIONS: Patients suffering from Gastric Cancer can be successfully recruited for clinical phase II/IV or health outcome studies using managed panels.

PRM10: ASSESSING THE RELATIONSHIP BETWEEN TREATMENT EFFECT AND BASELINE PROGNOSTIC FACTORS: NETWORK META-ANALYSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS TRIALS

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OBJECTIVES: To investigate the differences across randomized controlled trials (RCTs) evaluating biological therapies for the treatment of moderate to severe plaque psoriasis in terms of baseline risk in psoriasis area severity index score (PASI) and the association with treatment effects by means of network meta-analysis (NMA). METHODS: 25 RCTs reporting the proportion of patients experiencing a
75% improvement from baseline in PASI (PASI 75) at the end of the trial were identified from two recently published NMAcs focused on the efficacy of biologics in the treatment of moderate to severe psoriasis based on a systematic literature review. Differences in baseline risk of PASI 75 were explored graphically. The association between the treatment effect of 19 different biologics and baseline risk of PASI 75 was assessed by conducting emphasis on the baseline risk, covariate adjustment using a model assuming a constant treatment by covariate interaction, and a normal distribution for baseline risk. The model also allowed for the baseline risk adjustment of RCTs that did not include a placebo arm. RESULTS: Across the RCTs, PASI 75 at the end of the trial period for patients in the placebo arm ranged from 2% to 19%. The coefficient for baseline risk was a median of -0.33 (95% credible intervals: -0.79, 0.21) which suggested baseline risk was not significantly associated with the treatment achieving PASI 75 across the RCTs. Based on a NMA of RCTs regarding the efficacy of biologics in terms of PASI 75, it is unclear if baseline risk of PASI 75 acts as a treatment effect modifier. Further analyses are required to assess whether baseline risk may explain differences in associated with the proportion achieving PASI 75 across the RCTs.

**PRM11 RIDING THE E-PUBLICATION WAVE**
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OBJECTIVES: Submissions to Health Technology Assessment (HTA) bodies must include the most up-to-date information on comparator technologies. This enables HTA bodies to make fully informed decisions. In order to ensure up-to-date information is obtained, all relevant data sources should be searched. At present HTA model files generally specify a limited set of databases that are searched for embodiment of pharmacoeconomic evaluations in HTA model files. We undertook a search in the Cochrane Library, to identify any studies published since the guideline was published. We concurrently searched PubMed using a filter to identify studies only available as e-publications ahead of print. RESULTS: We identified one RCT meeting the inclusion criteria that was retrieved by the search in PubMed but was not identified by searching in the Cochrane Library. This RCT study aims to identify the pain instruments and study endpoints most commonly used in the clinical trial setting. METHODS: A structured, comprehensive literature review of ongoing registered trials (trial registries) and published clinical studies in PubMed (in the areas of chronic pain (cancer, non-cancer and neuro-pathic pain) and for elderly patients). The inclusion criterion was: study of pain therapies if new designs are required. If studies are missed from systematic reviews there can be important implications on clinical efficacy comparisons. To produce the most up-to-date systematic review, with all available papers it is necessary to search for e-publications ahead of print in PubMed as well as for all other publications in EMBASE, MEDLINE and Cochrane.

**PRM12 INDIVIDUALISED GROWTH RESPONSE OPTIMISATION (IGRO): A MULTILINGUAL SOFTWARE MEDICAL DEVICE TO PREDICT GROWTH RESPONSE IN CHILDREN TREATED WITH GROWTH HORMONE (GH)**

OBJECTIVES: To address the challenge of modern, accurate and predictive growth prediction tool in which growth prediction models (GPMs) were clinically validated. METHODS: GPMs support physicians to monitor and optimise GH treatment and response. They are validated, prospectively, in children receiving GH, to provide prediction of growth response and achievement of height targets in children with idiopathic growth hormone deficiency (IGHD), Turner syndrome (TS) and short children born small for gestational age (SGA). By using GPMs, realistic expectations of treatment outcomes are conveyed to patients and parents (important as children respond differently to treatment). A modern platform, a web-based tool, accessed via a secure password protected website, was easily navigated and provided a clear interface requiring little training. Data entry was quick and growth outcomes (i.e. graphical comparisons between patient’s actual growth response and one-year predictions) were easily viewed. CONCLUSIONS: IGRO, an accessible web-based tool, is an essential intervention for paediatric endocrinologists to support physicians to monitor patients’ response to GH treatment. It may potentially be used to detect discrepancies early.

**PRM13 STRENGTHENING EVIDENCE BASE FOR TRADITIONAL MEDICINE IN ASEAN: QUALITY OF REPORTING OF RANDOMISED CONTROLLED TRIALS OF HERBAL INTERVENTIONS IN THE ASEAN PLUS SIX COMMUNITIES.**

**OBJECTIVES:** Traditional Medicine and the use of herbal interventions are regarded as interventional and novel therapies in ASEAN (Asia). To date numerous randomised controlled trials (RCTs) of herbal interventions have been conducted within ASEAN. It is recognised that good quality reporting of RCTs of herbal interventions is crucial to the assessment of clinical significance. ASEAN has a dearth of documentation of RCTs of traditional medicine, especially in the strengthening of evidence base for herbal medicines. The objective of this study was to systematically review the quality of reporting of RCTs of herbal interventions published in ASEAN Plus Six Countries. METHODS: Searches were performed using PubMed, EMBASE and MEDLINE, The Cochrane Library, and Allied and Complementary Medicine (AMED), from inception through October 2013. The following limits were applied: Human; RCTs. Herbal species search terms were based on the Asian Network of Traditional Medicine [AMNET (Malaysia, 2011)]. Studies conducted in ASEAN Plus Six Countries, published in English were included. Quality of reporting was assessed according to the 22-item Extended CONSORT checklist for reporting RCTs of herbal interventions. RESULTS: Seventy-one articles were identified, of which thirty RCTs (42.5%) were conducted in ASEAN Countries, whereas 41 RCTs (57.75%) were from the Plus Six Group. Adherence to the recommended CONSORT checklist items for reporting of RCTs of herbal interventions was found to be poor. The RCTs of herbal interventions were judged to be insufficient as half of the RCTs reported methods used to generate random sequence allocation (item 8.47%), and implement random allocation sequence (item 9 allocation concealment, 29.58%). Less than a quarter of RCTs (18.31%) reported information on standardisation of herbal products. CONCLUSIONS: The present study highlighted the need to improve reporting quality of RCTs of herbal interventions across ASEAN Plus Six Communities.

**PRM14 ENDPOINTS IN PAIN: THE SUITABILITY FOR HEALTH ECONOMIC EVALUATION OF ENDPOINT DESIGNS IN CHRONIC PAIN STUDIES**
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**OBJECTIVES:** A wide range of instruments is used to measure outcomes in clinical studies of chronic pain. However, the suitability of study outcomes for economic evaluations may vary significantly between studies, and the need to improve reporting quality of RCTs of chronic pain. The majority of primary endpoints were pure pain measures (112), most common: numerical rating scale (NRS) (49), visual analogue scale (VAS) (38), and pain interference (19).Types of pain instruments currently used in clinical trials are limited and the failure of those that are in common use to adequately capture the dimensions of a patient’s experience of pain, including function, quality of life and tolerability. The current study aims to identify the pain instruments and study endpoints most commonly used in the clinical trial setting. METHODS: A structured, comprehensive literature review of ongoing registered trials (trial registries) and published clinical studies in PubMed (in the areas of chronic pain (cancer, non-cancer and neuro-pathic pain) and for elderly patients). The inclusion criterion was: study of pain therapies. The majority of studies still use simple pain measures as their primary outcomes. Useful economic outcomes such as quality of life and function are relegated to secondary endpoints and are inconsistently used. Types of pain instruments currently used in registered, ongoing or recently completed studies were identified. Future research is needed to consider which existing endpoint designs constitute best practice and if new designs are required.

**PRM15 COMPARATIVE REAL WORLD EFFECTIVENESS OF NOVEL AGENTS VERSUS CONVENTIONAL THERAPIES IN MULTIPLE MYELOMA PATIENTS IN SWEDEN**

**OBJECTIVES:** Comparing outcomes between different treatments based on real world evidence can be challenging, first because of confounding due to lack of randomization at treatment initiation, and secondly due to selection bias induced by selective treatment switching. To account for both sources of bias, we explored the inverse probability of censoring weights analysis (IPCW) to account for selection bias on a retrospective dataset of multiple myeloma patients in Sweden. METHODS: IPCW approach was used to additionally adjust for bias induced by selective treatment switching in 2 steps. First, time-weighing variables were estimated using multivariate logistic regression at each stage, including baseline characteristics as baseline covariates and M-protein as time-weighing variable. Secondly, these time-dependent weights were incorporated in a proportional hazards model, including time-dependent and baseline characteristics. After adjustment of subsequent therapy, ITT-estimates were generated using baseline proportional hazards model, including the same baseline covariates. RESULTS: In the total MM population (n=1638), the non-transplant population was 1125, of which 31% n=349 received novel therapy. The MM population (n=673) treated with novel therapy while 69% had conventional therapies in frontline. Mean age was 71/75 respectively. The mean baseline serum m-protein level was 30.9 g/l for both groups. The ITT HR in frontline was 0.56 [0.45, 0.70] and IPCW-adj. HR is 0.31 [0.23, 0.42]. ITT vs IPCW-adj HR for 2nd and 3rd line of therapy were 0.71 [0.58, 0.87] vs 0.66 [0.47, 0.91]
and 0.87 [0.68, 1.11] vs 0.655 [0.455, 0.944], respectively. CONCLUSIONS: This analysis showed that the model of patients who received ICW as compared to conventional therapies, across the different therapy lines. Additionally, results illustrate the impact of selection bias induced by selective treatment switching, and the need to apply novel approaches as ICW to make additional adjustments, for which traditional statistical techniques cannot be used for.

PRM16 COMPARING THE USE OF PATIENT-LEVEL DATA TO AN AVERAGE PATIENT PROFILE WITHIN A TYPE 2 DIABETES SIMULATION MODEL

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OBJECTIVES: Despite significant patient heterogeneity and complex treatment pathways, averages are commonly relied upon when defining patient populations and translating from a type 2 diabetes treatment model, as a result of the difficulty and struggle to relate results to the clinical setting. This study compares outcomes when using patient-level and average cohort inputs within a published simulation model, based on the UKPDS68 outcomes equations. METHODS: UK patient data (n=2,521) was collected from The Health Improvement Network (THIN). Simulations, performed over a medium-term horizon of 20 years, utilised either patient-level data, collating outputs over all replications, or average cohort data. The outputs (total costs, benefits and complication rates) were then compared. RESULTS: Average baseline characteristics were: age 63.36 (±11.14) years, HbA1c: 8.39% (±1.23); total cholesterol: 4.18 (±0.92) mmol/L, systolic blood pressure: 135.07 (±14.74) mmHg, weight: 89.85 (±19.01) kg. The mean treatment effect was a reduction in HbA1c of 1.51 (%1.23) % over 20 years. Fewer macrovascular and microvascular events (<2/1,000 patients) and higher all-cause mortality (>17/1,000 patients) were predicted when using patient-level data compared to the average profile. Differences in the frequency and timing of deaths were driven primarily by variability in identifiability in age and led to fewer estimated life-years (-0.66), quality-adjusted life-years (QALYs): -0.59) and costs (-£551) per patient. Patients estimated to have lower costs and higher QALYs at all time-points (there was no absolutely associated with age). Furthermore, patients were younger, with higher HbA1c and cholesterol but lower blood pressure at baseline. CONCLUSIONS: Modelling results differ depending on the use of patient-level or average cohort model inputs. Patient-level data may provide insight into the type of patients in whom the therapy is likely to be most beneficial. Furthermore, it enables the accurate simulation of correlation between patient characteristics and treatment effect, which are rarely accounted for as part of a standard probabilistic sensitivity analysis.

PRM17 QUANTIFYING NONLINEAR EFFECTS IN STOCHASTIC MARKOV SIMULATION USING UKPDS 68 AND UKPDS 82 EQUATIONS IN TYPE 2 DIABETES MODELING WITHIN THE CDM CORE DIABETES MODEL (CDM)

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OBJECTIVES: Previous studies have demonstrated incorporating parameter sampling (PS) is crucial to capture nonlinear effects (NE) in cost effectiveness modeling. NE are, among other causes, driven by the degree through which the symmetric sampling is translated into non-symmetrically distributed probabilities. PS increases the uncertainty in selecting survival models within individual studies, it may be reasonable to 'borrow' strength across studies. Methods: A total of 50 validation simulations were performed to data from ACCORD, ADVANCE, VADT, ASPEN, DCC and UKPDS. Simulations were conducted with and without PS using UK68 and UK82 REs. Predicted versus observed macrovascular (MAC) and microvascular (MIC) complications and all cause mortality (ACM) were assessed using the coefficient of determination (R2) goodness of fit measure. RESULTS: When the CDM was run without PS, validation studies produced an R2 statistic of 0.898 using UK68 and 0.853 using UK82 RE. This compared to R2 statistics of 0.876 and 0.791 in analysis with PS for UK68 and UK 82 REs, respectively. Overall, PS caused end point predictions for MAC, MIC and ACM to increase. Internal validations against UKPDS 80 demonstrated that PS increased event rate predications for myocardial infarction (MI), stroke, MAC and ACM by 4.4%, 21.5%, 19% and 16.4% when UK82 RE were applied and 26.5%, 67.4%, 54% and 34.8% with UK82 RE, respectively. CONCLUSIONS: The findings from this study have shown that external validity declined with PS in simulations using UK68 RE and UK82 RE. The degree by which PS increased end point predictions was considerable stronger in UK82 RE predictions for MAC and ACM but lower for MIC.

PRM18 INVERSE PROBABILITY OF CENSORING WEIGHTED ANALYSIS TO ADJUST THE TREATMENT EFFECT ON OVERALL SURVIVAL FOR SUBSEQUENT THERAPY: A CASE STUDY IN A CLINICAL TRIAL IN MULTIPLE MYELOMA

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OBJECTIVES: ITT-Analyses of oncology trials tend to underestimate the treatment effect when analysing the impact of all subsequent treatments. Inverse probability of censoring weighted analysis (IPCW) was explored to estimate an adjusted treatment effect on OS in VISTA, a phase III randomized clinical trial comparing melphalan and predrocimine vela-Salamanca (D-VMS) ([[Echinacea]] in previous treatment of multi- ple myeloma patients ineligible for stem cell transplantation. METHODS: The IPCW consisted of 2 steps. First, time-varying weights were estimated using multivariate logistic regression, including demographic data, M-protein measurement or clearance as baseline covariates and M-protein as time-varying covariate. In a second step, these time-dependent weights were incorporated in a proportional hazards model, including the same baseline characteristics, with patients censored at initiation of subsequent therapy. RESULTS: 338/434 patients receive subsequent treatment lines. This typically happens more frequently and earlier in the comparator arm, which may bias the estimate for the treatment effect on OS. The IPCW-approach was explored to adjust for this bias, which resulted in an increased estimate of the treatment-effect on OS of VMP vs MP, compared to the original ITT-analysis. With overall survival being a key input in economic evaluation, estimating the accurate effect on OS is key. Employing this type of approaches may result in more accurate cost effectiveness results and thus more consistent/appropriate Health Technology Assessment recommendations.

PRM19 SHARING OF INFORMATION ACROSS STUDIES TO INFORM CHOICE OF FUNCTIONAL FORM WHEN CONDUCTING PARAMETRIC SURVIVAL ANALYSIS

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OBJECTIVES: To explore the sharing of information across multiple studies in order to inform the choice of functional form when conducting parametric survival analysis. METHODS: Using the Bayesian Information Criterion (BIC) for an approach (iii) a single BIC statistic was calculated by summing the components of the BIC (n, k and ln (L)) across studies. Estimates of mean survival were derived for each model and bootstrap analysis was conducted to estimate both the uncertainty in model selection and the variance in mean survival estimates. RESULTS: Independent selection led to different functional forms being selected for each study with considerable uncertainty regarding the choice of model (the bootstrap estimation for the mean survival across four studies was 9.8 years) which resulted in an increased estimate of the treatment-effect on OS of VMP vs MP, compared to the original ITT-analysis. With overall survival being a key input in economic evaluation, estimating the accurate effect on OS is key. Employing this type of approaches may result in more accurate cost effectiveness results and thus more consistent/appropriate Health Technology Assessment recommendations.

PRM20 PREDICTIVE MODELING TO ASSESS PREDICTORS OF TREATMENT SUCCESS AND FAILURE: COMBINATION STATIN THERAPY PATIENTS

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OBJECTIVES: The objective of this study was to apply predictive modeling methodology to determine the predictors of success and failure in achieving LDL-C goals after combination statin-fibrate therapy in patients diagnosed with hypertriglyceridemia (HTG). METHODS: A large claims database was used to identify patients initiating a fibrate between January 2011 and December 2011 (index date). Diagnosis of HTG and the use of statins were confirmed within 6 months before the index date. A total of 622 patients were selected for the current analysis. Patients were categorized into very high risk, high risk, moderate risk, and low risk groups. Logistic regression and two-group discriminant analysis models based on 17 potential predictors for treatment success or failure were constructed. RESULTS: At index, the median triglyceride (TG) level among all patients was 95.5 mg/dL, LDL-C level was 92 mg/dL, and high-density lipoprotein (HDL) was 40 mg/dL. The mean age was 54 years. Two predictors were associated with combination statin-fibrate treatment success or failure. M-protein measured for 5% of the patients was associated with combination treatment between groups. Low LDL (defined as <40 mg/dL) (OR=0.35, 95% CI, 0.2-0.59) and peripheral arterial disease (OR=0.10, 95% CI, 0.02-0.38) were significantly associated with treatment failure. Low HDL variable was the key discriminator. CONCLUSIONS: Predictive modeling models may offer the potential for more accurate prediction of treatment success and failure of targeted drug classes. A set of key predictors may suggest opportunities to understand and predict treatment success and failure of targeted groups and/or drug classes. These predictors may be useful in developing treatment strategies that will optimize outcomes.

PRM21 PREDICTIVE MODELLING FOR OPTIMAL TARGET POPULATION AND REAL-WORLD STUDY DESIGN: AN EXAMPLE IN MOTHER-TO-CHILD TRANSMISSION OF HIV

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OBJECTIVES: For utilising the appropriate patient populations, including demographics and study design, when developing observational/submission modeling to optimise the impact of therapy. Aims: To develop a model that can be used to predict the risk of HIV transmission from mother to child. The model was developed using a combination of statistical and machine learning techniques. The model was validated using data from a real-world study, and the results were compared to the observed outcomes. The model was found to be accurate in predicting the risk of transmission, with a high sensitivity and specificity. The model was then used to predict the risk of transmission for new cases of HIV-positive mothers, and the results were compared to the observed outcomes. The model was found to be accurate in predicting the risk of transmission for new cases of HIV-positive mothers, with a high sensitivity and specificity. The model was then used to predict the risk of transmission for new cases of HIV-positive mothers, with a high sensitivity and specificity.
OBJECTIVES: This research will present the Bayesian decision analytic framework for estimating the value of an AIDS-specific ICD-10 code for the HES database and study success applied to optimal target population and study design. A real-world example in mother-to-child transmission of HIV conducted in Thailand will be used to illustrate the concepts throughout. METHODS: Predictive models describing virtual cohorts over time under various care strategies can be informed by Bayesian inference using all relevant data available on associations between population characteristics, relative drug efficacy, drug uses and design parameters. In the proposed example, historical transmission data from Thailand, 1984-1987, infected mother-infant pairs (MIPs) were modeled. A time-effect logistic regression adjusted for viral load, gestational age, CD4 count at delivery and infant treatment duration. Viral load was described as an exponential function of prophylaxis duration. Monte Carlo simulations were used to predict intrapatient transmission rates with and without single dose nevirapine (sdNVP) added to the standard of care (antenatal prophylaxis), and predict chance of success of a naturalistic Phase III study in Thailand under various assumptions on target population and adaptive study design. Sensitivity analyses were conducted with short prophylaxis (<6 weeks) and long prophylaxis >82 weeks to enable classification. RESULTS: Of 110 patients was chosen and the providers contacted to provide medical charts. Charts were reviewed to abstract data indicating PAH diagnosis, FC, and/or symptoms consistent with PAH. Study success was determined if ≥ 110 patients was chosen and the providers contacted to provide medical charts. Results of this study will be summarized. A47
set appears reasonably valid for research, particularly following accreditation. The dataset may be a suitable alternative to collecting primary data measures with a lead, although caution should be exercised with earlier data. Further work is ongoing to establish the nature of the missing data and the implications for cost differences.

PRM27
CAN USING A RESOURCE USE LOG IN AN ECONOMIC EVALUATION ALONGSIDE A RANDOMISED CONTROLLED TRIAL REDUCE THE AMOUNT OF RECALL BIAS? Nakita A.1, Hinks J.1, Wyllie R.1, Laguerre E.1, Marques EM.2
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OBJECTIVES: To determine whether giving patients a resource use log (RUL) at hospital discharge reduces recall bias in a follow-up resource use questionnaire (RQU). METHODS: Within the AFXE randomised controlled trials (RCTs) 86 patients undergoing joint replacement were randomised to receive or not receive an RUL at hospital discharge (The RUL trial). A postal RQU was then administered to all participants 6 months after surgery. Respondents were asked to recall all GP, hospital, pharmacy, and telephone calls, GP practice nurse visits and telephone calls, and prescribed medication in relation to the patient’s joint replacement were extracted from GP records from hospital discharge until completion of the 3-month RQU by a blinded assessor. Coefficients (CCC) were calculated as appropriate.

There was evidence of improved recall in favour of the RUL arm in relation to visiting surgery delayed, 3 died, 5 withdrew, 6 had GP practices outside of area, 4 did not complete the 3-month RQU. Information was then extracted for 66/67 patients. There was no difference in recall in favour of the RUL arm in relation to visiting a GP (Kappa=0.5312 vs. -0.0161). There was some slight evidence in favour of the non-RUL arm with regards to having a GP home visit (Kappa=0.335 vs. -0.9937). The RUL arm showed more agreement than the non-RUL arm between data sources in terms of number of visits to GPs (CCC=0.581 vs. -0.013), GP telephone calls (CCC=0.564 vs. 0.173) and prescriptions (CCC=0.418 vs. -0.13). CONCLUSIONS: At the conclusion of the research, we found the evidence that provision of an RUL reduces recall bias in relation to visit to GPs.

PRM28
SYSTEMATIC REVIEW AND CRITIQUE OF HEALTH ECONOMIC MODELS ON RELAPSING-REMITTING MULTIPLE SCLEROSIS IN THE UK
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OBJECTIVES: Several new disease modifying therapies have recently received marketing authorisations for the treatment of relapsing-remitting multiple sclerosis (RRMS). Given the recent appraisal by NICE of these therapies, the objective of this systematic and qualitative review was to systematically review and critically evaluate the techniques used in modelling relapsing-remitting multiple sclerosis in the UK. METHODS: Embase, Medline, Cochrane Library and the NICE website were searched systematically on 03.03.14 to identify articles relating to cost-utility models in RRMS with a UK perspective. Data sources, techniques and assumptions of the included models were extracted, compared and critically evaluated. RESULTS: 385 search results, 25 full texts were evaluated and 17 articles (relating to 12 different models) were included. Early models varied considerably in method and structure but convergence was apparent over time towards a Markov model with states based on disability score, a 1 year time horizon and lifetime time horizon. Recent models also showed agreement on the importance of disability improvement within the natural history of the condition. Considerable variation remains, however, with an increasing number of comparators over time, the need to treat sequencing and different assumptions around efficacy and productivity gains. These gains refer to the individual long-term productivity due to better physical and mental health as well as to the economic consequences of decisions made by households due to improved child survival. The second domain consists of ecological values which are related to the decline of prevalence and incidence of vaccine related diseases. The third domain encompasses different types of equity considerations. The fourth domain includes the impact of vaccine strategies on other health interventions. Finally, the fifth domain includes macro-economic effects, such as the impact of vaccine immunization strategies on GDP tax revenues and overall government savings.

CONCLUSIONS: Several models of vaccine use are still at an early stage. A comprehensive definition is needed to identify the most important broader value categories for vaccination.

PRM29
SHOULD CHANGES IN DRUG PRICE OVER TIME BE CONSIDERED IN COST-EFFECTIVENESS ANALYSES?
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OBJECTIVES: Cost-effectiveness analyses (CEA) are used to support funding decisions for new drugs by estimating their clinical and economic value. When prices of drugs may fall over time due to market competition, entry of generic drugs or negotiated price cuts, this is rarely accounted for in CEA. One reason for this is that data is often collected in a one-off manner from market entry to the current time. This is inappropriate, especially when evaluating new drugs in a developing market in which future price changes are likely to be incorrect in some of the CEAs. In most of the CEAs, sensitivity analyses assumed arbitrary ranges for the cost estimates (for example, plus or minus 50%) rather than using ranges from alternative cost models. CONCLUSIONS: Very little detail is provided in published CEAs about the methods used to identify primary disease-related cost studies and a rationale for selecting the costs is generally not provided.

PRM30
ESTIMATING COSTS IN A COST-EFFECTIVENESS ANALYSIS: ADHERENCE TO HTA GUIDANCE
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OBJECTIVES: Cost-effectiveness analyses (CEA) are used to support funding decisions by comparing the cost utility of different health care treatments. Since the results of a cost-effectiveness analysis (CEA) are generally very sensitive to the input cost parameter values selected for difference disease-related outcomes a systematic approach should be used to derive these estimates as suggested in HTA guidance. To determine the extent to which a systematic approach was used in the currently available CEA literature, we conducted a systematic literature review on primary cost studies and of the cost data used in published CEAs was performed for different stages of liver disease for those with chronic hepatitis C infection. The process described in the cost-effectiveness analyses by which they selected the input base-case cost values as well as the ranges used in the sensitivity analyses was reviewed to determine whether or not a systematic approach was used to identify primary cost studies and whether or not the a rationale was supplied for the values selected.

RESULTS: The hepatitis C systematic review focused on US costs and cost-effectiveness analyses. In most of the hepatitis C cost-effectiveness analyses, the cost estimating method was either taken directly or derived from previous primary cost studies. However, a systematic review was not generally used to identify the recent primary cost studies. In addition, the method used to adapt the data from the cost estimating methods for use outside of the country in which it was developed was not identified. The study used to identify the relevance of information with regard to the broader value of vaccines for decision makers in low and middle income countries. The method used to adapt the data from the cost estimating methods for use outside of the country in which it was developed was not identified.

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The relation between quality of life versus work-status, PRm34

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CPRD) were linked with Hospital Episode Statistics (HES) at the patient level, resource use to manage CLL and iNHL have mainly been based on clinical expert opinions of novel treatments in the UK for NICE appraisals. Up to now, levels of productivity has a significant relationship with HRQol, and this is even more apparent for absenteeism than for work-status and presenteeism. Therefore absenteeism should continue to be included in the costs and not in the QALY. Findings need to be confirmed in other disease areas.

PRA34

DO THE US PANEL RECOMMENDATIONS HOLD FOR EUROPE? INVESTIGATING THE RELATION BETWEEN QUALITY OF LIFE VERSUS WORK-STATUS, ABSENTEEISM AND PRESENTEEISM

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OBJECTIVES: In the last twenty years there has been an intense debate on how to value work-status, absenteeism and presenteeism in economic evaluations. According to the Washington panel, lost productivity influences health-related quality of life (HRQoL) and should thus be considered a health effect instead of a cost to avoid double counting.

RESULTS: On average, patient had 1.22 EOCs during the three months. Patient characteristics and resource use differed between the EOC-classes. Class I ‘Masculokkeletal’ had the highest number of episodes (17%). The mean COE was £165 (IQR £118-289) during the three month follow-up. The most expensive class was K ‘Circulatory’, with a mean COE £912. The most expensive single COE (£32,546) was in the group K. The most expensive one percent of COEs summed up 36% of total COEs.

CONCLUSIONS: Patient characteristics, resource use and costs differed between the ICP-2 classes, which could be taken into account in evaluations, planning and pricing.

PRM35

COSTS OF PREVIOUSLY TREATED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND IDIOLENT NON-HODGKIN’S LYMPHOMA (INHL) IN THE UNITED KINGDOM (UK)

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OBJECTIVES: Accurate and consistent, high-quality resource use data are required to inform cost-effectiveness assessments of novel treatments in the UK for NICE appraisals. Up to now, levels of resource use to manage CLL and INHL have mainly been based on clinical expert opinion. However, recently, two key primary care databases in the UK (THIN and CPRD) were linked with Hospital Episode Statistics (HES) at the patient level, thereby providing additional information on secondary care in England. This study aimed to generate more accurate resource use for the management of CLl and INHL by using the THIN-HES database.

METHODS: First, a MEDLINE and UK Health Technology Appraisals (HTAs) reviews were undertaken to identify studies documenting the cost of previously-treated INHL and CLl in the UK. Then, to collect patients health care resource use, THIN database linked to HES dataset was included. Statistically significant data was analysed. RESULTS: Three HTAs were identified as relevant, and cost estimates relied on assumptions from clinical experts. Assumptions varied as TA193 recommended CCL and the second scenario assumed that health care visits were three times more frequent (post-progression (3 consultations/month: £86) than pre-progression (1 consultation/month: £28.67) while another, TA202, assumed a rather constant number of visits across the two health states (1 clinic visit per month: £121.11). The sensitivity analyses of the THIN-HES linked to HES dataset, including more than 1,000 patients. OPCS4 codes and READ codes in the HES and THIN databases respectively, were used to identify treatments prescribed and procedures undergone by applying national clinical guidelines. CONCLUSIONS: To our knowledge, this analysis is the first retrospective observational study to assess the cost of managing previously-treated CCL and INHL in the UK. This study will serve as an important resource in the health economic evaluation of future treatments and will help ensure that appropriate policies are put in place to increase the standardization of disease management costs across HTAs.

PRM36

A SYSTEMATIC REVIEW OF METHODS TO ASSESS THE ECONOMIC IMPACT OF AIR POLLUTION

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OBJECTIVES: Despite the fact that short and long-term effects of the exposure to air pollution on health have been extensively analyzed, estimates of the health care costs are still limited. The aim of this paper was to produce a systematic review of the literature, with the aim of identifying the current major research focuses in the field and the topics that will need to be addressed in the future. The searches were performed using 1) ‘health care cost’/exp AND ‘pollution’/exp. Searches were limited to English and Italian texts.

RESULTS: The initial selection identified 775 records in MEDLINE and 466 in EBASE, 149 of which were classified as relevant. They focused on a wide range of pollutants, including volatile organic compounds, nitrogen dioxide, pesticides, ozone, particulate matter and tobacco smoke. Most of the studies assessed the health impact of environmental pollutants using direct and indirect cost estimates calculated from literature, mainly relying on cost of illness methods. 27 papers used an individual direct health care costs approach, but they usually didn’t involve indirect costs in the final computations. Finally, only a few studies distinguished between short-term and long-term effect of air pollution.

CONCLUSIONS: The results of our review identified two main topics that deserve further research: future health impact assessment methods that could integrate indirect costs and relevant indicators for air pollution; and the future research aspects concerning the impact of environmental pollutants on health.

PRM37

COST- EFFECTIVENESS ANALYSIS OF IPIlimubum in PREVIOUSLY UNTREATED PATIENTS WITH UNRESECTABLE MALIGNANT MELANOMA IN SCOTLAND

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OBJECTIVES: This analysis assessed the cost effectiveness of ipilimumab 3mg/kg as first-line treatment for metastatic melanoma. As ipilimumab has an existing second-line recommendation, the decision problem is ipilimumab first-line followed by best supportive care (BSC), compared with Scottish clinical practice dacarbazine or vemurafenib first-line followed by ipilimumab. METHODS: In line with SMC requirements, an area under the curve model was built comparing first-line ipilimumab, dacarbazine and vemurafenib. The model utilised progression, survival and utility data from CA184-004 for ipilimumab/dacarbazine and dacarbazine, survival data from MDX010-20 for ipilimumab second-line, and survival and progression data from BRIM-3 for vemurafenib. MDX010-20 and observational data, using the approved regimen, were tested within scenario analyses assessing the performance of ipilimumab 3mg/kg at first-line. 2013 costs were taken from Scottish or UK official sources.

RESULTS: Economic analysis, including patient access schemes for ipilimumab and vemurafenib, shows that ipilimumab first-line followed by BSC is cost-effective versus dacarbazine first-line followed by ipilimumab (incremental costs: £10,502, incremental quality-adjusted life-years [QALYs]: 0.35, incremental cost-effectiveness ratio [ICER]: £31,481). Compared with ipilimumab first-line followed by BSC, the sequenced approach followed by vemurafenib is associated with incremental QALYs (0.26) but also incremental costs (£33,306), resulting in a net cost-effectiveness trade-off (ICER = £130,488), i.e. ipilimumab first-line should be the preferred option. A scenario analysis that compared ipilimumab first-line with vemurafenib first-line alone resulted in ipilimumab being the dominant treatment option. Comprehensive sensitivity analyses identified survival parameters as having the largest impact on model results. ipilimumab first-line followed by BSC is associated with £3,000,000 per QALY gained against both comparators.

CONCLUSIONS: First-line ipilimumab treatment for melanoma is cost-effective, and as a first-line option it would expand clinician choice, enabling selection of the most appropriate therapy for patients depending on their disease characteristics and BRFM mutation status.
TREATMENT IMPLICATIONS

Innovative diagnostic technologies with no immediate health benefit may not be a good approximation to Time Trade Off. The headroom method in the early assessment of diagnostic technologies with no immediate treatment implications. In this study we explore the feasibility and usefulness of the headroom method in the early assessment of diagnostic technologies with no immediate treatment implications. METHODS: We applied the headroom method to the implementation of whole exome sequencing (WES) into the current diagnostic protocol. The polygenic health state was not included. Cluster and their optimal number were identified by means of the Ward algorithm with the Euclidean measure and the hierarchical clustering technique. The identified clusters in each case are compared in order to find whether they coincide. RESULTS: 3 clusters were determined: 1) Germany, Argentina, The Netherlands, Denmark; 2) Japan, South Korea, USA, Hispanic USA, Zimbabwe; 3) Spain, Chile, UK, 4 clusters were identified for NAS: 1) Belgium, New Zealand, Argentina, USA; 2) Denmark, Europe, UK, Sweden, Finland, Denmark. Argentina. Countries are not in the same clusters in both cases. CONCLUSIONS: Health-state valuations tend to be clustered in a few groups of countries but the groups differ depending on the valuation method. The Visual Analogue Scale may not be a good approximation to Time Trade Off.

PRM59

IMTA PRODUCTIVITY COST QUESTIONNAIRE (IPCQ)

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OBJECTIVES: Productivity costs often reflect a large part of the total cost in economic evaluations adopting a societal perspective. Currently, no consensus exists on how productivity losses can be measured. A methodology for measuring productivity losses for use in economic evaluations assessed the instruments' main quality criteria. RESULTS: A focus group of 13 productivity experts in the field on 3) Denmark, Finland, Germany, Argentina, The Netherlands, Denmark; 2) Japan, South Korea, USA, Hispanic USA, Zimbabwe; 3) Spain, Chile, UK, 4 clusters were identified for NAS. CONCLUSIONS: The IPCQ is based on previously available instruments and satisfies the current scientific state of play in productivity cost measurement and valuation. The instrument is understandable for the vast majority of the general public including low-educated people. To enhance the applicability of the IPCQ for national and international studies a translation in English is performed.

PRM40

FEASIBILITY OF THE HEADROOM ANALYSIS IN EARLY ECONOMIC EVALUATION OF INNOVATIVE DIAGNOSTIC TECHNOLOGIES WITH NO IMMEDIATE TREATMENT IMPLICATIONS

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OBJECTIVES: There is a growing need for early evaluation of innovative technologies to prevent ineffectve and expensive technologies to be widely diffused in health care. The headroom method was introduced for early determination of the potential value of new technologies. In this study we explore the feasibility and usefulness of the headroom method in the early assessment of diagnostic technologies with no immediate treatment implications. METHODS: We applied the headroom method to the implementation of whole exome sequencing (WES) into the current diagnostic trajectory of complex pediatric neurology. We determined the room for improvement regarding health-related quality of life (HRQoL), diagnostic yield and the duration of the current diagnostic trajectory. RESULTS: The headroom in a certain diagnostic trajectory can be calculated after the so-called effectiveness gap is established and monetised. The preferred measure for the effectiveness gap is HRQoL expressed in quality-adjusted life years (QALYs). Since the direct product of diagnostics is information, and not improved health, no impact on HRQoL is expected. Other measures, such as diagnostic yield, can also be used to calculate the effectiveness gap. Unlike QALYs, these appeared difficult to monetise, however. Despite this difficulty, effectiveness gap calculation using these effect measures is more informative on the room for improvement of the diagnostic trajectory. CONCLUSIONS: Despite some methodological challenger, the headroom method proved to be potentially useful in early health economic evaluation of diagnostic technologies with no immediate treatment implications.

PRM41

BCEA: A R PACKAGE TO PERFORM BAYESIAN COST-EFFECTIVENESS ANALYSIS

Bis C1

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OBJECTIVES: BCEA is a R library specifically designed to post-process the result of a health economic model. Typically, this consists in the estimation of a set of relevant parameters that can be combined to produce suitable measures of cost (i) and clinical benefit (e) associated with an intervention. Within the Bayesian framework (which is the natural environment for BCEA), this amounts to estimating a posterior distribution for the pair (c, e). Health economic evaluations then proceed by computing some relevant summary of the resulting decision process: is the innovative intervention more cost-effective than the standard intervention (I)? METHODS: BCEA provides a set of functions that can be used to produce a standardised analysis, by synthesising the decision process given the current evidence and uncertainty, as well as producing diagnostic output that can be used to perform Probabilistic Sensitivity Analysis (PSA) to parameter and model structure uncertainty. These include the Cost-Effectiveness Acceptability Curve and the analysis of the Expected Value of Information, which can be used to prioritise research. RESULTS: BCEA uses as inputs vectors of simulations from both decision models of the same average costs and benefits. This naturally fits the Bayesian framework, but a frequentist analysis can also be carried out by using tools such as the bootstrap. There is scope for linking R and programs such as Excel to facilitate a comprehensive view of BCEA, including diagnostic PSA. CONCLUSIONS: In this talk, I will present the main feature of BCEA and its applicability to the wider context of health economic evaluation and cost-effectiveness analysis.

PRM42

A METHODOLOGY FOR ESTIMATING THE POPULATION OF ADVANCED OR METASTATIC EGFR M+ NON-SMALL CELL LUNG CANCER PATIENTS IN THE UK AND IRELAND

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OBJECTIVES: Budget impact models (BIMs) which demonstrate the economic impact of introducing or increasing use of specific treatments are routinely used to assist the NHS with financial planning. A core component of any BIM is the estimation of the eligible patient population. The objective of this study was to identify an appropriate methodology for the development of the estimated population of advanced or metastatic small cell lung cancer (NSCLC) patient population eligible for first-line treatment with a tyrosine kinase inhibitor such as afatinib (Giotrif®). METHODS: A review of the existing costing statement NICE and the variation by treatment type. RESULTS: No costing statements for patients with advanced (stage IIIb) or metastatic (stage IV) EGFR M+ NSCLC was conducted. The costing statements of tyrosine kinase inhibitors afatinib, erlotinib and gefitinib were reviewed, as was the costing statement for the chemotherapy agent pemetrexed. RESULTS: Based on the reviewed approaches, the calculation can be broken down into six discrete steps from the estimation of the general population to the target population: (1) Incidence of lung cancer; (2) Proportion of NSCLC; (3) Proportion with stage IIb/IV NSCLC; (4) Proportion who receive first-line chemotherapy; (5) Proportion with EGFR mutation status; and (6) Proportion who are EGFR M+. A detailed breakdown of the methods used to calculate the patient population eligible for treatment with afatinib was not available in the respective NICE costing statement. However, the estimation was estimated by NICE, which states that this approach is reasonable. CONCLUSIONS: The methodology employed by NICE to estimate the proportion of stage IIb/IV EGFR M+ NSCLC patients was predominantly consistent across all costing statements considered. It is reasonable to assume that this approach, used to estimate the population of stage IIb/IV EGFR M+ NSCLC patients in England and Wales also be applicable in Scotland and Ireland.
OBJECTIVES: Diabetic nephropathy (DN) is a progressive kidney disease that occurs in about 40% of patients with diabetes, and the recommended treatment is an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB). Individuals' health-related quality of life (HRQoL) can be summarised by utility values, which reflect preferences for different health states, and are used in cost-utility analyses (CUA). This literature study identified the utility values for different models of ACEi/ARB treatment in patients with DN. METHODS: A combined protocol was developed to identify CUA of ACEi/ARB treatment in DN as well as studies that estimated utility values for DN for future economic models of DN therapies that robust utility values are available for future economic models of DN therapies that robust utility values are available for included health states. RESULTS: Of 3236 references identified from the combined search, 28 CUA were deemed after review of titles/abstracts, and eight after full text review. The CUA assessed (ACEi n=3, ARB n=4, both n=1) in patients with type 1 diabetes (diabetes 1D) or type 2 diabetes (2D) or unspecified diabetes were identified. Methodologies of the two CUA significantly vary. Markov model and one a decision-analysis tree. Health states in the models included microalbuminuria, proteinuria, nephropathy, end-stage renal disease (ESRD), non-ESRD, dialysis and transplant. ESRD was the most frequent, with utilities ranging 0.25–0.84. These studies varied in the number of health states modelled and the number of different studies. CONCLUSIONS: For CUA of ACEi/ARB therapy in patients with DN, few health states were included, and there was variation in values for the same health state due to a range of different reference sources being used. It is important for future economic models of DN therapies that robust utility values are available for included health states.

PM45 MODELLING DEPENDENCE BETWEEN DISABILITY STATUS AND HEALTH SERVICE COSTS OF PEOPLE WITH RHEUMATOID ARTHRITIS IN HUNGARY

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OBJECTIVES: The main objective of this study is to estimate the impact of the level of functional status and disability on health service costs related to rheumatoid arthritis (RA) disease in Hungary. It is straightforward to think that higher disability implies higher costs, where the nature of the relationship is unclear. In order to explore these relationships a bivariate approach is proposed. Instead of fitting trend lines for the cost by regression methods the entire bivariate distribution was modelled.

METHODS: Health Assessment Questionnaire's disability index data were collected for 47 RA patients (with 2004 observations) treated at the Rheumatology Center (AC) Buda Hospital of Hospitalist Brothers of St John from 1st January 2005 to 31st July 2013. The same patients were also found in the database of National Health Insurance Fund Administration (NHIFHA) and further parameters as e.g. relevant treatments, hospital weighted costs and extra costs (in- and outpatient) were collected. After merging AC and NHIFA database the 2 dimensional patterns of the HAQ-index measures versus costs (sum of relevant costs in the following quarter year) become available for bivariate modelling. The ingredients were the empirical distribution of HAQ-index and quarter year cost, and some parametric copula families (elliptical or Archimedean) creating the possibly non-linear) dependence structure. The performance of the different model assumptions were compared by goodness-of-fit tests. RESULTS: The fitted bivariate distribution based on the best-performing dependence model are shown in the original “HAQ-index vs. cost” scale. The differences of average costs for low/medium/high HAQ-index values are summarised by conditional distributions; the conditional cost distribution of costs are presented, respectively.

CONCLUSIONS: It has been proved that there is a significant positive dependence between the disability status of RA and health service costs. The dependence cannot be considered as linear but this non-linearity can be tackled easily by using copula methods.

PM46 PHARMACY COST CALCULATOR FOR HEPATITIS C VIRUS PATIENTS IN TURKEY

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OBJECTIVES: To design a user-friendly cost calculator to estimate and project health care costs of patients diagnosed with hepatitis C virus (HCV) infection in Turkey. METHODS: We used Visual Basic in a Microsoft Excel to program complicated models within an easy-to-use framework for providers and payers to calculate pharmacy costs for HCV patients in Turkey. The calculator, first, uses the starting perspective the model considers: costs of TB and/or test related. Indirect costs perspective the model considers: costs of tests; costs of TB onsets for rheumatologic patients who undergo biologics; costs of extending anti TB prophylaxis also costs of prophylaxis before initiating therapy are mandatory. However, there is not a unique solution for the model costs of TB. Costs for adverse events therapy and/or test related. The comparison also considers weighing the number of exacerbations and related hospitalizations in the previous 4 weeks and three 0.5-2 million in 2014 and approximately €2 million in 2015, using these rates.

CONCLUSIONS: The economic burden of HCV in Turkey is significant. A simple-to-use calculator that uses real-world data and econometric models to make improved evidence-based health care decisions.

PM47 A DE-NOVO ECONOMIC MODEL TO ASSESS CLINICAL AND ECONOMIC CONSEQUENCES OF BRONCHIECTASIS

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OBJECTIVES: Bronchiectasis (BE) is characterised by permanent dilation of bronchi with destruction of elastic and muscular components of their walls. Pharyngeal antibiotic treatment with acute management of exacerbation episodes is an important consequence of the treatment. Currently there are no approved therapies for BE in the reduction of 15.53 exacerbations and 3.23 hospitalisations per patient per year. The treatment could result in a reduction of medical cost by €10.777 and 0.11 QALY gain per patient per lifetime. CONCLUSIONS: All health care intervention that reduce the number of exacerbations and related hospitalizations in the previous 4 weeks and three 0.5-2 million in 2014 and approximately €2 million in 2015, using these rates.

CONCLUSIONS: The economic burden of HCV in Turkey is significant. A simple-to-use calculator that uses real-world data and econometric models to make improved evidence-based health care decisions.

PM48 DIFFERENT STRATEGIES FOR LATENT TB ASSESSMENT IN PATIENTS UNDERGOING ANTI-TNF TREATMENT: AN ECONOMIC MODEL

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OBJECTIVES: The economic burden of HCV in Turkey is significant. A simple-to-use calculator that uses real-world data and econometric models to make improved evidence-based health care decisions.
increases with higher test costs, smaller subgroup and smaller incremental effects due to the treatment change. **CONCLUSIONS**: The data collection of costs, survival, and quality of life of PMAs should be restricted to the subgroup for whom treatment changes. Therefore, cost-effectiveness analyses of PMAs should start with identifying that subgroup. Once the size of the subgroup, the cost-effectiveness of the treatment was tested, the cost components, the full cost-effectiveness can be calculated. The described function can also be used to assess the potential cost-effectiveness of future PMAs. If a PMA causes a treatment change in a full subgroup, the PMA can only be cost-effective with low test costs or large incremental effects.

**PRM53**

**COMPARISON OF GENERIC, CONDITION-SPECIFIC AND MAPPED HEALTH STATE UTILITY VALUES FOR PEDIATRIC DISEASES**

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**OBJECTIVES**: Many aspects of QALY measurement in children are not yet fully developed. This study is aimed at contextualizing the mapping methodology in a field not yet covered: paediatric asthma. The objective is to derive utility values from non-preference-based questionnaires, the estimated utility values will be used for QALY assessment by means of: i) evaluation of a linear mapping between the generic preference-based EQ-5D-3L (self- and proxy-versions) and the condition-specific non-preference-based Paediatric Asthma Quality of Life Questionnaire (PAQQLQ), ii) assessment of the capability of mapping to discriminate for disease severity. **METHODS**: Either PAQQLQ or PAQQLQ and EQ-5D-3L will be administered to 170 asthma children (<17 years of age) during a multi-center randomized placebo-controlled trial of allergen-specific sublingual immunotherapy coded EudraCT No. 2012-005678-76/FARM94793/N at baseline, month 12, and month 24 visits. Level of severity will be assessed using the Asthma Control Test (ACT) and the Childhood-ACT (C-ACT) questionnaires. The possibility of a linear mapping will be evaluated through a Tobit model, where either PAQQLQ or PAQQLQ will be tested as predictors of EQ-5D-3L answers. Capability of mapping to be sensible in changes of disease severity will be measured through a Pearson’s correlation between changes in estimated EQ-5D-3L scores and changes in C-ACT. **RESULTS**: Linear mapping, if feasible, applies the statistical relationship between either PAQQLQ or PAQQLQ and EQ-5D-3L, permitting PAQQLQ or PAQQLQ answers prediction of EQ-5D-3L score. EQ-5D-3L and PAQQLQ or PAQQLQ, as well as EQ-5D-3L built on PAQQLQ or PAQQLQ answers by applying the linear mapping is expected to discriminate for both patients’ level and changes in disease severity. **CONCLUSIONS**: The choice of the source of utility values and their discrimination across severity groups and responsiveness in asthma children.

**PRM54**

**ESTIMATING MEANS FROM MEDIANS: A CASE STUDY WITH TREATMENTS FOR METASTATIC COLORECTAL CANCER (MCCRC)**

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**OBJECTIVES**: Prostate cancer (PCa) incidence has been steadily increasing over the last twenty years, resulting in Ireland having the highest incidence rate in Europe in 2008. The main driver of this is widespread use of prostate specific antigen (PSA) testing in primary care as an ad-hoc detection mechanism. The objective of this study is to evaluate the effectiveness of screening strategies for prostate cancer using PSA testing in Ireland. **METHODS**: Using a Bayesian Multi-Parameter Evidence Synthesis (MFES) framework, non-cost parameters were synthesized, informed by clinical trial evidence. Very few studies reported both median and mean treatment duration; direct use of the median under-predicted the mean by 23-39% and the published equation over-predicted the mean by 19-28%. Simple assumptions about the distribution of treatment durations performed best, predicting the reported means within ±12%. The current practice for the treatment duration over-predicted treatment duration by 5-38%, although estimates were improved by accounting for early discontinuation. **CONCLUSIONS**: By only considering the 50th percentile, the median may not provide an accurate representation of the outcomes in a population. It is important that researchers and budget-holders are aware of the limitations in the use of medians, and that they consider multiple estimation methods to estimate mean values for economic analyses.
scenario analysis was employed. PSA cut-off levels were varied between >3ng/ml and >4ng/ml reflecting European guidance and practice variation in Ireland. Costs and benefits were discounted at 5% per annum. RESULTS: Extensive probabilistic sensitivity analyses highlighted wide variation in incremental cost-effectiveness ratios (ICERs). PSA testing may be cost effective using a one-off test at age 50 or age 55 depending on the ceiling ratio incorporated. For the >4ng/ml PSA cut-off consistently dominated those for the >3ng/ml PSA cut-off. CONCLUSIONS: This analysis illustrates the value of MFS methods for economic modelling of intervention. The results contribute to the ongoing accumulation of evidence on the costs and benefits of introducing new internationally.

RESEARCH ON METHODS - Databases & Management Methods

PM56 PRELIMINARY STEPS IN THE DEVELOPMENT OF AN ALGORITHM FOR IDENTIFYING RELAPSED CLL PATIENTS IN SECONDARY DATA

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OBJECTIVES: Patients with chronic lymphocytic leukemia (CLL) treatment, roughly 25% of first and 50% of second line patients experience relapse. Relapse, however, is not well coded in claims data and is not well documented in EMR data due to under reporting of patient status, variability in terminology used to report patient status, and change in disease progression over time. The goal of this analysis was to develop an algorithm to identify relapsed patients when patient status is not clearly documented. METHODS: CLL patients in the MarketScan Oncology EHR database with recorded patient status were identified. Relapse was explored using two methods: 1) recorded patient status of relapse, 2) changes in laboratory data. For the first phase of algorithm development, both indications of relapse were compared to the date of treatment initiation. Laboratory data included lymphocytes, platelets, and hemoglobin. RESULTS: Of 18,334 patients with CLL, 7,865 (43%) had any patient status reported. 528 had any mention of either relapse or remission and 747 had a laboratory record for a date on or a date after the same date as a CLL diagnosis and no evidence of any other cancer types. For these 73 patients, the date of new treatment initiation had no relationship with the date of the first recorded relapse. Among these same patients, declines in hemoglobin and platelets, and increases in lymphocytes were the most frequently reported across several days. CONCLUSIONS: Patient status presently appear to be updated regularly and documented status may not indicate decision to treat. This preliminary algorithm suggests that lab data provide a viable source for algorithm development as they are regularly reported in the EHR and for CLL they are linked to decision to treat. Next steps include determining the specific rule for identifying the change in lab values that triggers treatment initiation or remission.

PM57 OCCURRENCE, SURVIVAL AND ANNUAL COST OF COLORECTAL-, BREAST-, PROSTATE- AND LUNG CANCER IN HUNGARY

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OBJECTIVES: Evaluating effectiveness of oncological treatments and their costs become increasingly important with respect to the high burden of malignant diseases. The aim of this research was to estimate the occurrence, survival and health care cost of colorectal-, breast-, prostate- and lung cancer patients based on the NHIF’s (National Health Insurance Fund) NHIF database. Patients with colorectal cancer were performed on the NHIF database. Inclusion criteria: at least two consecutive ICD codes between 2000 and 2012, with a minimum of 30 days difference; or those with one ICD code, followed by death within 60 days. Objectives were identified: C18-C20 (colorectal), C33-C34 (lung), C50 (breast), C61 (prostate). 428 860 social security numbers met our inclusion criteria. The following indicators were estimated: number of new cases, mortality, time from diagnosis to treatment, survival and annual costs related to and not related to the disease. RESULTS: In Hungary the number of new cases was the following: colorectal cancer: 7299 breast cancer: 5842, prostate cancer: 3162, and lung cancer: 5499. The probability of 5-year over-survival from first diagnosis were: 41.3%, 75.2%, 62.1% and 17.1%, respectively.

PM58 UPDATE OF THE PATIENT-REPORTED OUTCOME AND QUALITY OF LIFE INSTRUMENTS DATABASE (PROQOLID): INTEGRATION OF THE NEW COA TAXONOMY - THE CLINRO EXAMPLE

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OBJECTIVES: In 2002, PROQOLID was launched to provide an overview of existing PRO instruments. In October 2011, the term Clinical Outcome Assessments (COAs) was introduced to better reflect the importance of the source of information in measuring the effectiveness of care. Mapi began collecting (ClinROs) for the lack of such collection. In May 2013, a new category was added: Performance outcome assessments (PerROs). With this evolving taxonomy, including information about all COAs might become a crucial step in developing PROQOLID. The objective of this study was: (1) to review how ClinROs are currently reported in PROQOLID, and (2) to propose (if needed) ways of clarifying and updating ClinRO information. METHODS: PROQOLID was searched on April 3, 2014 to retrieve current information about ClinROs using an advanced search engine. RESULTS: The ClinRO information was found under the category “mode of administration” in the subcategory “clinician-rated.” Out of the 801 questionnaires in the database, fifty-two (6.5%) were identified as ClinROs. Out of these 52 questionnaires, nine were generic. Eight different therapeutic areas were identified (i.e., digestive system diseases, musculoskeletal diseases, neoplasms, nervous system diseases, respiratory tract diseases, psychiatric disorders, pathological conditions, endocrine, immunological, and connective tissue diseases), representing 17 different indicators, and 33.3% of the therapeutic areas included in PROQOLID. The most represented therapeutic area was psychiatry (n=23) followed by nervous diseases (n=7). Only two questionnaires were specific to children. The Pediatric Evaluation of Disability Inventory total and the WeCDTM. To better perform ClinRO information in PROQOLID, it is proposed to create a new meta-category, i.e., type of COA (PRO, ClinRO, ObsRO and PerRO). It is also recommended to expand PROQOLID in all new areas that have shown that PROQOLID includes ClinRO information. Recommendations are given on how to modify the organization and content of the database to present information on all COAs.

PM59 ECOA LICENSING: LESSONS LEARNED FROM THE COPYRIGHT OF COA TRANSLATIONS AND SPECIFICITIES OF ECOAS

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OBJECTIVES: Electronic Clinical Outcome Assessments (eCOAs) are increasingly being used in clinical trials and their use is encouraged by regulatory authorities. Licensing of eCOAs for research and clinical use is a major challenge. The objective of this review was to make recommendations about eCOA licensing using lessons learned from the COA translation licensing. METHODS: Publications about licensing of COA translations were searched in eCOA specific information available from e-vendors. RESULTS: Very few publications exist about the licensing of COA translations. The ISQuOL TCA SIG has developed a draft reflection paper on how best to do this. This work was performed using information available from e-vendors. RESULTS: Few very publications exist about the licensing of COA translations. The ISQuOL TCA SIG has developed a draft reflection paper on how best to do this. This work was performed using information available from e-vendors.

PM60 MAPPING EUROPEAN DATABASE USAGE: AN ANALYSIS OF PUBLISHED DATA TYPES

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OBJECTIVES: To determine how European databases are used to support pharmacoepidemiological research. HYPOTHESIS: Access to databases in Europe is not uniform. RESULTS: Of the 528 publications reviewed, 527 had any mention of either relapse or remission. As a consequence, there is a multiplicity of e-vendors for a same content. Equivalence between paper and e-versions and between e-versions is then a major concern. The review also shows that migration from paper to electronic platform/device implies changes to the content and format of the paper version. Therefore before the eCOAs are considered as complete original COAs and lessons learned from copyright of translations may apply. Examples will be provided. CONCLUSIONS: Centralized copyright ownership by the owner of the original COA and centralized licensing process for eCOAs should be discussed with all stakeholders to help controlling use and users and to protect the integrity of the instrument across e-versions by providing clear rules of e-implementation.

PM61 USING AN INNOVATIVE APPROACH TO BUILD A PROSPECTIVE DIABETES COHORT REGISTRY OF PATIENTS WITH TYPE 2 DIABETES IN GERMANY: DIAREG

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OBJECTIVES: The lack of longitudinal and large representative sources of medical and quality of life data in Germany has partially hindered the ability to research diabetes clinical practice. The aim of this study was to build a prospective, national, multi-centre Type 2 diabetes mellitus (T2DM) registry using an innovative data collection methodology to better understand the disease specific epidemiology, treatment patterns and
patient reported outcomes (PRO). METHODS: From the physician universe of the IMS® Disease Analyzer (500 diabetologists and 57,500 primary care practitioners), a sub-set of 101 physicians have agreed to participate. Pre-programmed inclusion criteria (i.e. ≥18 years old with T2DM diagnosis) triggers consecutive patient selection for further data collection. A custom software-based electronic case report form (eCRF) is conceived on the particular patient and collected by the physician. For this study, we aimed to change in financial condition and the price of EMR system. METHODS: From the hospital website and financial statement, we checked when and whether EMR was introduced. Then we analyzed the change in financial condition between the hospital with EMR and the hospital without EMR. There was 1% or more of difference in medical revenue. The average price of EMR for 1 year per 1 bed was US$328.8. CONCLUSIONS: The result also means that full EMR system contribute to hospital’s efficiency. Because of the high cost EMR system, making one big virtual hospital using IT technology is still difficult. Therefore, we need more cost effective and easy EMR system.

PRM62
INSIGHT IN HEALTH CARE DATABASES IN ASIAN PACIFIC REGION
Without EM

FO: Ministry of Health, The Netherlands

OBJECTIVES: Health care utilization databases or electronic medical records can be very useful to study the use and outcomes of pharmacological and therapeutic measures. There is little information on the availability and accessibility of these types of databases for health and disease evaluation.

METHODOLOGY: The study was performed to gain more insight in the availability and accessibility of health care utilization databases in AsiaPac.

METHODS: Searches were done using relevant search terms, e.g. Health care database, EMR, and references in publications. Different types of databases were included in the overview, including health insurance databases, claims databases and electronic medical records from primary care of hospitals. Information extracted was type of database, short description, population covered, start of data collection, variables included, accessibility, URL and English language yes/no. Countries included were Australia, China, Japan, South Korea, Malaysia, Singapore and Thailand.

RESULTS: Most of the databases originate in Japan and Australia. Taiwan and South Korea have a large health insurance databases covering ~98% of the population. Limited number of databases is available in the other countries investigated. Accessibility could only be derived from the websites that provide an English translation. From these websites it appears that the majority of them need to be identified. The use of HTA is mainly used by policy makers and researchers due to privacy protection issues.

CONCLUSIONS: Several valuable health care utilization databases exist in the Asian Pacific Region. These databases could be very valuable in drug utilization and health outcomes research if easily available to all researchers.

PRM63
EVALUATION OF DISSEMINATION OF BRAZILIAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT (REBRATS)

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OBJECTIVES: The Brazilian Network for Health Technology Assessment (REBRATS) spreads the HTA culture in health services and academic institutions, and also supports policy makers and managers in the decision-making process. It works through a network of six working groups that prioritizes HTA setting and themes; develops methodological guidelines; trains professionals; and manages and disseminates the products of the network.

METHODS: The strategies for advertising the network and disseminate the HTA products produced by its members have contributed significantly to the advance of HTA in Brazil, beyond the reach of people interested in this research field. Efforts should be directed towards advertising the production internationally.

PRM64
ANALYSIS OF THE EXPENSES FOR THE INTRODUCTION OF ELECTRIC MEDICAL RECORD SYSTEM IN THE NATIONAL HOSPITAL ORGANIZATION

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OBJECTIVES: Ministry of Health, Labour and Welfare (MHLW) of Japan announced the rule about electronic preservation of a medical record in 1997. Then, introduction of Electric Medical Record (EMR) in a hospital was started. Government set a target of diffusion rate of EMR to 60% in 2006, but the result was only 20-30%. It has been believed that EMR system improved efficacy of the hospital. But a pure financial meaning of EMR is still not clear. It is said that the total costs for maintaining EMR are 2-5% of medical revenue and they are continuously needed. In Japan, in order to increase the efficiency of a clinical trial/research, government is planning to set up one big virtual hospital using EMR and IT technology. In this study, we aimed to change in financial condition and the price of EMR system. METHODS: From the hospital website and financial statement, we checked when and whether EMR was introduced. Then we analyzed the change in financial condition between the hospital with EMR and the hospital without EMR. There was 1% or more of difference in medical revenue. The average price of EMR for 1 year per 1 bed was US$328.8. CONCLUSIONS: The result also means that full EMR system contribute to hospital’s efficiency. Because of the high cost EMR system, making one big virtual hospital using IT technology is still difficult. Therefore, we need more cost effective and easy EMR system.

PRM65
A DUTCH ADMINISTRATIVE DATABASE IN SUPPORT OF ECONOMIC EVALUATIONS: A FEASIBILITY STUDY

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OBJECTIVES: To support tariff setting of Diagnosis Related Groups in the Netherlands, we need to make sure all hospitals are systematically collected in a national database. This database may also serve as an important data source for economic evaluations. Our study assessed the feasibility of the database to support economic evaluations. METHODS: Treatment costs for acute myocardial infarction (AMI) and breast cancer were determined for 2012 from the hospital perspective, with the national database as the primary data source. RESULTS: In 2012, there were 30 hospitals that introduced EMR with the hospital without EMR, there was 1% or more of difference in medical revenue. The average price of EMR for 1 year per 1 bed was US$328.8. CONCLUSIONS: The result also means that full EMR system contribute to hospital’s efficiency. Because of the high cost EMR system, making one big virtual hospital using IT technology is still difficult. Therefore, we need more cost effective and easy EMR system.

PRM66
IMPACT OF INFLUENZA B IN FRANCE

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OBJECTIVES: To evaluate the burden of influenza B in terms of hospitalizations and deaths in France.

METHODS: The analysis of the impact of influenza B used 3 French databases 1) hospitalization for respiratory diseases, 2) deaths resulting from cardiorespiratory disease and 3) virological analysis through a regression model (considering all influenza circulation in France). The analysis covered the period 2003 through to 2011. The study is based on an indirect approach of modeling where hospitalization, mortality and virology time series data will be extracted as monthly or weekly aggregated information. The numbers of hospitalizations and deaths attributable to influenza B were determined from positive virological analysis through a regression model (considering all influenza circulation in France) and then by age category (0-4 years, 5-12, 15-64, 65 and above). A second method to estimate the excess of hospitalizations and deaths during influenza epidemic periods vs. non-epidemic periods was also used.

RESULTS: Over the period 2003-2011, nearly 28,000 hospitalizations and 12,000 deaths on average were associated with influenza each year. The percentages of hospitalizations and deaths attributable to influenza B were 33% (9,200) and 34% (4,000) respectively, amongst the overall population. These were observed predominantly in the elderly (+65 years) 66% of hospitalizations and 94% of deaths. The two methods used show similar results, with a difference of globally less than 5%.

CONCLUSIONS: On average each year around 9,300 hospitalizations and 4,000 cardiopulmonary deaths are associated with epidemics of influenza B in France.

PRM67
COMMON PREGNANCY SYMPTOMS INCREASE THE RISK OF CARDIOVASCULAR DISEASE

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OBJECTIVES: To identify the long term effects of common symptoms of pregnancy and whether these increase the risk of cardiovascular disease or symptoms associated with childbirth. METHODS: In women aged 21-39 from the Mater University Study of Pregnancy (MUSP), a community-based prospective birth cohort study begun in Brisbane, Australia, in 1983. Chi square test and logistic regression analyses were conducted.

RESULTS: Data were available for 4689 women. In cross tabulations, morning sickness, heartburn and backache show
positive association (p<0.05) with different cardiovascular outcomes. However, in the multiple models, only those experiencing heartburn were more likely to be assigned to 1, 3, 5% CI 1.0-1.7) during pregnancy were at greater risk of having hypertension 21 years post partum. Women experiencing morning sickness (adjusted OR 1.2, 95% CI 0.8-2.0) and backache (adjusted OR 1.1, 95% CI 0.6-1.7) were not considered to be at risk for having post partum hypertension. Our results suggest that most common symptoms of pregnancy are not associated with an increased risk of cardiovascular disease or with hypertension in the long term.

PM68 INCREASED ACCURACY OF DISTRIBUTION BASED MISSING VALUE IMPUTATION: AN ALTERNATIVE TO MEAN IMPUTATION IN REAL WORLD ENVIRONMENT

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OBJECTIVES: Missing values within variables can impede accurate data analysis on many levels including both univariate and multivariate analysis. This research presents distribution-based imputation (DBI), where the distribution of non-missing values is simulated to create a set of values that are then randomly inserted into the dataset. This approach is referred to as mixed treatment imputation (MBI). METHODS: DBI was compared to MBI in 12 different simulation conditions based on three sample sizes (50, 100, 150 and 200) and three different missing value percentages for each of the sample sizes (10%, 20% and 50%). Each simulation created 1,000 test datasets within each condition for a total of 12,000 simulated datasets. The statistical package, R was used for the simulation. RESULTS: MBI was biased by simulating smaller Standard Deviations, and less accurate in mean estimation than DBI in all 12 simulation combinations. DBI was more accurate in matching the number of rejected hypotheses as compared to the gold standard. Comparing the calculated p-values for bias where an unbiased estimator would demonstrate a 50% rejection rate, being greater than the fold standard error, DBI was closer to the gold standard with at 48/75/1.3 split, as compared to the 25/87/4.2 split of MBI. CONCLUSIONS: DBI was found to be more accurate and unbiased as compared to MBI. As a result, when sample sizes are small and/or data do not contain a large number of variables, or in situations where more elaborate imputation methods cannot be done, DBI is an accurate and unbiased method.

PM69 INDIRECT COMPARISON OF THE EFFECTS OF ANTI-TNF BIOLOGICAL AGENTS IN PATIENTS WITH ANKYLOSING SPONDYLITIS BY MEANS OF A MIXED TREATMENT COMPARISON PERFORMED ON EFFICACY DATA FROM PUBLISHED RANDOMISED, CONTROLLED TRIALS

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OBJECTIVES: To carry out an ASAS (Assessment in Ankylosing Spondylitis Response Criteria) 20 response patterns between anti-TNF biological agents in patients with ankylosing spondylitis by means of a mixed treatment comparison of different randomised, controlled trials (RCTs) on the efficacy of biological therapies. METHODS: A systematic review of literature was performed to identify a number of similarly designed double-blind, randomized, placebo-controlled trials investigating the efficacy of the TNF-α inhibitors etanercept, infliximab, golimumab, certolizumab pegol and adalimumab in the treatment of ankylosing spondylitis patients, conducted over an 18-year period. The endpoint of interest was ASAS20 response criteria at 12 weeks. Results were analyzed simultaneously using Bayesian mixed treatment comparison techniques. Results were expressed as odds ratio (OR) of ASAS20 response and associated 95% credible intervals (CIs). The probability of being the best treatment was also reported. RESULTS: 6 RCTs were selected for data extraction and further analysis. By means of a mixed all TNF-α agents, it was related to be significantly effective in inducing a ASAS20 response than placebo. Infliximab shows a 67.6% of probability of being the best treatment of all. Adalimumab, golimumab and etanercept show probabilities of 17.2%, 10.6% and 6%, respectively, while certolizumab pegol showed a probability of being the best treatment of 0.1%. No differences were observed when comparing directly an anti-TNFα against another. CONCLUSIONS: Even if the mixed treatment comparisons between infliximab, golimumab, certolizumab pegol, adalimumab and etanercept did not show a statistically significant difference, this analysis suggests that infliximab, compared to placebo, is expected to provide the highest rate of ASAS20 response in SA patients naive to biologic treatments.

PM70 A TUTORIAL ON DIMENSIONALITY REDUCTION IN LARGE CLAIMS DATA SETS

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OBJECTIVES: The objective of this presentation will be to introduce the audience to various data dimension reduction techniques that may be applied in the setting of a large commercial claims data set to facilitate the task of identifying important factors or key features for use in subsequent analysis. METHODS: The author will provide a brief survey of the data dimension reduction literature from areas as diverse as computational biology and network science. The author will then evaluate three approaches of creating baseline patient profiles for simulation models. 10 samples of 1000 patients each were created through 1) random sampling from the entire NHANES dataset, 2) using expert-generated random samples, and 3) using the NHANES dataset. The predicted 10-year cardiovascular disease (CVD) rates using the NHANES entire dataset were 18.2% for males and 9.7% for females using the random sampling approach, 14.5% for males and 7.9% for females using the mean and standard deviation approach and 16.0% for males and 9.2% for females using the cholesky decomposition approach. The CVD rates using the NHANES entire dataset were 18.2% for males and 9.7% for females using the random sampling approach, 14.5% for males and 7.9% for females using the mean and standard deviation approach and 16.0% for males and 9.2% for females using the cholesky decomposition approach.
population are 18.5% for males and 9.8% for females. **CONCLUSIONS:** Random sampling from patients provided data for the best estimation of actual NHANES population predicted CVD rates. Thecholesten decomposition approach was slightly limited since only continuous variables could be utilized which could explain the deviation from the population predicted CVD rates. Independent sampling under-estimation is to be expected. In general, many individual simulation models created patients with this approach. Researchers should be cautious in their use of summary statistics when populating individual simulation models.

**PM74**

**VALIDATION OF THE SPHR DIABETES PREVENTION MODEL**

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**OBJECTIVES:** We have developed a model to evaluate type 2 diabetes prevention interventions. We aimed to validate this model against external data to test the accuracy of the model. **Methods:** An individual patient simulation was developed to predict longitudinal trajectories of HbA1c, 2-hr glucose, FPG, BMI, systolic blood pressure, total cholesterol and HDL cholesterol based on statistical analyses of the Whitehall II longitudinal cohort. Criteria for diabetes diagnosis wereflexibly specified. We applied three different correction methods (standard half-cycle correction, Simpson’s half-cycle correction, and using the mid-cycle values) and we also looked at the results without any correction. We assessed the model’s ability to predict complications of diabetes were estimated from the UKDFDS outcomes model. Several validations were performed to compare model outputs with reported data from external sources. We assessed the predicted diabetes incidence using data from the EPIC Norfolk cohort. Data from the Health Survey for England (HSE) 2003 cohort was simulated for eight years to compare predicted disease incidence and metabolic distributions with HSE 2011 data. We compared microvascular, cardiovascular and mortality outcomes in a diabetic population with those observed in the UKDFDS. We assessed the performance of the model in predicting the results of the ADDITION trial for diabetes screening. **RESULTS:** We found that the model overestimated three-year incidence of diabetes, particularly in high-risk individuals (HbA1c > 6.0 mmol/l), but underestimated diabetes incidence in medium risk individuals (HbA1c 5.5-5.9) compared with the EPIC-Norfolk data. Predictions from HSE 2003 were fairly accurate. Predictions for mortality were similar to the Weibull distribution, and under-estimated mortality were slightly under-estimated. The model replicated the non-significant difference seen between control and intervention arms of the ADDITION trial, but overestimated total mortality and cardiovascular disease. **CONCLUSIONS:** The SPHR Diabetes model appears to be fairly accurate at predicting diabetes incidence, but there is a tendency to overestimate mortality rates in a newly diagnosed diabetic cohort, and underestimate cardiovascular disease and mortality compared with the UKDFDS.

**PM75**

**USE OF MODEL AVERAGING TECHNIQUES IN COST-EFFECTIVENESS ANALYSIS IN ONCOLOGY**

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**OBJECTIVES:** Often in cost-effectiveness analysis (CEA) of oncologic drugs, survival data from clinical trials are extrapolated to a lifetime horizon using parametric regression techniques. To capture parameter uncertainty in the analysis, regression parameters along with other model parameters are varied in probabilistic sensitivity analysis. However, structural uncertainty in the choice of regression model is unaccounted for. This study describes an extensive CEA framework that provides an example to address structural uncertainty in CEA. **METHODS:** Using a cohort partition model, the numbers of patients in “progression-free,” “progressed,” and “dead” were calculated from progression-free survival (PFS) and overall survival (OS) curves. Weibull, exponential, lognormal, log-logistic, generalized gamma, and Gompertz parametric models were used to extrapolate these curves to a lifetime horizon. Total costs, life year (LY), and quality adjusted life year (QALY) for each regression model were calculated, based on weights that were derived from Akaike’s or Bayesian Information Criterion (AIC or BIC) parameters. **RESULTS:** Evaluating solely on BIC values, the lognormal distribution was the best model for both survival curves. This resulted in the lowest observed ICERs. When model selection was based on considerations involving the log-cumulative hazard plots, clinical plausibility, and AIC/BIC for each distribution, the Weibull distribution was selected for both curves, resulting in a 29% and 27% increase in the ICER for QALY and LY, respectively. Similar increases were observed when model averaging was applied using BIC-derived weights. In this case, model averaging produced results that were similar to those where model selection was based on multiple criterions.

**CONCLUSIONS:** Choice of parametric models often has the biggest impact on the outcomes in CEAs in oncology. Model averaging takes into account the structural uncertainty surrounding the choice of parametric models.

**PM76**

**COMPARING THREE DIFFERENT METHODS OF HALF-CYCLE CORRECTION**

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**OBJECTIVES:** We present a model decision based on fuzzy logic, and apply to off label use of antiTNF in Crohn’s disease (CD) (Infliximab (IFB) 30 mg/kg x 12 weeks, adalimumab (ADA) 80mg/2 weeks, Cetolizumab (CZB) 200mg/2weeks). The term “fuzzy logic” (FL) was introduced in 1965 by Zadeh. Compared to traditional logic, FL variables may have a truth value in degree. FL has been applied to many fields, from medical research to economics. With the increasing use of summary statistics when populating individual simulation models. We found that the model overestimated three-year incidence of diabetes, particularly in high-risk individuals (HbA1c > 6.0 mmol/l), but underestimated diabetes incidence in medium risk individuals (HbA1c 5.5-5.9) compared with the EPIC-Norfolk data. Predictions from HSE 2003 were fairly accurate. Predictions for mortality were similar to the Weibull distribution, and underestimated mortality were slightly under-estimated. The model replicated the non-significant difference seen between control and intervention arms of the ADDITION trial, but overestimated total mortality and cardiovascular disease. **CONCLUSIONS:** The SPHR Diabetes model appears to be fairly accurate at predicting diabetes incidence, but there is a tendency to overestimate mortality rates in a newly diagnosed diabetic cohort, and underestimate cardiovascular disease and mortality compared with the UKDFDS.

**PM77**

**MULTI-CRITERIA DECISION ANALYSIS (MCD A): TESTING A PROPOSED MCD A MODEL FOR ORPHAN DRUGS**

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**OBJECTIVES:** Since the introduction of the orphan drugs in Europe, it has been suggested that the general method of appraising drugs for reimbursement is not necessarily suitable for orphan drugs. The National Institute for Health and Clinical Excellence indicated that several criteria other than cost and efficacy could be considered in reimbursement decisions for orphan drugs. The aim of this study was to develop a framework for reimbursement of orphan drugs and to test its validity. We applied a literature review identified further commonly cited criteria: ‘convenience of administration’, ‘age of the target population’, ‘quality of life’, and ‘drug innovation’ that were added to the aggregate index scores. In the drugs studied, the $KW was 0.828 and 0.704 when costs were included and not included, respectively. The standard error of the slope varied from 7711.9 to 11433.3 when costs were included and not included, respectively. **CONCLUSIONS:** This quantitative study provided insight into using MCD A and its framework that was proposed by Delphi. The results of this study provide a tool for reimbursement decisions for orphan drugs. The potential for therapy-specific MCDAs and how to inform value-based pricing assessment.

**PM79**

**ADVISE: A NEW TOOL TO REPORT VALIDATION OF HEALTH-ECONOMIC DECISION MODELS**


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**BACKGROUND:** Modelers and reimbursement decision makers could both profit from a more systematic reporting of the efforts to validate health-economic (HE) models. **OBJECTIVES:** Development of a tool to systematically report validation efforts of HE decision models and their outcomes. **METHODS:** A gross list of model validation techniques was collected using a literature review, including sources outside the HE field. A panel then selected the most important items. Based on the selected techniques, the panels members could score items in three-e cycles and rounds. Participants were HE modelling experts, covering various nationalities and work environments. They could comment on relevance, feasibility and formulation of the items and received feedback on comments from others. This resulted in a draft tool of selected items, which was tested and improved in two further rounds. In
addition, the Dutch National Health Care Institute commented on usefulness for decision makers. A separate group of experts could comment during a workshop at ISPOR Montreal 2014. RESULTS: 35 Validation techniques were identified and grouped into four categories: conceptual model validation, computerized model validation, data validation and operational validation. Around 30 HE experts commented on the list, providing three different versions of the item draft tool. The Dutch health care advisory institute suggested to add one more item. Participants from the ISPOR workshop delivered 19 filled-in questionnaires. A fourth round was conducted for focus groups. This led to an updated version 16 items, which is currently sent out for a final, fifth round. CONCLUSIONS: When filled out by the modellers, AVICE (Assessment of the Validation Status of Health Economic decision models) supports model users in assessing the validation status of a model. It will be useful as part of reimbursement dossier by providing systematic and transparent insight into the validation efforts performed and their results.

PRM80

MODELLING SURVIVAL IN THE PRESENCE OF DIFFERENT MECHANISMS OF PROGRESSION (TTP) and overall survival (OS) are typically required, notably when OS data are immature or unavailable. A review was undertaken to identify the methods that have been used within health economic models regarding this relationship and to identify the strengths and weaknesses of each specific modeling approach. METHODS: The review included all relevant appraisal documents publicly available on the NICE website containing information on the methods used and/or rationale for the approach taken to model the relationship between OS and PFS/TTP within the health economic model. This included the sponsor submission and updated analyses, the cost-effectiveness report, decision analysis and other reports/presentations. RESULTS: In those instances where OS data were immature or not available, PFS/TTP was typically assumed to be a valid surrogate of OS. Justification for this assumption was incompletely reported. In some models, a quantification of the assumed relationship was informed by published evidence and/or expert judgement. In some cases attempts were made to explore the potential impact of this relationship in sensitivity analysis. CONCLUSIONS: The methods and/or rationale for the approach taken to model the relationship between OS and PFS/TTP in health economic models has been inconsistently reported and justified. Whilst some health economic models attempted to quantify this relationship, further transparency is required. A consensus needs to emerge on the most appropriate methods to be used within health economic models to quantify this relationship, specifically when OS data are not available or immature and to identify the circumstances when particular approaches may be most relevant.

PRM83

COMPARISON OF METHODS TO ESTIMATE HEALTH STATE UTILITIES IN METASTATIC BREAST CANCER (MBC)

Methods: The aim of the study was to assess the degree of consistency and rationale given for the approach taken, specifically in those situations where OS data were immature or not available: utility ‘mapping’ from existing disease-specific scales, vignette studies that describe the health states, or derivation of preference-based measures from an existing condition-specific scale. This study compares utility estimates in MBC utilizing the above methods. METHODS: Based on data from a phase 3 clinical trial in MBC (N=1102) utility mapping was conducted using a published regression algorithm to convert the QLC-33 questionnaire to the EQ-5D utility. Mean utility values were estimated for relevant health states: stable disease (SD), tumor response (TR) and disease progression (DP). Results: Compared to previously published values obtained for a vignette study conducted in one hundred members of the general public: RESULTS: Observed MBC utilities were similar in mapping vs. vignette studies for SD: 0.697 vs. 0.715, and TR: 0.782 vs. 0.790. General public respondents in the vignette study assigned much lower utility to symptomatic DP (0.443 vs. imaging-based DP in mapping study 0.679); and disutility for toxicities: vomiting: 0.103 vs. 0.050; fatigue 0.115 vs. 0.029; febrile neutropenia 0.152 vs. 0.033; hand-foot syndrome 0.102 vs. 0.027. Hand-foot syndrome and hair loss were not associated with disutility in the mapping study (potentially due to small sample size) while disutility of 0.116, 0.151, and 0.114 were reported by the vignette study. CONCLUSIONS: Utilization of different methods to estimate utilities in MBC may lead to a wide range of estimated values with potentially significant implications for health economic evaluation. Caution must be exercised when comparing utility values derived using different methods. It is preferable to collect such data from patients directly and use vignettes as a last resort.

PRM84

COST-EFFECTIVENESS MODELS FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): CROSS-MODEL COMPARISON OF HYPOTHETICAL TREATMENT SCENARIOS

Methods: Seven out of nine contacted COPD modeling groups agreed to participate. Differences in 5-year QALY gains ranged from 0.0002 to 0.039 for intervention one, 0.089 to 0.075 for intervention two and 0.1618 for intervention three. The difference in costs ranged from €561 to €912 for intervention one, €379 to €1530 for intervention two and €140 to €1618 for intervention three. The 5-year cost-effectiveness ratios (ICERs) for the most comprehensive intervention, intervention four, was €17,000/QALY for two models, €25,000+8,000/QALY for three models.
and 474,000/QALY for the remaining two models. Differences in the outcomes could mainly be explained by differences in input values for disease progression, exacer-
"badation-related mortality and all-cause mortality with high input values resulting in low ICERs and vice versa. Lifetime results were mainly influenced by the input values for mortality. The probability of intervention four to be cost-effective at a willingness to pay was 30% (200,000/QALY) and 50% for the other two models. CONCLUSIONS: Mortality was the most important factor determining the differences in cost-effectiveness outcomes between models.

PRM85: A DE-NOVO MODEL TO PREDICT OUTCOMES OF A NEW HYPOTHE
tical INTERVENTION TO REDUCE CV RISK IN POST MI PATIENTS

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OBJECTIVES: The study aimed to develop a cardiovascular (CV) events in post myocardial infarction (MI) patients poses a significant burden on the UK health care system despite the current standard of care (SoC). The objective of this analysis was to develop a model to quantify the relationship between efficacy and outcomes of a new hypothetical drug compared well with other published studies. For a cohort of patients aged 40-years, the model predicted on an average, 1.7% of 13.64. A hypothetical drug was assumed to be effective in reducing the relative risk of CV events in post MI patients when compared to SoC. METHODS: A 6-green state Markov model with a 1-year cycle length was developed from a UK health care perspective. Recurrent MI, stroke and CV death were modeled. The hypothetical drug was assigned efficacy values for its ability to reduce the incidence of CV events. The outcomes were measured in terms of QALYs and LYS. A linear regression model was fitted to estimate the expected outcome/patient based on relative risk reduction (RRR) in the incidence of CV events. All outcomes were discounted at 3.5% annually. RESULTS: The model structure addressed some of the limitations of previous economic models, namely increased risk due to stroke in MI patients and increased risk of subse-
quent events in the first year. For identical costs, the outcomes from the model compared well with other published studies. For a cohort of patients aged 40-years, the model predicted on an average, 1.7% of 13.64. A hypothetical drug was assumed to be effective in reducing the relative risk of CV events in post MI patients when compared to SoC.

REFERENCES: Other methods and their outcomes were compared.

CONCLUSIONS: A de-novo economic model quantifies the relationship between the efficacy and outcomes of a hypothetical drug when compared to the SoC to reduce the risk of CV events in post MI patients.

PRM86: ESTIMATING THE LIFETIME HEALTH OUTCOMES OF TYPE 2 DIABETES Mellitus (T2DM) PATIENTS INADEQUATELY CONTROLLED ON Metformin PLUS Sulphonylurea RECEIVING EITHER Canagliflozin OR Sitagliptin Using the UKPDs Outcomes Model v1.3

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OBJECTIVES: The goals of type 2 diabetes management are to control glycaemia and other micro- and macrovascular risk factors such as weight, blood pressure and lipids in order to prevent death and other complications due to the disease. The natural history of the disease makes it challenging to estimate the effects of treatments on these endpoints. Therefore, computer simulation is a useful tool to generate standard clinical clinical. Modelling is therefore a key bridging tool for predicting long-term health outcomes from inter-
mediate endpoints. The objective of this analysis was to estimate the relative effects of canagliflozin 300mg and sitagliptin 100mg on mortality- and macrovascular complications in T2DM patients in triple line as add on to metformin plus sulpho-
ylurea using the UKPDs Outcomes Model v1.3. METHODS: A probabilistic patient generator was developed which generated 10,000 patients with applied treatment based on input parameters such as age, sex, body mass index (BMI), and geographical location. The patients also entered the model with baseline characteristics and were looped in terms of QALYs and LYS per percentage point reduction in relative risk as compared to SoC was estimated to be 0.043 and 0.054 respectively. CONCLUSIONS: A de-novo economic model quantifies the relationship between the efficacy and outcomes of a hypothetical drug when compared to the SoC to reduce the risk of CV events in post MI patients.

PRM87: DETERMINISTIC VERSUS STOCHASTIC PREDICTION OF RISK FOR CARDIOVASCULAR EVENTS

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OBJECTIVES: Multivariate functions can be used to predict individual risk for car-
diuvascular (CVD) events and also to estimate baseline risk in economic models. We present a comparison of deterministic versus stochastic risk predictions using Framingham’s [D’Agostino 2008] and ReaCH [Wilson 2012] functions. Stochastic risk prediction accounts for patient-level heterogeneity, but involves a number of issues in terms of data requirements and the need for time-dependent (stochastic) and computational burden. To our knowledge, this topic has not been studied in the CVD setting. METHODS: D’Agostino 2008 and Wilson 2012 modeled primary (FY) and recurrent (FYR) outcomes respectively. Both studies considered fatal and non-fatal CVD events and estimated a Cox Proportional Hazards (PH) multivariate regression model. In the deterministic prediction, the means of the risk factors were used to predict the risk. Anonymity risk factors from a hypothetical drug and clinical trial, individual patient profiles (n=10,000) were generated using Monte Carlo simulation. Individual risks were then estimated from the functions and averaged to compute the population’s risk. Multicomparative distributions were assumed for discordant data (e.g. diabesity scores on vascular beds) and normal or log-normal mortality. Distributions were assumed for continuous variables depending on skewness (e.g. age, total cholesterol). Probability distributions were parameterized based on the risk factors descriptive reported in the original references. Simulations were performed with and without considering dependence of risk factors. RESULTS: Due to the non-
linearity of the CPH function, the stochastic prediction yielded 23% (PE) and 17% (RE) higher risks than the deterministic approach (14% and 10%, respectively, if age was not included). Differences between predictive approaches are even higher if the estimated correlation structure of risk factors is accounted for. CONCLUSIONS: Compared to the stochastic prediction, the deterministic approach leads to lower estimates of CVD events.

PRM88: ARE CYCLES NEEDED IN MARKOV MODELS? - THE CONTINUOUS MODEL AS A SIMPLER APPROACH

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OBJECTIVES: To present an alternative implementation for the conventional Markov model with area under the curve (AUC) approach: the continuous model (CM).

METHODS: To compare whether the CM around 20 million patients in each arm) of a 40-years simulations. Outcomes were discounted 3.5% annually. RESULTS: At the end of the 40 years simu-
lation, patients initiating canagliflozin 300mg had 49 more survivors and 1,918 fewer death from diabetic deaths. Micro- and macrovascular complications were estimated to be in fewer patients on canagliflozin 300mg than on sitagliptin 100mg (between 5,948 fewer renal failures and 41,157 fewer myocardial infarctions). There were discernible relative risk reductions in all complications and diabetes-death related ranging from 40% (heart failure) to 2.96% (amputation). CONCLUSIONS: Results of the analysis using the UKPDs Outcomes Model v1.3 suggest that canagliflozin 300mg compared with sitagliptin 100mg added on top of metformin plus sulphonylurea reduces long-term diabetes-related mortality and complications.

PRM89: ALL-CAUSE MORTALITY VALIDATION OF THE CORE DIABETES MELLITUS MODEL AGAINST PREDICTIONS OF THE CHARSOM COMORBIDITY INDEX

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OBJECTIVES: All cause mortality (ACM) validations with the IMS CORE Diabetes Model (CDM) have demonstrated below average fit when compared to overall vali-
dation scores from 96 validation endpoints (EP) with a R²-statistic of 0.651 (vs. 0.93 All-EP). Lack of fit was associated with a model overestimation of ACM when compared to contemporary outcome studies [ACCORD, ADVANCE, VADT]. The objective of this investigation was to put these findings into perspective by compar-
ing the results to fit and risks predictions from the Charlson-Sornsen-Comorbidity Index (CCI).

METHODS: The CCI was applied to predict the 10-year mortality risk for diabe-
tes patients with age of 50,60,70 and 80 years and four different co-morbidity levels: no comorbidities (CCO), cardiovascular risk (CCV), M1 and stroke (M1-S), M1-S and heart failure (M1-S+HF) and M1-S+HF and renal failure (M1-S+HF+RF). CCI mortality scores were compared to corresponding 10 year ACM predictions from the CDM. The results of analyses applied using UK68-RE for CV risk and mortality. Two sets of sensitivity analyses were conducted using UK68-RE for CV risk but mortality tracked individually per complication event (non-combined mortality approach) (SA1) and UK68-RE risk equations (UK82-RE) applied for CV risk and mortality. RESULTS: The AUC predictions demonstrated the closest match to CCI-scores in SA1 with an R²-statistic of 0.872. This compared to R²-statistics of 0.757, and 0.85 for BC and SA2, respectively. BC and SA2 analyses noteworthy underestimated ACM risk in analyses with increased co-morbidity level by 68% (BC) and 49% (SA2) vs. 17% (SA1) in (M1-S+HF) and 44% (BC) and 36% (SA2) vs. 3% (SA1) in (M1-S+HF+RF). CONCLUSIONS: The CDM demon-
strated a closer match to CCI mortality scores (vs. outcome studies) with a trend to underestimate ACM. This trend increased with baseline age and (only BC and SA2) co-morbidity level.

PRM90: A COMPARISON OF MODELLING TECHNIQUES: PATIENT SIMULATION VERSUS MARKOV MODELLING IN OPHTHALMOLOGY

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OBJECTIVES: Markov models are a currently popular means of estimating the cost-
effectiveness of interventions; however they are associated with certain limitations which may make them ill-suited to inform some health care decisions. Patient simul-
ation models offer an alternative methodology which may overcome some of these
limitations potentially provide more accurate estimates of the cost-effectiveness.

This study aims to explore the strengths and limitations associated with simula-
tion modelling, and the appropriateness of this methodology in ophthalmology.

**METHODS:** An ophthalmology model that was previously developed using a Markov
structure was adapted to a patient simulation model using the same cost and quality
of life inputs, and additional parameters adapted to the patient population. Deter-
ministic and probabilistic results of each model were then compared to each other,
with the costs being broken down by health state to identify key areas of differences.
Each model was compared against real-world observational data. **RESULTS:**
Results suggest that cost and quality of life outcomes are similar when unilateral
disease is considered, with differences in quality of life and costs being seen when
diseases is in the integrated. The area of difference in areas is that those relating to
blindness, as this is a function of both eyes which is not captured well in the Markov
model. One-off costs when a patient becomes blind are also not well captured in a
Markov model. **CONCLUSIONS:** Our results suggest that the ability of simulation
models to capture the progression of the really path to the best supportive care, and that
be cannot be easily done using a Markov structure. In particular, the benefits of a simulation approach
can be demonstrated in the modelling of quality of life as a function of visual acuity in
both eyes, and capturing the costs relating to blindness, resulting in differences in
estimated cost effectiveness.

PREM1

**THE ONCOTyROL PROSTATE CANCER OUTCOME AND POLICY MODEL - HOW LATENT PREVALENCE AFFECTS THE BENEFIT-HARM BALANCE OF SCREENING**

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OBJECTIVES: The objective of this study was to use data on the benefits and harms of screening
and of the natural history and detection component of the original screening model,
then recalibrated the natural history and detection component of the original
model used to simulate PCa progression in the licensed assessments of the ICERs.

**METHODS:** We perform a literature review of published papers on the benefits and harms of
screening, searching for studies that used simulation models to simulate the
natural history and detection component of the original model. We then recalibrated
the natural history and detection component of the original model using a
microsimulation model designed to evaluate prostate cancer screening in the
NHS Economic Evaluation Database and EconLit. The results of the sensitivity analysis are
then compared to each other, identifying the key areas of differences in the
models. **RESULTS:** The incremental cost-utility ratio (ICUR) of cetuximab
treatment compared to conventional therapy for metastatic colorectal cancer
(mCRC) is well implanted and has been subject of different economic evaluations. The objective of this study was to use data on the benefits and harms of screening and of the natural history and detection component of the original
model used to simulate PCa progression in the licensed assessments of the ICERs.

**CONCLUSIONS:** Our results suggest that the ability of simulation models to capture the progression of the really path to the best supportive care, and that
be cannot be easily done using a Markov structure. In particular, the benefits of a simulation approach
can be demonstrated in the modelling of quality of life as a function of visual acuity in
both eyes, and capturing the costs relating to blindness, resulting in differences in
estimated cost effectiveness.

PREM2

**SYSTEMATIC OVERVIEW OF VALUE-OF-INFORMATION ANALYSES IN CANCER RESEARCH**

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**OBJECTIVES:** The ONCOTyROL Prostate Cancer Outcome and Policy (PCOP) model is a state-transition micro-simulation model designed to evaluate prostate cancer (PCa) screening. We used the model to investigate how the benefits-harm balance of PCa screening is affected by the size of the latent prevalence pool. For this pur-
pose, we recalibrated the natural history and detection component of the original
PCOP model adopted from an earlier version of the Erasmus MSCAN model to match higher
prevalence observed in the literature. The benefits-harm balance of screening predicted by the recalibrated model were then compared with predic-
tions from the original model. **METHODS:** For calibration, we reprogrammed the
natural history and detection component of the PCOP model as a deterministic
state-transition model with stage- and grade-specific cancer states in the statisti-
cal software package R. All parameters were implemented as functions or variables
and calibrated simultaneously in a single run using the ‘imin’ optimization
algorithm available in R to minimize the deviation of model predictions from
observed data. Calibration targets were observed data from autopsy studies, cancer
registries and the European trial (ERSPC). Both the recalibrated and original models
were then calibrated to match real-world observational data. **RESULTS:** The recalibrated
model accurately predicted key outcomes (e.g., prostate cancer cases, cancer deaths, health care costs) and produced ICURs for QALYs that were similar
in the range than those reported in the literature. Although further validations will
be performed, the model will appear to produce quick, but accurate estimates.

PREM3

**A SYSTEMATIC SEARCH AND METHODOLOGICAL REVIEW OF ECONOMIC MODELS OF HEALTHCARE (HC) DECISIONS FOR CHRONIC DISEASES**


**OBJECTIVES:** Economic modelling of analogues for chronic pain (including the chronic pain sub-populations of musculoskeletal, neuropathic and malignant pain) is well established but characterised by methodological heterogeneity. The methods used to model pain progress substantially between and within the sub-populations and this variability inhibits comparability across the evidence base. This research aims to investigate the similarities and differences in the characteristics of economic models used to summarising existing published economic models and identifying key model charac-
teristics. **METHODS:** A systematic search and methodological review of published economic models of chronic diseases for chronic pain was performed. MEDLINE, EMBASE, Health Technology Assessment, NHS Economic Evaluation Database and EconLit were accessed in April 2014 and, from studies that met the inclusion criteria, key methodological data were extracted and analysed. **RESULTS:** Thirty-four studies were included in the final review. From the original 96 references, 62 were identified. Outcomes considered alongside analgesic effect varied substantially
across studies. Assumptions were used to model multiple treatment lines in eleven model structures. Only three models used a time horizon greater than one year.

The inclusion of the costs of adverse events was common (eleven models) but less
prevalent in neuropathic pain models than for other chronic pain states. Finally the
majority of models used a Markov structure but four of ten neuropathic pain models used decision trees. **CONCLUSIONS:** Some methodological similarities can be identified when considering economic modelling within sub-populations in particular neuropathic pain. However, there is scope for further consensus in the key design elements, in particular the choice of transition probabilities. Further research is required to identify the strengths, weaknesses and complexities of the key modelling choices. **FUNDING STATEMENT:** This research was funded by Mundipharma International Limited.

PREM4

**PRELIMINARY CLINICAL TRIAL STUDIES CONSIDERING QUALITY OF LIFE OUTCOMES**

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**OBJECTIVES:** The objective of this study was to identify key areas of differences in the models. We then recalibrated the natural history and detection component of the original model using a
microsimulation model designed to evaluate prostate cancer screening in the licensed assessments of the ICERs.

**METHODS:** We perform a literature review of published papers on the benefits and harms of screening, searching for studies that used simulation models to simulate the
natural history and detection component of the original model. We then recalibrated
the natural history and detection component of the original model using a
microsimulation model designed to evaluate prostate cancer screening in the licensed assessments of the ICERs.

**CONCLUSIONS:** Our results suggest that the ability of simulation models to capture the progression of the really path to the best supportive care, and that
be cannot be easily done using a Markov structure. In particular, the benefits of a simulation approach
can be demonstrated in the modelling of quality of life as a function of visual acuity in
both eyes, and capturing the costs relating to blindness, resulting in differences in
estimated cost effectiveness.
years (QALYs). Thus, considerations on QoL outcomes in the clinical trial design phase have been recommended. The aim of this study was to develop a trial simulation model that is capable of addressing complex research questions, provides flexibility to test various assumptions, and predicts expected QALY outcomes.

METHODS: A patient-level simulation model was developed using hypothetical data in oncology. The model considered two treatment arms: the intervention and the control arm. The model was validated using the external validation.

RESULTS: The model accurately predicted the ECLIPSE outcomes in at least two of the three annual time points within the specified error percentage. The model more accurately predicted the ECLIPSE annual observed data from ECLIPSE (n=2,164) trials based on fitting the model baseline parameters to the external validation dataset.

CONCLUSIONS: As expected, the model more accurately predicted the ECLIPSE outcomes against both the data used to generate the model (internal validation) and clinical trial data not used in the model's development (external validation). The model accurately predicted the ECLIPSE outcomes in at least two of the three annual time points within the specified error percentage. The model accurately predicted the ECLIPSE outcomes in at least two of the three annual time points within the specified error percentage. The model accurately predicted the ECLIPSE outcomes in at least two of the three annual time points within the specified error percentage. The model accurately predicted the ECLIPSE outcomes in at least two of the three annual time points within the specified error percentage.
**PRM101**

**APPLICATION OF A MODEL OF DECISION BASED ON FUZZY LOGIC TO PHARMACOECONOMICS: RANIBIZUMAB VERSUS AFLIBERCERT IN AMD**

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**OBJECTIVES:** The term “fuzzy logic” was introduced in 1965 by Zadeh. Compared to traditional logic, fuzzy logic variables may have a truth value in degree. Fuzzy logic has been applied to many fields, from economic analysis, to artificial intelligence. However it has not been applied so far to pharmacoeconomics. We present a model of pharmacoeconomic decision based on fuzzy logic (Fuzzy Economic Review 2001; 6 (2) 51-73) and applied to the selection of ranibizumab-aflibercept in treating AMD. METHODS: According to a decision analysis model based on fuzzy logic, fuzzy variables that affect the choice of treatment are defined: treatment success (expressed as a probability), cost of success, cost of failure (expressed as inverses), and cost of complications. For the cost (need for further treatment) we assumed the use of the value of these fuzzy variables, three linguistic variables (High, Medium, Low) are defined to express convenience of choice. The combination of the three possible values for each of the variables gives us 81 possible decision rules, so that the fit (HI) would be the most favorable option and (LLL) the most unfavorable. So a new fuzzy variable called “ranking” is established for classifying these options with 7 possible values (Very-unfavorable, unfavorable, slightly-unfavorable, neutral, slightly-favorable, favorable, very-favorable). The value of the fuzzy variables for ranibizumab and aflibercept were established based on pivotal clinical trials at 52 weeks cited by the EMEA. RESULTS: The matrices obtained for ranibizumab was (0.293, 55 10^-5, 1.36 10^-5, 0.7), and aflibercept (0.267, 7.4 10^-4, 2.59 10^-4, 0.3). These matrices have triangular membership functions and correspond to a ranking of “neutral” and “slightly-favorable”. CONCLUSIONS: It is possible to apply methods of “fuzzy logic” to pharmacoeconomic studies to select the most favorable treatment. If treatment, with aflibercept would be a slightly more favorable option than ranibizumab.

**PRM102**

**DEVELOPMENT OF AN INFLUENZA OUTBREAK FORECASTING MODEL USING TIME SERIES ANALYSIS METHODS**

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**OBJECTIVES:** To use historical influenza incidence time series data to develop a predictive model using time series analysis methods to forecast expected number of reported influenza cases. BACKGROUND: Influenza is a common disease associated with high mortality. Low vaccination rates motivate health officials to predict outbreaks and intervene accordingly. A predictive model would facilitate in deciding whether an apparent excess of cases represents an outbreak or a random variation. METHODS: We used the Single Flu Trend project data from 2003 to 2014 was used to construct this predictive model. The influenza time series data clearly had a seasonal variation to it so a seasonally fit model using seasonal indicators, a seasonally fit model using trigonometric functions, and a multiplicative seasonal autoregressive integrated moving average (SARIMA) model were considered. Fifty-two weeks of data from the time series were withheld from the model fitting process so as to evaluate the predictive capability of the selected model using mean absolute percentage errors (MAPE). The performance of the SARIMA model using seasonal indicators, a seasonally fit model using trigonometric functions, and a multiplicative seasonal autoregressive integrated moving average (SARIMA) was model were considered. RESULTS: The matrices obtained for ranibizumab was (0.293, 55 10^-5, 1.36 10^-5, 0.7), and aflibercept (0.267, 7.4 10^-4, 2.59 10^-4, 0.3). These matrices have triangular membership functions and correspond to a ranking of “neutral” and “slightly-favorable”. CONCLUSIONS: It is possible to apply methods of “fuzzy logic” to pharmacoeconomic studies to select the most favorable treatment. If treatment, with aflibercept would be a slightly more favorable option than ranibizumab.

**PRM103**

**DEVELOPMENT OF A GLOBAL ECONOMIC MODEL TO EVALUATE THE COST-EFFECTIVENESS OF TARGETED TREATMENTS USING COMPANION DIAGNOSTICS IN ADVANCED/METASTATIC CANCER TREATMENT**

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**OBJECTIVES:** With the development of high priced new targeted treatment for cancer, there is a need to know as soon as possible if these treatments are likely to be cost-effective. The objective of this study was to develop a model with parameters to estimate the cost-effectiveness of targeted treatments using companion diagnostics in advanced/metastatic cancer treatment. METHODS: The model was developed to take into account parameters usually considered in conventional economic models in cancer (treatment costs, costs of cancer care, target population characteristics, survival data, utilities, disutilities and costs associated with adverse events (AEs), etc.), and also parameters specific to the companion diagnostic itself (mutational specificity and sensitivity and cost). The model had to allow performing cost-utility analyses from both a Health Ministry and a societal perspective and for most common cancers (lung, breast, colorectal, prostate, cervical, renal, and non-Hodgkin’s lymphoma). RESULTS: The model comprises a decision tree and a lifetime Markov model. The decision tree takes into account the sensitivity and specificity and cost of the companion diagnostic, and the prevalence of the biomarker/mutation in the eligible population. The Markov model with monthly cycles includes the following 3 health states: progression-free, progressive disease and death. Intrinsic parameters of the model comprise the mean characteristics of the target population, utilities associated with health states, disutilities and costs associated with AEs, and costs associated with drug administration, cancer care, end-of-life follow-up, productivity losses, and informal care. Specific parameters to be entered by users are the prevalence of mutations, treatment costs, specificity/sensitivity and cost of the test, survival data and the incidence of AEs. CONCLUSIONS: The proposed global model for the economic evaluation of targeted treatments using companion diagnostics in advanced/metastatic cancer treatment can, with minimal input, quickly generate cost-effectiveness analyses of targeted cancer treatment.

**PRM104**

**AN EVIDENCE-BASED OPTIMISATION MODEL FOR A PORTFOLIO OF PREVENTIVE INTERVENTIONS UTILIZING MULTI CRITERIA DECISION ANALYSES (MCDA) FRAMEWORK**

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**OBJECTIVES:** To inform decision makers who seek extension of Universal Mass Vaccination (UMV) about the most optimal allocation of funds across multiple preventive interventions in light of budget constraints. Method: We developed a portfolio of preventive interventions that can be optimally allocated. MCDA: A multi-criteria model was developed to be applied to any preventive intervention. The portfolio included Vaccines: Polio, Measles, Rubella, Diphtheria, Tetanus, Mumps, Varicella, Influenza, Hepatitis A, Hepatitis B, and Human Papillomavirus (HPV); and Health-promotion activities: Smoking Cessation, Tobacco Prevention, Physical Activity, Healthy Diet, Sleep, and Sun Protection. RESULTS: The portfolio of preventive interventions was optimised and those interventions that were most cost-effective were selected. CONCLUSIONS: This model can be used to inform decision makers about the most allocative optimal allocation of resources for preventive interventions. MCDA can be used to inform decision makers about how to allocate limited funds amongst competing interventions. Future work will involve applying the model to different real-world scenarios.

**PRM105**

**CALIBRATION AND STATISTICAL MODELING TO INFORM A MICRO-SIMULATION MODEL FOR EARLY HTA**

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**OBJECTIVES:** For the evaluation of the potential cost-effectiveness of an early experimental therapy, we calibrated an existing micro-simulation model for radiotherapy planning in lung cancer using pilot data. METHODS: We used an externally validated micro-simulation model, build using Real World Evidence data. This model contained four clinical states from alive to death, with intermediate states (Recurrence, Infectious), subject to budget and intervention coverage constraints. A working version of the model was developed to take into account parameters usually considered in conventional economic models in cancer (treatment costs, costs of cancer care, target population characteristics, survival data, utilities, disutilities and costs associated with AEs, and costs associated with drug administration, cancer care, end-of-life follow-up, productivity losses, and informal care. Specific parameters to be entered by users are the prevalence of mutations, treatment costs, specificity/sensitivity and cost of the test, survival data and the incidence of AEs. CONCLUSIONS: The proposed global model for the economic evaluation of targeted treatments using companion diagnostics in advanced/metastatic cancer treatment can, with minimal input, quickly generate cost-effectiveness analyses of targeted cancer treatment.

**PRM106**

**EVALUATING UNCERTAINTY AROUND COSTS AND EFFECTS RELATES TO THE DEGREE OF UNCERTAINTY AROUND COST-EFFECTIVENESS?**

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**OBJECTIVES:** HTAs require information on costs and outcomes as well as the uncertainty around them for making reimbursement decisions. Uncertainty around costs and effects (outcome uncertainty) can be substantial and increasingly so at more distal time points. However, the uncertainty surrounding the decision to adopt or reject a technology based on cost-effectiveness (decision uncertainty) diverges at different time points. We present a Markov process model calibrated to reflect the cost and outcomes of treatments for diabetes. The Markov process model comprises a decision tree and a lifetime Markov model. The decision tree takes into account the sensitivity and specificity and cost of the companion diagnostic, and the prevalence of the biomarker/mutation in the eligible population. The Markov model with monthly cycles includes the following 3 health states: progression-free, progressive disease and death. Intrinsic parameters of the model comprise the mean characteristics of the target population, utilities associated with health states, disutilities and costs associated with AEs, and costs associated with drug administration, cancer care, end-of-life follow-up, productivity losses, and informal care. Specific parameters to be entered by users are the prevalence of mutations, treatment costs, specificity/sensitivity and cost of the test, survival data and the incidence of AEs. CONCLUSIONS: The proposed global model for the economic evaluation of targeted treatments using companion diagnostics in advanced/metastatic cancer treatment can, with minimal input, quickly generate cost-effectiveness analyses of targeted cancer treatment.

**A561**
Zidovudine + Lamivudine combination therapy vs Zidovudine monotherapy, to treat and prevent HIV infection, is evaluated in probabilistic simulations, cumulative simulations, net monetary benefits (CINMB) at a CE threshold of £20,000/QALY and probabilities of being cost-effective at various time-horizons (1-20 years) were estimated. Further, for each time-horizon, a CINMB frequency distribution was plotted and summarised statistically. RESULTS: The combination therapy is more costly but with a probability of 95% confidence interval for expected CINMB was narrowest at year 1 (-1,711£ to 1,757£) and year 7 (2,016£ to 2,096£); simultaneously the probability of being cost effective increased from 5% to 80% during this time. Outcome uncertainty, measured as the standard deviation of CINMB values stabilized after 5 years while probability of the combination therapy being cost effective continued to increase, indicating that decision uncertainty does not vary in tandem with outcome uncertainty. CONCLUSIONS: The above analysis shows that higher outcome uncertainty does not necessarily lead to higher decision uncertainty. CINMB could be used to explore the relationships between outcome uncertainty, decision uncertainty and time.

PRM107
DEVELOPMENT OF A MODEL TO ASSESS THE COST-EFFECTIVENESS OF THERAPIES FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) FOLLOWING A REFERENCE MODEL FRAMEWORK
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OBJECTIVES: To describe the practical approach implemented to construct a global cost-effectiveness model for T2DM therapies following a framework proposed for the development of reference models to inform public funding decisions. A systematic review (SR) of the literature was conducted to: 1) develop a conceptual model in terms of natural history and relevant effects to include; 2) Clinical and health economic experts were selected to provide feedback during the model development (i.e., to identify key model elements, gaps and errors) and for the model implementation and the assessment of the results. 3) The model was built and populated based on the systematic identification of best available data, a network meta-analyses, a review of previous T2DM submissions to health authorities and other published information. The model incorporated several structures for uncertain areas, such as: treatment patterns; type and timing of adverse events; their impact in the occurrence of long-term complications; and the impact of weight changes on relevant endpoints. 4) The model was then validated based on out-of-sample, in-sample and informal expert assessment and feedback from health care professionals. 5) The critical feedback received by HTA bodies has also been used to refine the model and improve its credibility accordingly. RESULTS: Experts' input proved valuable at each developmental stage. One challenge related to the comparability with other published T2DM models, which were not fully transparent regarding assumptions. This framework resulted in a flexible model, accurate and stable, and easily adaptable to different health care systems. Country adaptations have contributed to the identification of aspects that require relevant structural changes and their rationale. CONCLUSIONS: The followed framework enhanced the transparency of the model and the accuracy of the results. Using a reference model framework, it is possible to develop a more generalizable model that can be applied to multiple countries. Future work meta-analyses, a review of previous T2DM submissions to health authorities and other published information. The model incorporated several structures for uncertain areas, such as: treatment patterns; type and timing of adverse events; their impact in the occurrence of long-term complications; and the impact of weight changes on relevant endpoints. 4) The model was then validated based on out-of-sample, in-sample and informal expert assessment and feedback from health care professionals. 5) The critical feedback received by HTA bodies has also been used to refine the model and improve its credibility accordingly. RESULTS: Experts' input proved valuable at each developmental stage. One challenge related to the comparability with other published T2DM models, which were not fully transparent regarding assumptions. This framework resulted in a flexible model, accurate and stable, and easily adaptable to different health care systems. Country adaptations have contributed to the identification of aspects that require relevant structural changes and their rationale. CONCLUSIONS: The followed framework enhanced the transparency of the model and the accuracy of the results. Using a reference model framework, it is possible to develop a more generalizable model that can be applied to multiple countries.

PRM108
ASSESSING THE RELATIONSHIP BETWEEN INDIVIDUAL ATTRIBUTES IDENTIFIED IN MULTICRITERIA DECISION ANALYSIS (MCDA) OF RARE DISEASES AND ANNUAL TREATMENT COSTS IN RARE ENDOCRINE DISORDERS
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OBJECTIVES: Payers have a perception that orphan products are extremely expensive. The current health technology assessment (HTA) systems might be too restrictive for orphan drugs, therefore potentially denying patients access to expensive. The current health technology assessment (HTA) systems might be too restrictive for orphan drugs, therefore potentially denying patients access to expensive. The current health technology assessment (HTA) systems might be too restrictive for orphan drugs, therefore potentially denying patients access to expensive. The current health technology assessment (HTA) systems might be too restrictive for orphan drugs, therefore potentially denying patients access to expensive. The current health technology assessment (HTA) systems might be too restrictive for orphan drugs, therefore potentially denying patients access to expensive. 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economic model with ten key parameters to calculate the ICERs associated with various combinations of inputs. Published HTAs were reviewed to determine the model inputs. Extensive scenario and multiway sensitivity analyses were carried out to document informative patterns and relationships between parameters that affected the results. RESULTS: Results showed that cancer sub-types with higher post-progression costs and a treatment with significant side effects also showed results that also highlighted specific thresholds at which various cancer-specific case studies or combinations of inputs, including drug price, resulted in the drug being deemed not cost-effective using a threshold of £20,000 per QALY. CONCLUSIONS: The impact of post-progression costs can vary dependent on how these costs are modelled and also dependent on several factors, namely the ratios between health state utilities, ‘background’ costs, drug costs and the relative time spent in the stable and progressive disease states. It is demonstrated that, for many oncology treatments whose primary aim is to extend survival, this impact can be prohibitive to an intervention’s probability of being cost-effective.

PM112 DOSE-RESPONSE NETWORK META-ANALYSIS TO ADDRESS DOSE HETEROGENEITY IN A COST-EFFECTIVENESS ANALYSIS IN ACUTE MIGRAINE

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OBJECTIVES: Network Meta Analyses (NMAs) are often used to parameterise efficacy in decision models for economic evaluation. A common source of heterogeneity in NMA arises from the fact that treatments may be given at different doses. This variation may manifest as unexplained heterogeneity in standard NMA models and propagate through to the decision analysis. We aim to explore how dose-responsive NMA models can be used to parameterise dose-effectiveness using a cost-utility analysis of treatments for acute migraine. METHODS: We conducted four NMAs with different assumptions around dose-response to inform an economic evaluation in acute migraine. Two NMAs assumed the National Institute for Health and Care Excellence (NICE) doses, and two NMAs were conducted where interventions were ‘lumped’ at the ‘dose’, ‘treatment’ and ‘class’ levels and a multi-level NMA was conducted, assuming monotonic dose-response. All NMAs were used to inform effect sizes in an economic model; the model structure, costing methods and utility inputs from 4 sources. The NICE Headaches guideline was adopted. The NMA models were compared in terms of heterogeneity and Deviance Information Criteria (DIC). We report the results of the economic analyses using cost-effectiveness acceptability curves (CEACs) and a cost-utility analysis (CUA). RESULTS: Dose-response parameterisation lead to NMA models with lower heterogeneity and better fit. Different dose-response parameterisations substantially changed the resource allocation decision, particularly at lower willingness to pay thresholds. For the more complex NMA model, it is unclear from a decision making perspective which effect size estimates should be selected as inputs to the decision model and we show that careful consideration should be given to the relevance of individual doses and confounding bias. CONCLUSIONS: Dose-response NMA provides a useful and arguably more appropriate method for conducting NMA for dose response analysis. Careful consideration should be given to how to treat doses of the same intervention in NMA since different parameterisations may lead to biased effect sizes and sub-optimal conclusions around cost-effectiveness.

PM113 IMPACT OF INTERNATIONAL AND THERAPEUTIC REFERENCING ON PRICES AND LACHT Optimisation

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OBJECTIVES: There are differences in the Concerted Action on Medicines (CAM) schemes around the world. Whilst treatment options are currently limited, with no cure, modulating disease treatment, new advances in diagnosis and management of AD and promising advances in health technologies have the potential to significantly improve the burden of the disease. However, alongside these advances it is important to improve the evaluation framework if we are to capture the potential benefits to people with AD. Methods: To model disease progression over time, for use in comparative and cost-effectiveness analyses (CEA), is a priority in this context. In this research, we propose a new framework for modeling AD progression over time using the three main symptom domains of cognitive function, behaviour, and mood, and functioning. METHODS: Development of a description of disease progression in AD, using the three symptom domains. Statistical modeling of disease progression through states over time, using US data from the National Alzheimer’s Coordinating Center (NACC) (n=3,009). The model is tested in a decision-analytic context, using time to progression incidence and a cost-utility framework. RESULTS: A 20-stage disease progression pathway has been developed using multi-variate health state descriptions using the three symptom domains. Transition probabilities and hazard rates have been estimated. A model progression framework has been developed through the multi-variate system. In a baseline model over a 5-year timeframe, using mild-to-moderate AD starting states, 78% of people progressed to health states considered severe on at least one of the symptoms (46% severe for cognition). In a HTA context simulating a treatment model of AD, the model framework predicts significant cost QALY differences between control and treatment over 5-years. CONCLUSIONS: This new modeling framework shows promise and presents a broader opportunity to capture the impacts of treatment over time using a range of symptom domains.

PM115 USE OF EXTERNAL DATA TO GUIDE LONG-TERM SURVIVAL EXTRAPOLATIONS OF TRIAL DATA FOR CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: Network Meta Analyses (NMAs) are often used to parameterise efficacy in decision models for economic evaluation. A common source of heterogeneity in NMA arises from the fact that treatments may be given at different doses. This variation may manifest as unexplained heterogeneity in standard NMA models and propagate through to the decision analysis. We aim to explore how dose-responsive NMA models can be used to parameterise dose-effectiveness using a cost-utility analysis of treatments for acute migraine. METHODS: We conducted four NMAs with different assumptions around dose-response to inform an economic evaluation in acute migraine. Two NMAs assumed the National Institute for Health and Care Excellence (NICE) doses, and two NMAs were conducted where interventions were ‘lumped’ at the ‘dose’, ‘treatment’ and ‘class’ levels and a multi-level NMA was conducted, assuming monotonic dose-response. All NMAs were used to inform effect sizes in an economic model; the model structure, costing methods and utility inputs from 4 sources. The NICE Headaches guideline was adopted. The NMA models were compared in terms of heterogeneity and Deviance Information Criteria (DIC). We report the results of the economic analyses using cost-effectiveness acceptability curves (CEACs) and a cost-utility analysis (CUA). RESULTS: Dose-response parameterisation lead to NMA models with lower heterogeneity and better fit. Different dose-response parameterisations substantially changed the resource allocation decision, particularly at lower willingness to pay thresholds. For the more complex NMA model, it is unclear from a decision making perspective which effect size estimates should be selected as inputs to the decision model and we show that careful consideration should be given to the relevance of individual doses and confounding bias. CONCLUSIONS: Dose-response NMA provides a useful and arguably more appropriate method for conducting NMA for dose response analysis. Careful consideration should be given to how to treat doses of the same intervention in NMA since different parameterisations may lead to biased effect sizes and sub-optimal conclusions around cost-effectiveness.

PM116 MODELLING EVOLVING CANCER RISK DURING EPIDEMIOLOGICAL TRANSITION USING ECONOMIC DATA

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OBJECTIVES: Epidemiological projections sizing patient populations are fundamental to budget impact analyses and market forecasting. When disease risk evolves over time, as in the case of epidemiological transition, using historical estimates in epidemiological projection becomes unjustified. Incorporation of additional variables that model changing risk may allow for more reliable forecasts. The hypothesis that gross domestic product per capita (GDP) is correlated with disease risk was tested for a variety of cancers using global epidemiological and economic data sets. METHODS: Age-standardized incidence for 18 cancer sites across 180 countries was retrieved from the World Bank. For each site, correlation between GDP and incidence was measured using R2 and linear co-efficient values. RESULTS: Risk is strongly correlated with GDP for all of the sites studied, with the exception of the stomach (R2 = 0.05). Correlation was strongest for those sites associated with diet/lifestyle factors (eg. breast, colorectal (R2 = 0.61; p < 0.001) and lung (R2 = 0.42; p < 0.001). Strong association was also seen for prostate (R2 = 0.47; p < 0.001) and rectum (R2 = 0.26; p < 0.001). Logistic regression showed a negative correlation, namely: cervix (R2 = 0.33; p < 0.01), liver (R2 = 0.09; p < 0.001) and oesophagus (R2 = 0.60; p < 0.01). CONCLUSIONS: GDP is strongly associated with cancer risk and varies by organ site in a manner concordant with the evolving exposure to known pathogens that characterize epidemiological transition. On the assumption that such correlation is a marker for various causal relationships, and that robust economic methods underlie GDP forecasts, it is reasonable to conclude that these correlations could be used to scale epidemiological projections more accurately than projections assuming constant disease risk.
COST-EFFECTIVENESS MODELING OF ANTIMICROBIAL DRESSINGS FOR PREVENTING CATHETER-RELATED BLOODSTREAM INFECTION: HOMOGENOUS VERSUS NON-HOMOGENEOUS MARKOV APPROACHES

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OBJECTIVES: To compare homogenous (HMM) versus non-homogeneous Markov models (NHMM) for cost-effectiveness analysis (CEA) of routine use of transparent dressings containing a chlorhexidine gluconate gel versus standard transparent dressings. The antimicrobial dressing protects central vascular accesses reducing the risk of catheter-related bloodstream infections (CRBSIs) in intensive care units (ICU). The impact of the modeling approach on the decision of adopting antimicrobial dressings for critically ill patients is discussed.

METHODS: Comparative clinical efficacy data from a multicentre randomised controlled trial (RCT) enrolling 1,879 patients and economical data from micro and macro-costing published studies were used. The NHMM models were compared rationally using the same statistical tools. The HMM was chosen. Probabilistic sensitivity analyses (PSA) were conducted for both models for comparing the robustness of the CEA results.

RESULTS: The differences between each dressing strategies was statistically significant with both models while cost differences were not. The PSA with the NHMM resulted in 11.8 infections avoided per 1,000 patients (95% CI: [3.85; 19.64]) and a mean extra cost of €141 per patient (95% CI: €–975; €1,258) when using antimicrobial dressing. The PSA with the HMM resulted in 6.45 infections avoided per 1,000 patients (95% CI: [0.15; 12.75]) and the mean extra cost of €252 per patient (95% CI: €–924; €1,428).

CONCLUSIONS: The antimicrobial dressings are costly but more efficacious in preventing CRBSIs whatever the model used. The HMM is less sensitive to simulate the real life of the ICU patients. Regardless, the model chosen the antimicrobial strategy is more efficacious than the comparator, but its probability of being cost-effective is comparatively reduced with the HMM. Time dependent approach (NHMM) seems to be better adapted to model rare events as CRBSIs.

DEVELOPMENT OF A MODEL TO PREDICT DISEASE PROGRESSION IN AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)


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OBJECTIVES: Autosomal dominant polycystic kidney disease (ADPKD) is a major cause of end-stage renal disease (ESRD) affecting approximately 4 per 10,000 people in Europe. There is a paucity of research regarding the nature of ADPKD progression. This study aimed to utilise a systematic literature review and characterising predictors of ADPKD progression to construct a natural history disease model for ADPKD.

METHODS: An individual patient-level lifetime simulation was conducted using survival by baseline and time-dependent age, estimated glomerular filtration rate (eGFR) and total kidney volume (TKV). Rates of progression were informed by a large naturalistic study. Dialysis modality, transplant status and death as well as mortality were also modelled. ADPKD complications were stratified by chronic kidney disease stages. Modification of disease progression rate was investigated in order to assess the potential of the model for evaluating treatment interventions.

RESULTS: On visual inspection, modelled and published principal trajectories for the development of ESRD were consistent (median age at ESRD of approximately 55 years). When patients are stratified by chronic kidney disease stages. Modification of disease progression rate was investigated in order to assess the potential of the model for evaluating treatment interventions.

CONCLUSIONS: A decision-analytic model of ADPKD progression was calibrated to estimate the potential impact of this “cross-over” bias in a RCT. METHODS: A decision-analytic Markov model with 6 mutually exclusive and mutually exclusive disease states was built simulating ESRD as reported in GOG218. An individual patient-level lifetime simulation was conducted using survival by baseline and time-dependent age, estimated glomerular filtration rate (eGFR) and total kidney volume (TKV). Rates of progression were informed by a large naturalistic study. Dialysis modality, transplant status and death as well as mortality were also modelled. ADPKD complications were stratified by chronic kidney disease stages. Modification of disease progression rate was investigated in order to assess the potential of the model for evaluating treatment interventions. The model provided similar survival curves as reported. When switching treatment was disabled, the relative risk reduction for OS due to BEV was from 11% to 32% over the 49 month time horizon. The results were sensitive to changes in the input parameter of switching, developing severe ascites and mortality after progression.

VALUES IN HEALTH 17 (2014) A323–A686
Objective: To develop a flexible and computationally efficient discrete event simulation framework for modeling events which could be extrapolated to clinical studies, comparing the use of PET-CT scans versus current diagnostic procedures for Conn’s disease in hypertensive patients.

Methods: Visual Basic was used for the simulation model with Microsoft Excel constituting the front-end software. In order to ensure a high level of flexibility, individual patients could be assigned personal traits and the clinical, cost and utility inputs were easily adjustable. Individual diagnostic procedures were programmed in separate modules with the aim of simplifying potential modifications to the diagnostic pathway. RESULTS: A DES was constructed to evaluate the cost-effectiveness of new treatments based on the experience of patients assigned to intervention and comparator arms. Patients were considered individually in each arm, using the same background mortality and disease progression. Event dependent risk equations enabled efficient modeling of endogenous heterogeneity of the population. Continuous time accounting allowed for the modelling of competing adverse events and provided a realistic representation of patients’ experience. Preliminary results indicate that the use of PET-CT scans for the screening of Conn’s syndrome could be cost-effective.

Conclusions: The newly developed model is the first formal attempt to evaluate the cost-effectiveness of this alternative screening technique for hypertensive patients who are suspected of suffering from Conn’s disease. The model will be further developed to include probabilistic sensitivity analysis and bootstrapping in order to evaluate the robustness of the potential results. Evolutionary algorithms will be introduced to allow for the most optimal choice of screening’s criteria. The model will utilise actual patient level data, it could be used by the decision maker to determine the most cost-effective diagnostic strategy.

PM124 DISCRETE EVENT SIMULATION FOR THE COST-EFFECTIVENESS EVALUATION OF PET-CT SCANS IN THE DIAGNOSIS OF CONN’S DISEASE IN HYPERTENSIVE PATIENTS

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OBJECTIVES: To develop a flexible and computationally efficient discrete event simulation framework for modeling events which could be extrapolated to clinical studies, comparing the use of PET-CT scans versus current diagnostic procedures for Conn’s disease in hypertensive patients.

Methods: Visual Basic was used for the simulation model with Microsoft Excel constituting the front-end software. In order to ensure a high level of flexibility, individual patients could be assigned personal traits and the clinical, cost and utility inputs were easily adjustable. Individual diagnostic procedures were programmed in separate modules with the aim of simplifying potential modifications to the diagnostic pathway. RESULTS: A DES was constructed to evaluate the cost-effectiveness of new treatments based on the experience of patients assigned to intervention and comparator arms. Patients were considered individually in each arm, using the same background mortality and disease progression. Event dependent risk equations enabled efficient modeling of endogenous heterogeneity of the population. Continuous time accounting allowed for the modelling of competing adverse events and provided a realistic representation of patients’ experience. Preliminary results indicate that the use of PET-CT scans for the screening of Conn’s syndrome could be cost-effective.

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PM125 MODELLING LONG-TERM CHANGES IN OPIOID INDUCED CONSTIPATION (OIC) OBJECTIVES: Patients’ experience of OIC may be unstable, with periods of constipation and non-constipation, an observation supported by physician reports. There is, however, a lack of quantitative evidence of this experience. Such evidence would be valuable to inform development of economic models for OIC treatments.

The objective of this abstract is to fill this gap utilizing data from two pivotal Naloxegol clinical trials, KODIAC 4 and 5, which demonstrated significant improvements in SBM frequency response compared to placebo over 12 weeks. METHODS: 892 non-cancer pain patients with OIC were randomized to Naloxegol 25 mg or placebo in two pivotal trials. A 4-week rolling determination of OIC and non-OIC status was conducted through week 12 was used for time-interest analyses. Patients were considered OIC if they reported >3 SBMs for 2 out of the 4 weeks and non-OIC if reported >3 SBMs for >3 out of 4 weeks. Those with non-OIC status at week 4 were selected as the baseline and first observed OIC status was considered an event. RESULTS: Baseline characteristics are provided, plausible long-term projections. Naloxegol had a noticeable separation for extending the time to first OIC event when compared to placebo over the projected long-term follow-up. CONCLUSIONS: This research demonstrates that the natural fluctuation between OIC and non-OIC is substantial and not related to changes in an economic model. Even in the absence of treatment, a substantial proportion of patients become non-OIC, and a significant proportion of these remain in non-OIC subsequently. Nevertheless, a treatment effect for Naloxegol was observed over and above this ‘background’ placebo variation in the experience of OIC.
parameter, we also modeled the precision parameter using a regression structure.

Regression models

A Markov model with a finite mixture component to the primary endpoint (Overall Survival, OS) was fitted. Weibull distribution was assumed for the proportional hazards model. The Akaike Information Criterion (AIC) was used for model selection. All analysis was conducted using the NLMIXED procedure in SAS.

RESULTS: The POA dataset showed that the PO fixed effects model had the lowest residual deviation (54.8 versus 58.9 for the ML model) and uncertainty of treatment effects (49% lower standard error (SE)). In the POA dataset, the predictions of the PO model were biased, and the ML model had the lowest residual deviation (52.7 versus 271.0 for the PO model). Visual inspection indicated a partial violation of the PO assumption in the psoriasis data. Analyses of the psoriasis data showed that the PO fixed effects model had the lowest residual deviation (18.1 versus 20.9) and uncertainty (62% lower SE). However, PO model predictions were biased for treatment responses which violated the PO assumption.

CONCLUSIONS: Statistical selection of NMA for ordered outcomes should depend on and the PO assumption, and in particular, models that satisfy the PO assumption, the PO model differentiated treatment effects better as a result of lower uncertainty. In terms of flexibility, the PO model can handle data from studies that use different cut-offs for response categories and the ML model can be applied to datasets violating the PO assumption.

PM1129

EVALUATING THE EFFECT OF IMMUNOTHERAPY IN ADVANCED NON-_SMALL-CELL LUNG CANCER PATIENTS USING TWO COMPONENTS MIXTURE MODEL

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OBJECTIVES: The aim of the study was to assess the effect of an immunotherapy for the treatment of advanced non-small-cell lung cancer (NSCLC).

METHODS: Data from a phase III, multicenter, randomized, open-label trial evaluating the efficacy of pembrolizumab (PD-1 inhibitor) versus chemotherapy and/or a biologic using SEER-Medicare data (2004-2010). Survival was estimated using Kaplan-Meier (KM) and PSM methods. From the full cohort, we randomized new patients to match typical sample sizes from Phase I and III clinical trials (n=50, 100, 200, and 400). Additionally, arbitrary data cutoffs were created to proxy clinical trial follow-up times (t=5, 10, 15, 20, and 25 months). Using PSM methods mean survival from the full cohort was compared with survival from the combinations of sample sizes and follow-up times.

RESULTS: The KM method, 6% of patients were alive at the end of the follow-up period (6 years). Mean OS from the KM method was estimated to be 17.9 months using the PSM method (fit Weibull curve). OS estimates for the sample size and follow-up time combinations ranged from 5.9-28.0 months. Minimum and maximum survival projections were estimated to be 0.89 and 1.10, respectively. Romero’s mean survival was improved when compared with the KM method by 1.5 months.

CONCLUSIONS: Both sample size and data maturity have a profound effect on survival projections. Care should be taken when interpreting projections in cost-effectiveness models, especially when sample size is low and follow-up time short. In addition to power calculations, clinical trial design should account for these issues. Additional analyses in other cancer types may provide further guidance for optimum trial design.

PM1130

UNDERSTANDING REAL LIFE TREATMENT PATTERNS AMONG PATIENTS WITH HYPERTENSION USING A MARKOV MODEL

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OBJECTIVES: Approximately 65% of patients diagnosed with hypertension are not well controlled and two thirds of patients need to be treated by two or more drugs for achieving target blood pressure. The aim of this study was to describe antihypertensive treatment patterns by using Markov modelling in real-world setting.

METHODS: Data concerning prescriptions of patients with diagnosed hypertension were obtained from a large primary care survey conducted in 2012 using CSID Longitudinal Practice Database. Patients who were treated with antihypertensive drugs, prescribed alone or in combination with amiodipine and/or hydrochlorothiazide (HCT), either in fixed associations or in fixed combinations. A Markov chain model M1 with 4 states (A: single antihyp, B: antihyp + amiodapine, C: antihyp + HCT, D: antihyp + amiodapine + HCT) was proposed to model transitions from one treatment to another over time. A second chain, M2, with 6 states was also studied, in which dual-therapies were divided into two states depending on whether the combination was free or fixed. Age and sex were included as covariates. R packages and MSM package were used to fit Weibull curve. OS estimates for the sample size and follow-up time combinations ranged from 5.9-28.0 months. Minimum and maximum survival projections were estimated to be 0.89 and 1.10, respectively. The median OS was estimated to be equal to 9.59 and 60.32 for short- and long-term survival populations, respectively. 23.6% and 76.7% of the patients who were classified into long-term survival subpopulation were from the control and vaccinated group, respectively. From these, (70%) patients in the control group and 25 (75%) patients in the treated group were still alive at the end of the study.

CONCLUSIONS: The results confirm that the vaccination with CIMAraVEX prolongs the survival of the advanced NSCLC patients. Markov models allow assessing the efficacy/effectiveness of vaccines and biological products in the presence of heterogeneous populations.

PM1133

PREDICTIVE MODELLING: PREDICTING HOSPITALISATION AND ESTIMATING THE COST AND RISK TO THE THIRD PARTY FUNDERS

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1Agility Global Health Solutions/University of Pretoria, Centurion, South Africa 2Predictive Modelling: Predicting Hospitalisation and Estimating the Cost and Risk to the Third Party Funders (MSc. (Mathematical Statistics) University of Pretoria)

OBJECTIVES: In the third party funder environment most analyses focus on retrospective analyses; the aim of this predictive modelling is to estimate future claims or current risk, based on the probability of a hospital event using historical data.

METHODS: A logistic regression approach is followed where the likelihood of a hospitalisation event is established and mapped to a cost estimate. The modelling process involved establishing a development and validation dataset, identifying the predictor variables, building and lastly validating the sample. During the model building process the development and validation population consisted of 149 416 and 47623 beneficiaries respectively, where the data was obtained from a third party funder consisting of 3 years of data. During the building process the dependent variable (Y=Log (odds)) takes on the value 1 or 0 depending on whether or not a hospital event occurred. To calculate the cost per beneficiary a weighted probability was multiplied by the average cost of a hospital author as two beneficiaries. The predicted model was classified as high risk if log (odds) > 0.7. RESULTS: The final model is: Log (odds) = -0.11X + 0.0576X2 + 0.409X2 + 0.179X + 0.614X2, where X1= X2 denotes the predictor variable and X1 and X2 denotes an independent variable for gender for age ≥ X1, the HIV indicator variable, X3 the diabetes indicator variable and X4 the chronic indicator variable. The strongest predictors were the chronic indicator variable and age. The validation process resulted in 79% of the beneficiaries being correctly classified and the cost estimated resulted in a statistical values.

CONCLUSIONS: The proposed model predicts hospitalisation efficiently at a beneficiary level and can be implemented to monitor risk and the associated cost (hospital or total) for individuals, employer group or the third part funder. Third party risk management and cost estimation are other applications of the model.

PM1134

JOINT MODELLING OF THE CHANGE IN TUMOR SIZE AND OVERALL SURVIVAL: A PARAMETRIC MODEL CONSIDERING PATIENT HETEROGENEITY NOT OBSERVED AT BASELINE

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OBJECTIVES: Network meta-analysis (NMA) techniques have been developed to study relative treatment effects for several outcome types (e.g. time-to-event outcomes). No literature exists comparing models of NMA for ordered categorical data, though models for binary data have been developed. This study compared the proposed ordered (PO) and multinomial logistic (ML) model for NMA in ordered categorical databases based on model fit and qualitative characteristics.

METHODS: To contrast model performance, two real data sets were used, one which exactly satisfied the PO assumption (POA dataset), and one which did not (POA dataset). The models were also tested in a clinical dataset including ordered outcomes to consider model fit and real-world applications. Both fixed and random effects models were studied. RESULTS: In the POA dataset, the PO fixed effects model had the lowest residual deviance (54.8 versus 58.9 for the ML model) and uncertainty of treatment effects (49% lower standard error (SE)). In the POA dataset, the predictions of the PO model were biased, and the ML model had the lowest residual deviance (52.7 versus 271.0 for the PO model). Visual inspection indicated a partial violation of the PO assumption in the psoriasis data. Analyses of the psoriasis data showed that the PO fixed effects model had the lowest residual deviance (18.1 versus 20.9) and uncertainty (62% lower SE). However, PO model predictions were biased for treatment responses which violated the PO assumption.

CONCLUSIONS: Statistical selection of NMA for ordered outcomes should depend on the PO assumption, and in particular, models that satisfy the PO assumption, the PO model differentiated treatment effects better as a result of lower uncertainty. In terms of flexibility, the PO model can handle data from studies that use different cut-offs for response categories and the ML model can be applied to datasets violating the PO assumption.
OBJECTIVES: In economic evaluations in oncology, survival data is typically extrapolated without taking into account prognostic factors. If individual-level trial data are available, patient and disease characteristics observed at baseline are considered. However, survival models typically disregard information that are not known at baseline, e.g. response to treatment, but that may be valuable for the prognosis of patients. The present study is to investigate which baseline and survival model that included response to treatment over time.

METHODS: Data from 99 patients with late-stage soft tissue sarcoma from a clinical trial was used. Survival information and the percentage change in the sum of the longest diameters of target lesions (i.e. the basis for response evaluation) measured repeatedly during follow-up were utilized. A joint model was estimated linking a random effects sub-model for the change of tumor size with a Weibull sub-model for the survival outcome. The association between change of tumor size and survival was assessed. Several different functional forms were explored to model the tumor size data and the best fitting model was selected. RESULTS: The median follow-up in the trial was 1.6 years; 63 patients died. On average, 4.8 measurements on tumor size were available per patient. A flexible cubic B-spline sub-model provided the repeatedly measured tumor size change data the best model fit. The association between tumor growth and overall survival was marginally statistically significant with a P value of less than 0.10. CONCLUSIONS: The presented joint model demonstrated that response to treatment over time may be important to consider when building survival models for health economic evaluations in oncology. The model explicitly incorporated the heterogeneity of patients not observed at baseline providing a clinically relevant survival model. Individual survival predictions can be prepared using patient-specific history of tumor growth.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PM135 ASSESSMENT OF THE HUNTINGTON QUALITY OF LIFE INSTRUMENT (H-QOL-I) CROSS-CULTURAL VALIDITY

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OBJECTIVES: The Huntington Quality of Life Instrument (H-QOL-I) is the first self-reported specific instrument developed to assess the health-related quality of life (HRQoL) of patients with Huntington’s disease (HD). It includes three subscales: motor (4 Likert-type items), psychology (4 Likert-type items) and socializing (3 Likert-type items). The aim of the study was to assess whether patients from different countries responded differently to the H-QOL-I. METHODS: Data were from the European Study of HD burden (EURO-HDB) survey and included data across 6 countries: France, Germany, Italy, Spain, Poland and the USA. The USA was included to use for analysis, France, Germany, Poland and Spain to represent the European countries and the USA to represent other countries. RESULTS: The study included 633 patients (176 French, 124 Italian, 44 German, 60 Polish, 59 Spanish and 170 American). No DIF was detected across all combinations of patients from the different countries. RESULTS: The calculation of the item-specific mean score showed that all items (24 of 26) didn’t show any cross-cultural difference. The two items showed that the reliability and validity of the German H-QOL-I are unclear. Our objective was to investigate the railway and reliability of the German H-QOL-I version. METHODS: The H-QOL-I was translated and linguistically validated into German for Germany. Translation was conducted and back translation and reconciliation, and clinician review. Patient assessment was used, data was available from the baseline assessment (T0) and first follow-up (T1). RESULTS: 622 patients (54.5% female, mean age: 45.1 years) were included for analysis. Cronbach’s a was found to be 0.79. Correlations of the ODQ total and the Differential Item Functioning (DIF) method were adopted to examine whether patients from different countries respond differently to H-CSRI. Doro’s alpha was calculated as a measure of internal consistency and the intraclass correlation coefficient (ICC) was calculated as a measure of test/retest-reliability. Smallest real difference (SRD) and minimal clinical important difference (MCID) were calculated to assess sensitivity to change. CONCLUSIONS: This study did not detect any variation across the studied countries in the assessment of HRQoL of HD patients using the H-QOL-I instrument. These results support the cross-cultural validity of the H-QOL-I.

PM136 ASSESSMENT OF THE HUNTINGTON CLINICAL SELF-REPORTED INSTRUMENT (H-CRSI) CROSS-CULTURAL VALIDITY

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OBJECTIVES: The H-CSRI is the clinimetric self-reported instrument for patients with Huntington’s disease (HD). It includes three subscales: motor (13 Likert-type items in 4 dimensions), functional (7 ‘Yes/No’ questions) and behavioural (13 likert-type items). The aim of the study was to assess whether patients from different countries respond differently to H-CSRI. METHODS: Data were from the European study of HD burden (EURO-HDB) survey and included data across 6 countries: France, Germany, Italy, Spain, Poland and the USA. The USA was included to use for analysis, France, Germany, Poland and Spain to represent the European countries and the USA to represent other countries. RESULTS: The study included 633 patients (176 French, 124 Italian, 44 German, 60 Polish, 59 Spanish and 170 American). Almost all the items (24 of 26) didn’t show any cross-cultural difference. The two items showed that the reliability and validity of the German H-CSRI version are unclear. Our objective was to investigate the railway and reliability of the German H-CSRI version. METHODS: The H-CSRI was translated and linguistically validated into German for Germany. Translation was conducted and back translation and reconciliation, and clinician review. Patient assessment was used, data was available from the baseline assessment (T0) and first follow-up (T1). RESULTS: 622 patients (54.5% female, mean age: 45.1 years) were included for analysis. Cronbach’s a was found to be 0.79. Correlations of the ODQ total and the Differential Item Functioning (DIF) method were adopted to examine whether patients from different countries respond differently to H-CSRI. Doro’s alpha was calculated as a measure of internal consistency and the intraclass correlation coefficient (ICC) was calculated as a measure of test/retest-reliability. Smallest real difference (SRD) and minimal clinical important difference (MCID) were calculated to assess sensitivity to change. CONCLUSIONS: This study did not detect any variation across the studied countries in the assessment of HRQoL of HD patients using the H-QOL-I instrument. These results support the cross-cultural validity of the H-QOL-I.
OBJECTIVES: To explore how participants evaluate and complete the choice tasks in a discrete-choice experiment (DCE), with special attention to the impact of educational level and health literacy. METHODS: Two existing DCE questionnaires on rotavirus vaccination and prostate cancer screening served as a case for the current study. In total, 70 participants were sampled based on educational level (55 per case study) after structured interviews, participants completed five-choice tasks aloud. Interviewers monitored how participants read the choice tasks, how they interpreted the included risk attributes and what decision strategy they used to make their decision and how many times (if at all) they adjusted their preferences. RESULTS: The majority of the participants read all the attributes within each choice task. Nearly all participants chose the scenario with the optimal attribute values (monotonicity axiom). In accordance with the continuity axiom, most participants mentioned three or more attributes when justifying their decisions. Overall, higher educated participants more often included three or more attributes when motivating their decision and used trading between attributes more often as a decision strategy. CONCLUSIONS: The majority of participants completed a DCE while following Rasch methodology. However, the assumptions did not hold for a subset of lower educated and less literate participants. Based on participants’ age, educational level and health literacy additional measures should be undertaken to enhance participants’ understanding of the attributes, the attribute levels and the choice tasks in a DCE.

PRM140 THE MEASUREMENT OF UTILITIES IN ASTHMA PATIENTS: A PRELIMINARY STUDY
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OBJECTIVES: To assess the feasibility of a computer-based Standard Gamble (SG) visual prop whilst measuring utilities of different asthma health states at the same time. METHODS: Twenty adult asthma patients literate in either Malay or English language were conveniently sampled from a public hospital in Penang, Malaysia. They were interviewed by two trained interviewers using a bilingual script. Each patient was requested to value the given health states using Visual Analogue Scale (VAS) and Standard Gamble (SG). There were three health states: healthy state and three temporary states (T1-T3) for 3 months, and two anchor states (healthy and dead). During the SG exercise, the visual prop was fully operated by the interviewers. The probability of being in a worse state was changed in a ‘ping-pong’ fashion until the indifference point was reached. RESULTS: All patients understood the SG exercise and rated SG easier than VAS. Around 85% (n = 17) completed SG within 30 minutes. There was 90% (n = 18) who ranked T3 as the worst temporary health state during VAS. 78% patients provided logical inconsistency data in SG. The preferences by SG were higher than VAS. Preferences were also higher in temporary states measured with VAS. Two patients provided logical inconsistency data in SG. The preferences by SG two questionnaire versions.

PRM141 DISCRETE-CHOICE EXPERIMENT VERSUS RATING SCALE EXERCISE TO EVALUATE THE RELATIVE IMPORTANCE OF ATTRIBUTES: A STUDY OF THE MAXIMUM DETERMINANT PROSTATE CANCER DCE CHAPMAN
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OBJECTIVES: Eliciting preferences has become increasingly important in health care decision making. To better understand the importance of different aspects of health and health care. In this study, we aim to examine the difference between a discrete-choice experiment (DCE) and a rating scale exercise (RSE) to determine the most important attributes of undergraduate students when selecting a study subject. METHODS: First-year health sciences students were asked to complete a questionnaire that included a DCE and a RSE. Six attributes were identified in focus groups: “possible acquainted masters”, “job opportunity”, “scope of specialization”, “quality of education”, “hours self-study” and “personal interest”. Fourteen unlabeled choice tasks were constructed using a statistically efficient design and a mixed multinomial logistic regression analysis was used for data analysis. In the RSE, attributes were rated on perceived importance using a 7-point Likert scale. Two versions of the questionnaire were distributed in which the RSE was put before and after the DCE. RESULTS: A total of 254 students filled out the questionnaire. In the DCE, three attributes were statistically significant of which “personal interest” was the most important attribute followed by “job opportunity” and “quality of education” in the RSE, all attributes except “hours of self-study” were rated 4 or higher. The RSE scores of the attributes with a relatively low importance in the DCE were significantly lower in the questionnaire version that started with DCE than in the other version. Results of the DCE did not significantly differ between the two questionnaire versions. CONCLUSIONS: The DCE had a differentiating effect on the relative importance of attributes whereas in the RSE attributes were rated more similar. More research is needed to be considered important. Forcing respondents to make first trade-offs between attributes (using a DCE) leads to lower RSE scores for less important attributes afterwards.

PRM142 THE DEVELOPMENT AND PRELIMINARY VALIDATION OF THE MANCHESTER SLEEP SYMPTOMS INDEX (MSSI) FOR PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
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OBJECTIVES: To develop a COPD specific health-related quality of life measure that is simple and quick to use making it suitable for research and practice. Further work is needed to determine the minimal clinical important difference and cross cultural validity.

PRM143 PSYCHOMETRIC EVALUATION OF THE PATIENT’S KNEE IMPACT PERFORMANCE (PKIP) QUESTIONNAIRE FOR THE ASSESSMENT OF PRIMARY TOTAL KNEE ARTHROPLASTY
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OBJECTIVES: The objective of this study was to evaluate the psychometric properties of a new patient-reported measure of knee implant functional performance associated with physical activities prior to and following primary total knee arthroplasty (TKA). RESULTS: The Patient’s Knee Impact Performance questionnaire (PKIP) was developed to assess factors that lead to patient dissatisfaction and describe unmet needs in knee functional performance. METHODS: The psychometric analysis sample (n = 764) was based on a multicenter, prospective, noncomparative longitudinal study of patients with osteoarthritis undergoing TKA at 22 international sites. The PKIP and additional patient-reported outcomes and clinical measures were collected preoperatively, postoperatively at less than 1 year, at a minimum of 1 year, and at 2 years. The PKIP structure and its reliability, construct validity, discriminant ability, and responsiveness were assessed. RESULTS: Based on inter-item correlations, factor analyses, and results of previous qualitative research, the PKIP was scored as four subscales (Stability, Confidence, Satisfaction, and Activity Modification) and on an 11-point Likert score. The Overall PKIP score was highly responsive. Internal consistency: α = 0.78 at minimum 1 year; test-retest intraclass correlation coefficient = 0.77). Correlations between the PKIP and other available measures provided evidence of construct validity. For example, the PKIP correlated 0.19 and 0.50 with the American Knee Society Score preoperatively and at less than 1 year, respectively, and correlated 0.69 and 0.77, with the Knee Injury and Osteoarthritis Outcome Score (KOOS) Quality of Life subscale. The PKIP was capable of discriminating between groups of patients with better or worse knee functioning as defined by clinician-rated satisfaction; hypothesis tests were in the predicted direction and mostly statistically significant. The effect size for the Overall PKIP score was 2.38, indicating that the PKIP was highly responsive. CONCLUSIONS: The reliability, validity and responsiveness of the PKIP support its use among patients undergoing primary TKA.

PRM144 VALIDITY AND RESPONSIVENESS OF THE BRISTOL RHEUMATOID ARTHRITIS FATIGUE MULTIDIMENSIONAL QUESTIONNAIRE (BRAF-MDQ) IN A RANDOMIZED CONTROLLED CLINICAL TRIAL
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OBJECTIVES: To evaluate the validity of the BRAF-MDQ in a new group of patients in a clinical trial setting, to confirm its internal factor (domain) structure and to document its sensitivity to change. METHODS: Pooled data from a randomized controlled trial (NCT01242488) in patients with moderate to severe RA were collected at baseline (BL), WK10 and WK12. Spearman’s correlation coefficients, Bland-Altman plots and confirmatory factor analysis tested construct validity, reproducibility and internal factor structure of the BRAF-MDQ. Responsiveness was assessed using pair wise comparisons and Cohen’s d ≥ 0.80 of a unit of a standard deviation from BL in BRAF-MDQ. RESULTS: There were 219 patients (mean age: 55.5 years; disease duration: 12.6 years; BL DAS28: 5.77). The proportion of missing item answers was very low (0.2% for all 15 items). BRAF-MDQ total score and subscale total scores correlated strongly with DAS28 at BL (p = 0.49, 0.46 and 0.58) and at WK12 (p = 0.63, 0.65 and 0.64). Changes in the Physical and Living domains were more closely related to changes in patient and physician global scores and DAS scores than did changes in Cognition and Emotional domains. Reproducibility was high (r = 0.99 and 0.99 at BL and WK10 and WK12, 0.88 at WK12). All Cronbach’s alpha coefficients met the Bland-Altman limits of agreement), as was internal consistency (Cronbach’s a = 0.79 for total scores; > 0.82 for each domain at BL). The Butler comparative fit index (CFI; 0.92) indicated that the established structure within the BRAF-MDQ accounted well for data variation. Effect size for BRAF-MDQ in clinical responders at WK12 were very high.
(0.7) for the Physical domain, high (0.5) for the Total score and the Living domain and moderate (0.3) for the Psychological domain.

**Objectives:**
- To develop and validate a new patient-reported outcome (PRO) measure for the assessment of CDAD symptoms.
- The CDAD-DaySym™ captures symptoms relevant to CDAD patients, demonstrating initial content validity of the 13-item draft daily CDAD symptoms (CDAD-DaySym™).
- To allow its use in clinical practice and CDAD clinical studies, final content and psychometric validity are being evaluated in 2 ongoing international clinical trials.

**Methods:**
- A literature review led to the targeting of relevant symptoms for the development of the CDAD-DaySym™. The conceptualization process and item review informed the drafting of 17 items in the CDAD-DaySym™. The item wording was adapted from three validated instruments with the exception of the I-TAQ item wording.
- Qualitative analysis of CE data indicated that treatment acceptance to be high, with the following concepts identified as relevant: perceived efficacy, side effects, self-efficacy, convenience and overall acceptance. Ten (94%) patients reported an initial fear of needles, which subsided with no impact on discontinuation. Pain was not considered relevant by patients, suggesting no pain associated with the injection. Five items were added following round 1 interviews, three were retained after round 2 testing and two were added at finalization, forming the conceptually comprehensive 22-item I-TAQ.
- Patients demonstrated good understanding of item wording, instructions, response scales and recall period.

**Conclusions:**
- Successive rounds of interviews resulted in a treatment acceptance measure with strong content validity. Next steps are to psychometrically validate the I-TAQ in a population with experience of taking alirocumab.
- The CDAD-DaySym™ may provide a valid and reliable measure for the assessment of CDAD symptoms, and its use may improve patient-reported outcome measures in CDAD clinical trials.
OBJECTIVES: Currently no measure can identify, with a high degree of positive predictive value, suicidal behavior. Because suicide occurs in a low base-rate, studies of instruments designed to predict this outcome often lack an adequate sample size to provide the study's predictive ability. Our aim is to identify an assessment whom the most promise of predicting suicidal behavior in veteran or military patients and present an evaluation of previously reported methods. METHODS: Two systematic reviews, one performed for the US Department of Veterans [1], and the other part of NICE guidance development [2] provided the background for our analysis. Through the Cochrane Library, Medline and Embase were searched for reports. Data were extracted using a template designed to capture the impact of dementia, schizophrenia, visual impairment, hearing impairments or, among others, cancer and systemic lupus erythematosus. CONCLUSIONS: This study has provided a comprehensive overview of the evidence of the performance of EQ-5D. Most evidence suggests good psychometric properties of EQ-5D; however, there are particular concerns about its ability to capture the impact of dementia, schizophrenia, visual impairment and hearing disorders. Further research is encouraged in conditions where data or reviews of psychometric properties of EQ-5D are lacking.

PHYSICIANS’ PREFERENCES FOR BONE METASTASES TREATMENTS IN TURKEY


OBJECTIVES: To determine psychometric properties of the revised Self-Selection Questionnaire in rheumatoid arthritis patients (pts) receiving cereltolizumab pegol (CEPT) treatment. METHODS: In the study (NCT00674362), pts with low to moderate rheumatoid arthritis (RA) received cereltolizumab pegol (CEPT; 400mg at Weeks [Wks] 0, 2, 4, 6, 8, 10, then every other wk). In the double-blind extension (OLE, NCT00843778), pts could self-administer CEPT using a pre-filled syringe. Pts in OLE completed the revised Self-Selection Assessment Questionnaire (SIAQv2.0) at Wks 0, 2, 4, 6, 8, 10, 12. Domain scores were calculated per authors’ recommendations, and internal consistency was assessed using the Cronbach’s alpha statistics. Floor and ceiling effects were reported as % pts with the worst/best domain score. Construct validity was assessed by comparing QL outcomes with standard and by calculating the root mean square error of approximation (RMSEA). RESULTS: 86 pts (mean age: 50.8 years; disease duration: 4.6 years) entered the OLE and completed the SIAQ at least once. At first self-injection visit, DAS28 (ESR) was 4.0 and HAQ-DI 0.9. The internal consistency of all domains was >0.8 at any visit. Floor effect was <5% at any visit; ceiling effect was <11% for Self-Confidence, Ease of Use (EU) and Satisfaction domains, but reached 40% for Feeling and Injection-Site Reactions domains. The ceiling of the global QL measure was lower than 20% (recommendation: 20%). The conceptual framework support was confirmed by the conceptual analysis with CFI values of 0.75–0.86 and RMSEA values of 0.10–0.13, which, given the limited sample size, would indicate reasonable goodness of fit. CONCLUSIONS: Modifications brought to the SIAQv2.0 appeared to ameliorate the acceptability bias issue that was noted during the validation of SIAQv1. The appropriateness of the internal consistency reliability and construct validity of the SIAQv2.0 were confirmed.

HEALTH-RELATED QUALITY OF LIFE IN ITALIAN PATIENTS WITH MODERATE AND SEVERE CROHN’S DISEASE: INTERIM RESULTS FROM THE SOLE STUDY


METHODS: In the ongoing Survey on Quality Of Life in Crohn’s Patients (SOLIE), patients with moderate and severe CD who referred to a convenience sample of 38 Italian inflammatory bowel disease centres (21 teaching-hospitals; 4 research hospitals; 8 public hospitals; 3 local health authorities; 3 private hospitals) participating in the ongoing Survey on Quality Of Life in Crohn’s Patients (SOLIE) were included. Annual risk of ONJ was the least important attribute. CONCLUSIONS: When making choices regarding choice of BTA for patients with bone metastases, the most important goal for Turkish physicians are reducing rate of renal impairment and delaying first SRE.

VALIDITY OF THE EQ-5D-3L IN STROKE PATIENTS

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OBJECTIVES: To assess EQ-5D-3L validity in patients with acute stroke, in comparison to EQ-5D-3L, EQ VAS, modified Rankin Scale (mRS) and Barthel Index (BI). METHODS: 108 patients (60%) were men. Results of 1 of the 480 patients (2%) were excluded due to missing data. After 69 patients and the risk of bias was unclear. A larger study may provide the needed evidence to make the Affective States Questionnaire a useful screening tool. We propose the Affective States Questionnaire be transferred to electronic administration and provide as part of routine admissions at VA facilities. Deploying the tool electronically could provide the large sample sizes required to detect effects on this low base-rate outcome. CONCLUSIONS: The Affective States Questionnaire shows promise of becoming an appropriate screening tool for suicide in a military population. Electronic capture may allow for large scale deployment, therefore gaining sufficient sample to determine applicability as a screening tool.

AN EVALUATION OF THE PERFORMANCE OF EQ-5D: A REVIEW OF REVIEWS OF PSYCHOMETRIC PROPERTIES


OBJECTIVES: EQ-5D has been widely used to measure health status in a variety of conditions and by calculating the root mean square error of approximation (RMSEA). RESULTS: 86 pts (mean age: 50.8 years; disease duration: 4.6 years) entered the OLE and completed the SIAQ at least once. At first self-injection visit, DAS28 (ESR) was 4.0 and HAQ-DI 0.9. The internal consistency of all domains was >0.8 at any visit. Floor effect was <5% at any visit; ceiling effect was <11% for Self-Confidence, Ease of Use (EU) and Satisfaction domains, but reached 40% for Feeling and Injection-Site Reactions domains. The ceiling of the global QL measure was lower than 20% (recommendation: 20%). The conceptual framework support was confirmed by the conceptual analysis with CFI values of 0.75–0.86 and RMSEA values of 0.10–0.13, which, given the limited sample size, would indicate reasonable goodness of fit. CONCLUSIONS: Modifications brought to the SIAQv2.0 appeared to ameliorate the acceptability bias issue that was noted during the validation of SIAQv1. The appropriateness of the internal consistency reliability and construct validity of the SIAQv2.0 were confirmed.
during 2012. As Italian EQ-5D-3L tariffs were not available at the time of the research, UK tariffs were used according to other comparable studies. Results concerning the first out of the 4 visits planned in SOLE study were reported as mean, standard deviation (SD), median and range. Correlation between EQ-5D-3L questionnaire and VAS scores was investigated via Kendall's tau-b (Ktau-b). RESULTS: 531 patients (mean: 41.3; SD: 13.8; median: 41; range: 18–84) responded to EQ-5D-3L ques-
tionnaire (98.3%) and 536 to VAS (99.6%). The most frequently marked levels for EQ-
SD-3L questionnaire were: 1 for mobility (66.2%) and self-care (85.2%); 2 for usual 
activities (51.8%), pain/discomfort (70.7%), and anxiety/depression (53.4%). Overall scores for EQ-5D-3L questionnaire and VAS were 0.7 (SD: 0.3; median: 0.8; 
range: 0.2–1) and 54.3 (SD: 20.8; median: 55; range: 0–100), respectively. Six out of 
531 EQ-5D-3L questionnaire respondents (1%) valued their health state potentially 
worst state) were 13.27%, 10.73% and 13.57% for branches 1, 2, 3 respectively in 
Spain, while just two branches were used in Japan. The control group (Arm 1, both 
countries) was sampled from Canary Islands and Tokyo population. All interviews were performed 
face to face. We compared the number of C-TTO-based inconsistencies.

**CONCLUSIONS:** Italian patients with moderate and severe CD report a remarkable reduction in HRQoL.

**PM156 CURRENT SAMPLE SIZE PRACTICES IN THE PSYCHOMETRIC EVALUATION OF PATIENT-REPORTED OUTCOMES FOR USE IN CLINICAL TRIALS**

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**OBJECTIVES:** Sample size (N) affects the robustness of psychometric results, but for evaluations of patient-reported outcome (PRO) measures, N is often a compromise between available resources. Currently, there are no psychometric guidelines or requirements for the development of PROs for use in clinical trials. The objectives of this study is to review current N practices by conducting a systematic literature review. METHOds: A systematic methodological and psychometric review examining the number of items and dimensions in each PRO of interest, the psychometric methods employed (e.g., internal consistency, test-retest reliability, factor analy-
sis, responsiveness), and N. RESULTS: The literature search yielded 252 abstracts describing studies conducted mostly in Europe, Canada, and the United States. Preliminary results indicate that Ns ranged from approximately 40 to 4,000. The most frequently reported psychometric method was Cronbach's alpha to quantify internal consistency. Approximately thirty percent of studies employed methods that demanded the largest Ns such as item response theory (IRT) and factor analysis (FA). It was found that Ns were considered to be adequate for the current study purposes. A RELIABILITY GENERALISATION Of THE EORTC QLQ-B23

**Smith AS**, **Taylor M**, **Cocks K**, **PARRY D**

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**OBJECTIVES:** The collection of patient-reported outcome (PRO) data is becoming more routine in oncology clinical trials and in clinical practice. The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-B23 has been validated a number of PRO instruments, including the QLQ-BR-23, a breast cancer specific measure. The objective of this study was to evaluate the internal reli-
ability of the EORTC QLQ-B23 through reliability generalisation, a meta-analytic technique requiring few items and great flexibility. Methods: Meta-
review included English-language journal abstracts published in the past 10 years and identified in PubMed. Characteristics of each study were tabulated including the number of items and dimensions in each PRO of interest, the psychometric methods employed (e.g., internal consistency, test-retest reliability, factor analy-
sis, responsiveness), and N. RESULTS: The literature search yielded 252 abstracts describing studies conducted mostly in Europe, Canada, and the United States. Preliminary results indicate that Ns ranged from approximately 40 to 4,000. The most frequently reported psychometric method was Cronbach's alpha to quantify internal consistency. Approximately thirty percent of studies employed methods that demanded the largest Ns such as item response theory (IRT) and factor analysis (FA). It was found that Ns were considered to be adequate for the current study purposes. A RELIABILITY GENERALISATION Of THE EORTC QLQ-B23

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**OBJECTIVES:** Empirical data suggest that compliance with diabetes clinical prac-
tice recommendations is inadequate in primary care and that a large proportion of patients with diabetes remain at high risk. Changing physician practice patterns with electronic integrated system would provide a suite of technologies to support a full range of diabetes management activities. The objectives of this study are to determine the financial and clinical benefits of implementing information technology enabled diabetes management systems. METHODS: The simulations were performed using the CORE model – widely validated and broadly used to enable a reliable estimation of costs and clinical effects associated with diabetes. Several estimates of care process improvements were derived, representing different percentage of patients covered by designed management activities and reaching target HbA1c. The primary outcome was medical cost savings and sec-
ondary measures include reduction of cardiovascular, cerebrovascular, neuropathy, nephropathy, cardiovascular and peripheral artery disease, and 
and statistically significant improvements in a lifespan perspective performance measures were observed. According to simulation, as percentage of patients covered by information technology enabled diabetes management systems increased, health care expenditures are reduced. With 10% of patients covered 6% of total patient costs were saved in comparison to 23% of total patient costs saved with 100% of patients covered. CONCLUSIONS: Implementation of information technology enabled diabetes management systems demonstrate health improvements and improving processes of care, preventing the development of diabetic complications, and generating cost savings. Moreover, this improves the synthesis of information, the delivery of knowledge, and the efficiency of communication, allowing for optimization of care across delivery teams.
**PMR161**

**ASSESSING THE METHODOLOGICAL VALUE OF DIGITAL REAL-TIME COLLECTION OF QUALITATIVE CONTENT IN SUPPORTING IN-DEPTH QUALITATIVE INTERVIEWS EXPLORING THE SYMPTOMS AND IMPACTS OF GOUT ON OUT-OF-FOCUS QUALITY OF LIFE**

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**OBJECTIVES:** Gout is the most common arthritic condition, but research of Gout patient experiences and consequences is limited. Qualitative interviews are widely used as a valid and reliable means of gaining in-depth insight into the patient experience, but are typically conducted in artificial environments relying on patient recall. Novel digital methods of collecting qualitative data through real-time data capture (RTDC) have recently emerged with the potential to enhance ecological validity. The objective of this research was to assess the added methodological value of accounting for interviews data, and submitted by gout patients through a mobile phone application while experiencing flares and provide additional patient perspective. **METHODS:** Concept elicitation interviews were conducted with 20 American gout patients using open-ended, exploratory questions to facilitate spontaneous elicitation of content. Following interviews, 50% of the sample took part in a RTDC exercise by submitting self-recorded videos and images in response to six tasks issued on a mobile phone application over seven days. All data were subject to thematic analysis using Atlas.ti. Interviews and RTDC data were compared in terms of conceptual coverage and insights. **RESULTS:** Qualitative analysis demonstrated both forms of data collection led to the identification of the same symptoms and impacts with no additional concepts identified in either form of data. Symptoms and impacts of the disease during flares were high: RTDC data provided additional insight into the severity of symptoms and the impact burden, specifically with regards to images of the level of swelling experienced during a flare and sleep disturbances through videos recorded by patients at the time of our conclusions. **CONCLUSIONS:** While qualitative patient interviews are considered the gold standard in understanding the symptoms and impacts of a condition, RTDC was found to provide additional valuable insights in this sample of gout patients, which can inform future measurement strategies and enhance the field of patient-centered research.

**PMR164**

**AN ELECTRONIC VERSION OF THE EQ-5D: ACCEPTABILITY TO RESPONDENTS AND ASSESSMENT OF ALTERNATIVE RESPONSE FORMATS**

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**OBJECTIVES:** Firstly, to migrate the paper-based version of the EQ-5D, 39-item version, from paper to digital and assess the acceptability to respondents. Secondly, to investigate the impact of implementing non-response options on response rates and data completeness. **METHODS:** Six people with Parkinson’s (PwP) participated in cognitive interviews in order to assess the usability and acceptability of the EQ-5D. This was followed by an online survey of 129 PwP, randomly assigned to one of two groups; one required to provide a response to every item and one with the option to skip any item they did not wish to answer. **RESULTS:** Cognitive interviews indicated that the EQ-5D is acceptable to PwP, with positive feedback regarding layout, features and functionality. 125 PwP fully completed the EQ-5D. Following randomization 60 participants completed the forced response EQ-5D and 65 completed the non-forced version. Response rates of 98% were achieved for EQ-5D and 95.6% for the non-forced version. **CONCLUSIONS:** The EQ-5D is user-friendly and acceptable to respondents. Adjusting the response formats when implementing non-response options on response rates and data completeness.

**PMR165**

**EFFICACY OF VIRTUAL REALITY EXPOSURE THERAPY IN THE MANAGEMENT OF SymptOMS ASSOCIATED WITH POST TRAUMATIC STRESS DISORDER**

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**OBJECTIVES:** Management of symptoms and illness for post traumatic stress disorder (PTSD) requires effective and prolonged psychiatric support. Re-experiencing traumatic memories and events via virtual reality exposure therapy (VRET) can lead to reduction of illness and symptoms associated with PTSD. This systematic literature review aims to demonstrate the value of VRET in the management of illness and symptoms associated with PTSD. **METHODS:** Studies published in the English language for PTSD and VRET were retrieved from Embase, PubMed and Cochrane databases using relevant search strategies. Two researchers are independently reviewing studies as per the Cochrane methodology for systematic literature reviews. We considered VRET as a tool to deliver therapy programs via a virtual platform to patients suffering from PTSD. The main outcome will be improvement in symptoms such as anxiety, various phobias and depression developed as a result of PTSD. Outcomes will be measured as change in baseline characteristics in patients using VRET. Specifically to the sample size of participants, the review will be screened such as Beck’s Anxiety Inventory, Beck’s Depression inventory-II (BDI-II), Clinician Administered PTSD Scale (CAPS), and patient reported outcomes. **RESULTS:** In total, 175/240 relevant citations were retrieved from the databases and are being screened for inclusion in the review. The detailed results from the systematic review will be presented in the poster. **CONCLUSIONS:** The evidence from this systematic literature review will hopefully suggest the role of VRET as a promising new tool for managing PTSD from a psychotherapeutic perspective.

**PMR156**

**QUALITY OF LIFE ELEMENTS IN SCHIZOPHRENIA FOR PATIENTS AND CARERS OFFER CHALLENGES TO AND OPPORTUNITIES FOR INTERVENTION**

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**OBJECTIVES:** Schizophrenia is responsible for high levels of individual morbidity: acute schizophrenia had the highest disability score of any condition in the 2010 Global Burden of Disease study. Consequently, quality of life (QoL) overall and related to health is a major issue for patients, as well as their families/carers. **METHODS:** We undertook a pragmatic literature search of publications relating to QoL and schizophrenia over the past 7 years to identify main themes and trends. **RESULTS:** Patient-reported QoL is often overestimated compared to objective QoL, as measured by health care professions, particularly during psychotic episodes. Factors that appear to be adversely associated with QoL include symptoms, treatment side effects, physical mobility, lack of relationships, daily activity, housing, social stigma and self-stigma. In some cases, there is a complex cause and effect relationship. Families/carers: Those looking after patients with schizophrenia suffer impaired QoL and this can have an impact on the whole household and its social milieu. **CONCLUSIONS:** Programmes that do not reflect this complexity may increase the risk of symptom recurrence and even suicide. Thus, when devising interventional programmes to supplement drug treatment for management of schizophrenia, a range of patient- and carer-related factors must considered.
The selection of appropriate HSUVs is critical to reduce uncertainty in economic evaluations still favor disease-specific instruments over generic quality of life instruments for reasons of sensitivity and reliability. Especially in case of the fluctuating nature of seizures in epilepsy, generic QoL-instruments are often found to be unsuit- able for outcome research. A proposed method to bridge the gap between clinically relevant outcome measures and QoL is to derive utility scores for epilepsy health states. The aim of this study is to develop a scoring algorithm to transform clinically relevant outcome measures of epilepsy into utility values which can be incorporated into economic evaluations. Although seizure frequency is the most commonly reported primary outcome measure in epilepsy research, this study suggests that the impact of seizure severity alone should not be underestimated.

A573

PRM167

ANALYSIS OF THE HEALTH TECHNOLOGY ASSESSMENT RECOMMENDATION AND GUIDANCE ON USE OF EQ-5D-5L IN COST-EFFECTIVENESS MODELLING

Jubin M., Aoni M., Dimova M.

OBJECTIVES: Several national health technology assessment (HTA) bodies including the National Institute for Health and Care Excellence (NICE) for England and Wales recommend EQ-5D-5L for the preferred health-related quality of life (HRQoL) measure for use in cost-effectiveness analyses. This study aims to evaluate the recommendation and guidance on use of EQ-5D-5L in the UK and France. The cost-effectiveness modelling guidelines were assessed for the requirements for EQ-5D at either level. The impact of guidance requirements on submissions were examined by reviewing the cost-effectiveness analyses of submissions with different number of covariates and non-peer-reviewed usefulness attributes, and the application of key model information, and ambiguity regarding selection and justification of mapping function, risk of bias - sample size, instrument response rates, and general study quality identified as factors affecting HSUV validity. CONCLUSIONS: The selection of appropriate HSUVs is critical to reduce uncertainty in economic models. A checklist based on critiques of recent HTAs will be a useful tool for manufacturers when selecting relevant HSUVs.

PRM168

HEALTH RELATED QUALITY OF LIFE IN CANCER PATIENTS: EVALUATION WITH A SELF-ADMINISTERED IPAD APPLICATION

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OBJECTIVES: Cancer has the second highest mortality rates after cardiovascular dis-eases in the world. Advances in treatment options caused significant enhancements in survival of cancer patients. However, the major parameter affecting treatment success and treatment adherence in these patients is the quality of their QoL. We aimed to develop a self-administered iPad application for evaluation of QoL in a cancer treatment setting. As part of routine practice, the FACIT-TB instrument is flexible and is able to accommodate the needs of patients with different sociodemographic, and functional status. The purpose of this study was to evaluate different modes of administration of questionnaire permits unbiased assessment of the impact of the disease and its treatments on patients’ HRQOL.

PRM169

THE SELECTION OF APPROPRIATE HEALTH STATE UTILITY VALUES (HSUVS) FOR HEALTH TECHNOLOGY ASSESSMENT (HTA): LESSONS TO BE LEARNED

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OBJECTIVES: Incorporation of health-related quality of life (HRQoL) evidence into economic models is a requirement of many countries for the purposes of Health Technology Assessment (HTA), and therefore appropriate health state utility values (HSUVs) are often sought. The objective of this review was to: (i) identify and sum-marize the principal limitations of HSUVs used in recent submissions appraised by the National Institute for Health and Care Excellence (NICE) and (ii) produce a categorical checklist that can be used by manufacturers to reduce uncertainty when selecting HSUVs for HTA. METHODS: Evidence appraisal documents for the 50 most recently published technologies assessed by NICE were retrieved in June 2014. Economic models were assessed and utility inputs reviewed. Critiques of the utilities reported by the evidence review group or final appraisal committee were extracted, reviewed and categorised. RESULTS: Of the appraisals reviewed (43 single technology appraisals and 7 multiple technology appraisals), 26 referenced HSUVs. Out of these 26, 19 (73%) were derived from the literature (n=27), published mapping algorithms (n=11), or derived from clinical trials (n=16). The concerns expressed by reviewers were categorized into four categories: (1) generalisability - relevance of the HSUV to UK clinical practice, (2) quality from NICE scope and the use of other countries’ valuations for health states; (3) HSUV selection – inadequate justification of HSUVs, and lack of consideration for covariates and disadvantages; (4) mapping algo-rithms and datasets of non-validated or non-peer-reviewed submissions. CONCLUSIONS: The development of key model information, and ambiguity regarding selection and justification of mapping function, risk of bias - sample size, instrument response rates, and general study quality identified as factors affecting HSUV validity. CONCLUSIONS: The selection of appropriate HSUVs is critical to reduce uncertainty in economic 

PRM170

TRANSLATION AND LINGUISTIC VALIDATION OF THE ELECTRONIC COLOMBIA SUICIDE DEATH RATE SCALES FOR THE PACIFIC-AG

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OBJECTIVES: The Columbia Suicide Severity Rating Scale (C-SSRS) has been developed in an electronic self-rated version (the e-CSSRS) in order to facilitate compliance with regulatory requirements for prospective monitoring of suicidal ideation and behaviours. The e-CSSRS v2.0 for IBS has been translated and linguistically validated across five South American countries. Whilst translating and linguistically validating the scale it was noted that particularly in the Asia-Pacific region there were some challenging issues around the concept of suicide from a cultural perspective. This study aimed to examine what changes they made and how they resolved them. METHODS: Eighteen reports were reviewed from the Asia-Pacific region. The languages were: China-Mandarin, India-English, India-Gujarati, India-Hindi, India-Kannada, India-Malayalam, India-Marathi, India-Tamil, Indonesia-Indonesian, Japan-Korean, and Malaysia-Malay. The reports were reviewed and recommendations for changes in the cultural language were noted. RESULTS: Across all reports specific homophonic confu-sions were encountered within two target languages: Indian Hindi the same word was used for “pill” and “bullet”; in Singapore Malay the words for “end” and “saving” sound similar, occasioning confusion in prompts about attempts to end life. Furthermore, the type of a gun in suicide attempts was found to be rare or unknown: in Singapore English the relevant prompt was clarified to minimise confusion, for Malayalam for Kerala, where shooting is rare and hanging is common, “getting a gun” was changed to “getting a rope” wherever appeared and for similar reasons “collecting pills” was changed to “collecting a poison.” CONCLUSIONS: The e-CSSRS v2.0 IBS is now available for use in over 50 countries. Further work is required to use the Chinese and Indian languages in the future.

PRM171

FROM CLINICALLY RELEVANT OUTCOME MEASURES TO QUALITY OF LIFE IN EPILEPSY

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OBJECTIVES: Utilities can be easily derived using generic utility scores for quality of life (QoL) instruments. However, problems in selecting utility scores cross cultural and clinical evaluations still favor disease-specific instruments over generic quality of life instruments for reasons of sensitivity and reliability. Especially in case of the fluctuating nature of seizures in epilepsy, generic QoL-instruments are often found to be unsuit- able for outcome research. A proposed method to bridge the gap between clinically relevant outcome measures and QoL is to derive utility scores for epilepsy health states. The aim of this study is to develop a scoring algorithm to transform clinically relevant outcome measures of epilepsy into utility values which can be incorporated into economic evaluations. Although seizure frequency is the most commonly reported primary outcome measure in epilepsy research, this study suggests that the impact of seizure severity alone should not be underestimated.

PRM172

COmPARABILITY OF INTERVIEW AND SELF-ADMINISTRATION OF THE FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TUBERCULOSIS (FACT-TB) INSTRUMENT IN IRAQI PULMONARY TUBERCULOSIS PATIENTS

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OBJECTIVES: To investigate the extent to which two different modes of adminis-tration (interview by a trained interviewer versus self-administration) yielded a comparable estimate of health-related quality of life (HRQoL) in pulmonary tubercu-losis (PTB) patients. METHODS: The study was conducted between September 1st 2012 and July 31st 2013, among consecutive PTB patients treated at Thomeen Respiratory Disease Specialist Centre in Baghdad, Iraq. The mode of administration of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACT-TB); a new tuberculosis (TB) -specific instrument, at baseline was registered in 305 sub-jects. RESULTS: Although the FACT-TB was designed for self-administration, most patients in our sample (N = 193,63,2785) requested some help from the interviewer to fill out the questionnaire. Mann Whitney U test showed that those patients capable of completing a younger than 41 years of age (18.6 ± 12.93 versus 43.8 ± 16.41 years, P = 0.005) and required less time to complete the questionnaire compared to those who were interviewed by a trained interviewer (14.64 ± 3.24 versus 17.22 ± 2.61 minutes, P < 0.001), while Chi-Square statistics showed that this group of patients had a higher education level (P = 0.001). No differences in gender were observed. HRQoL score across all domains for those who interviewed a trained investigator was slightly lower than those who answered the questionnaire by self-administration. However, the results did not reach statistical significance (P = 0.05). CONCLUSIONS: Technical equivalence has been demonstrated in the sample of PTB patients in Iraq. FACT-TB instrument is flexible and is able to accommodate the needs of patients with different sociodemographic, and functional status. The purpose of this study was to investigate the extent to which two different modes of administration of questionnaire permits unbiased assessment of the impact of the disease and its treatments on patients’ HRQOL.
effects associated with EQ-5D-5L, this measure is still not a key requirement for cost-effectiveness modeling. If a selected HTA submission is based on EQ-5D-5L, it has the potential to distort the true cost-effectiveness in conditions that are insensitive to the measure. Awareness and requirements for the use of EQ-5D-5L should increase amongst manufacturers and HTA bodies to ensure submissions present accurate and robust cost-effectiveness models. Further, the validation and development of cost-effectiveness results between these two measures following the introduction of validated independent value sets for EQ-5D-5L is encouraged.


OBJECTIVES: In patients requiring frequent blood transfusions due to transfusion dependent anemia (TDA) e.g., sickle cell disease (SCD) and myelodysplastic syn-
drome (MDS), life expectancy is directly related to the quality of chelation therapy, and poor adherence to treatment increases the risk of complications and shortages and survival. Improved palatability ratings and gastrointestinal (GI) tolerability could have positive impacts on adherence with iron chelation therapy (ICT). Therefore, patient-reported outcomes (PROs) measuring compliance, GI symptoms, and palatability were developed and the Satisfaction with Iron Chelation Therapy (SICT) questionnaire was modified, as electronic PROs (ePROs) specific to a new formulation of the ICT. METHODS: Eleven patients were provided consent and were included in this qualitative study. Two sets of face-to-face cognitive interviews were conducted iteratively, modifications to items were decribed in the second. Interviews began open endedly to elicit patients’ spontaneous experiences with ICT. Interviews were audio recorded and transcribed. An item tracking matrix documented the changes made for each item. Data analysis used ATLAS. t software. The first interview was conducted according to best practices for development and modification of ePROs in an ePRO format. RESULTS: Patients were 73% (n=8) male and 27% (n=3) female with a mean age of 43 (range 34-81 years); 45% (n=5) had SCD, and 27% (n=3) had MDS. Patient spontaneous reports and cognitive debriefing responses were extracted in the draft ICT. Deemed different for all items, changes made after cognitive debriefing ensured the comprehensibility, lack of redundancy, and appropriate instructions and response options. The resultant PRO included 4 items of compliance (2 items), GI Symptom Diary (6 items), Palatability (6 items), and modified SICT (13 items). CONCLUSIONS: Results support the content validity of PRO measures of compliance, GI symptoms, palatability, and satisfaction with ICT. These measures require psychometric validation of psychological validity, reliability and responsiveness before recommending their use in future clinical research.

PRM174 THE IMPORTANCE OF MIGRATION ASSESSMENTS: ECOA TRANSLATIONS AND LANGUAGENAL VALIDATION Sweeney E, Kelley T TransPerfect, New York, NY, USA

OBJECTIVES: As the use of clinical outcomes assessments (COAs) in global studies continues to increase, early collaboration between eCOA and linguistic validation providers becomes critical to the success of global initiatives. Early involvement of a local language partner in the eCOA development process results in more relevant migration issues that may not be present in the English version of the instrument, but if not identified, can lead to study delays as well as increased costs for the sponsor. METHODS: An extensive literature review was conducted to identify previous linguistic validation projects. This review included either newly developed eCOA instruments or pen/paper to eCOA migration. A comparison of various eCOA platforms, the corresponding issues, and details relating to migration solutions were assessed. RESULTS: Frequently, a line of text is present in an eCOA platform (e.g., software, Excel,etc.) is coded such that it populates into the eCOA device in multiple locations. These segments are sometimes referred to as “computed text” and are commonly used for response options that repeat for multiple items of a questionnaire. While this may work adequately in English, many languages require a variance in the translation used based on the context of the item and/or response choice. While a pen/paper version may allow for these variances, the initial eCOA programming may not. The variance is only determined further into the linguistic validation process and presents challenges if the device requires re-programming. CONCLUSIONS: A migration assessment, separate from equivalency testing, allows for the eCOA and linguistic validation partners to assess the initial development of the eCOA software. This assessment can determine whether system modifications are necessary to allow for the translations to properly be mapped and displayed. This additional step will also prevent study delays as well as quality issues as it allows issues to be addressed early and avoid later difficulties.

PRM175 PATIENT-DRIVEN QUESTIONNAIRE DEVELOPMENT: ITEM FEEDBACK FROM USERS OF A PATIENT NETWORK Castaigné N1, Harrington M2, Campillo-Alvarez A3, Rebollo P4

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OBJECTIVES: CAT-Health is a generic health related quality of life computer adaptive test developed and validated in Spain. Based on its 96 item pool, a new instrument is being developed in English. The objective of the present study was to obtain subjective feedback from patients on the CAT-Health instrument using the PatientsLikeMe online platform, that centralizes FROM research and is integrated with PatientsLikeMe, an online community. METHODS: The item pool was split in four sets of 24 items each. All patients were asked, in conditions favorable, to access an e-search tool and link to a survey open for 7 days. They were asked to answer one of the sets and give feedback on a 4 point scale for applicability, comprehensibility and appropriateness of the item. They were also encouraged to leave free-text feedback. RESULTS: A total of 218 subjects provided feedback, 61.47% female. Mean age was 55.78 years, with patients from 18-80 years, 40.37% between 55-65 years. The most represented conditions were Parkinson’s (27), Fibromyalgia (23), Multiple Sclerosis (19), and Rheumatoid Arthritis (19). The mean number of quantitative assessments per item was 55.74, while the mean number of comments was 11.64. Considering a cut-off of 2 points in the 0-3 scale, 18 items had low applicability, 17 items had low comprehensibility and 15 items had applicability and comprehensibility options. CONCLUSIONS: An impressive amount of feedback was obtained in just a week using the Open Research Exchange platform. The lowest scores were in applicability. However, as the items are destined to an adaptive test, some of them are very extreme (destined to severe cases). Therefore applicability was considered a secondary concern. With this caveat, quantitative feedback was very positive, and added to the great amount and detail of qualitative feedback support some changes that we think will greatly improve the instrument.

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OBJECTIVES: To measure and compare the quality of life in patients undergoing hemodialysis with respect to time. METHODS: An observational, prospective study conducted in 2012/2013 consisting of 50 patients with Terminal Chronic Kidney Disease, undergoing HD in a public clinical care within the metropolitan area of Fortaleza. We used the KDQOL instrument early in therapy and one year after its beginning in order to observe changes in quality of life over time. Statistical analy-
sis included frequency distribution and measures of central tendency. RESULTS: The dimensions “physical function” and “social function” had the lowest scores early in therapy. It is observed that these same dimensions showed significant improve-
ment in both. CONCLUSIONS: Only “general quality of life” was not significant. At baseline, specific dimensions of the instrument as “professional role”, “sexual function” and “disease overload” have the lowest scores and remain the same after one year of the begin of therapy, showing that the time difference has no statistical significance. The quality of life of patients undergoing hemodialysis after a year of therapy is superior to the quality of life showed at the beginning of treatment although this difference is not statistically significant. It is important to seek for alternatives that can positively influence the quality of life of these patients.

PRM177 METHODS TO USE MEASURE PATIENT PREFERENCES IN PSORIASIS TREATMENTS – AN OVERVIEW WITH REGARDS TO THE GERMAN IQWIG AND G-BA Kania I., Kirschner O., Augustin M1.1 University Medical Center Hamburg Eppendorf, Hamburg, Germany

OBJECTIVES: According to the methodology of the German Institute for Quality and Efficiency in Healthcare (IQWiG), the benefit assessment of a new treatment intervention offers a comparison of different patient-relevant outcomes. The existence of different patient-relevant outcomes the Federal Joint Committee (G-BA) can engage the IQWIG to aggregate these to one comprehensive benefit measurement. So far, the German methodology represents one of the more prominent frameworks among the benefit QALY, the IQWIG refers to methods of multi-criteria decision making or preference evaluation like analytic hierarchy process and conjoint analysis. For psoriasis, one of the most frequent skin diseases, preference evaluation is lacking due to the high costs of treatment interventions is available. In the light of recent discussions, the objective was to give an overview of methods which have been used to date to prioritize and weight patient-relevant outcomes in psoriasis treatment. METHODS: The present review is based on a systematic literature research until 31 December 2013 in the databases PubMed, Embase, Ovid Medliner, Cochrane Library, Ecom.Lit and CINAHL using the keywords “psoriasis” and “preferences”. RESULTS: The search resulted in 288 hits without duplicates. 16 articles met the predefined inclusion criteria. In addi-
tion to methods to calculate QALY like time-trade off and standard gamble, conjoint analysis, willingness-to-pay and other preference methods were used. In method of the IQWIG, no study exists in the field of psoriasis where the analytic hierarchy process was used. CONCLUSIONS: The results of the presented review show, that the analytic hierarchy process was not used in psoriasis studies, so far. The use of this method in future studies might provide new essential knowledge in the evaluation of patient preferences in psoriasis treatment.

PRM178 IMPACT OF OSTEOPOROTIC FRACTURES ON QUALITY OF LIFE – DESIGN OF A MAPPING STUDY OF QUALIOST TO EQ-SD Hansen L1, Vestergaard P2, Petersen K3
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OBJECTIVES: The QUALIOST instrument is one of the most commonly used osteoporosis-specific health-related quality of life (HRQoL) questionnaires and it is often used in clinical studies to document the longitudinal changes in patients with osteoporosis and related fractures. Therefore, it is better at estimating HRQoL for osteoporotic fracture patients compared to the com-
monly used EQ-5D questionnaire. Preference scores have not yet been developed for the QUALIOST and, thus, cost-utility analyses are difficult to perform. The purpose of the presented study was to describe the design of a future study that will map the QUALIOST to the EQ-5D questionnaire. METHODS: A questionnaire, containing both EQ-5D-5L and QUALIOST, is distributed to patients in an orthopedic outpatient clinic in Denmark. The aim is to include 150 patients. Patients above 50 years of age and with a recent fracture (less than 2 weeks old) are invited to participate in the study.
The patients are asked to complete the questionnaire at initial contact with the out-patient clinic (before and 12 months post-fracture). The last inclusion date will be December 31st 2014. RESULTS: The hypothesis is that the QUALIOST will provide a better estimate of the impact of osteoporosis-related fractures on HRQoL as it contains disease-relevant aspects, which might not be existing in QoL questionnaires only focused on general HRQoL. We will develop a mapping algorithm to predict EQ-5D derived utilities for Danish fracture patients from the QUALIOST, which can be used in future studies, where utilities then may be estimated from QUALIOST results.

**CONCLUSIONS:** Mapping from QUALIOST scores to EQ-5D-5L derived utilities will enable estimation of preference-based HRQoL utilities for patients with osteoporotic fractures.

**PRM179**

**REVIEW OF PATIENT-REPORTED OUTCOMES IN DIABETIC MACULAR EDEMA**

**Itshik R., Nuramutis A., Adachi K**

**OBJECTIVES:** Diabetic macular edema (DME) is a serious condition occurring in patients with diabetic retinopathy (DR) which is a common complication of diabetes. Understanding not only objective measures such as visual acuity, but also the patients’ perspectives is important in gaining a comprehensive understanding of the impact of DME and its treatment on their functioning and well-being. The aim of this study is to understand possible measurements to investigate the impact of DME on health-related quality of life (HRQoL), by identifying currently available measures, their ability to differentiate between DR and DME, and possible reasons for difficulties in measuring HRQoL specifically for DME.

**METHODS:** We performed a literature review on articles describing instruments of patient-reported outcomes (PRO) for DME. As we summarized the current evidence on the usefulness of the instruments and whether they differentiate between DR and DME. In addition, we investigated possible hurdles in measuring HRQoL for DME, given the clinical understanding of the systemic aspects of DME.

**RESULTS:** We identified seven condition-specific or vision-specific measurements and seven general measurements, including generic HRQoL and utilities for possible instruments for DME. However, real-world clinical practice and developed and validated by patients with DR or DME.

**The possible reasons could be:**

1. DME is not the primary disease,
2. Many of DME patients have comorbidities such as DR, cataracts, and DR-induced glaucoma,
3. Those comorbidities may lead to decreased visual acuity with decreased HRQoL.

**Additionally, evidence is limited when measuring the impacts of DME on diabetic patients largely due to the lack of an effective PRO instrument for DME.**

**The major difficulties in developing such instruments is that:** DME patients have complex health states which provides for multiple reasons in decrease of QoL which may not be directly due to their DME.

**PRM180**

**DEVELOPMENT OF THE BEHAVIOR RATING INVENTORY OF EXECUTIVE FUNCTION - PRESCHOOL VERSION (BRIEF-P) IN 10 LANGUAGES**

**Vanara E.1, Isquith PK.2**

**OBJECTIVES:** The Behavior Rating Inventory of Executive Function Preschool Version (BRIEF-P) was designed to provide a better understanding of preschool children’s self-control and problem-solving skills. It is composed of 63 items organized into five clinical scales, which are examples of executive functioning (EF) domains. Published measures, such as the Abetz-Webb L., Patient-Centred Outcomes Assessments LTD, Macclesfield, UK.

**METHODOLOGY:**

1. **Translators’ training:**
   - Translators were trained by the lead clinician in the clinical meaning of items in the BRIEF-P.
   - Translators were trained on the translation principles used for the BRIEF-P, which includes: (a) forward and backward translation steps, (b) use of the back-translation process, (c) use of consensus groups, and (d) use of a back-translation process.

2. **Translation and back-translation:**
   - The process included a back-translation process, which was used to ensure the accuracy of the translated version of the BRIEF-P.
   - The back-translation process was used to ensure that the translated version of the BRIEF-P was equivalent to the original version.

3. **Consensus group meetings:**
   - Consensus group meetings were held to ensure that the translated version of the BRIEF-P was equivalent to the original version.

4. **Cultural adaptation:**
   - Cultural adaptations were made to the translated version of the BRIEF-P to ensure that it was culturally appropriate.

**RESULTS:**

- **Reliability:** The translated version of the BRIEF-P was found to be reliable, with high internal consistency and test-retest reliability.
- **Validity:** The translated version of the BRIEF-P was found to be valid, with high construct and convergent validity.
- **Responsiveness:** The translated version of the BRIEF-P was found to be responsive, with high sensitivity to change.

**CONCLUSIONS:** The translated version of the BRIEF-P is a valid and reliable tool for assessing executive functioning in preschool children, and it is a useful tool for assessing the impact of DME on HRQoL.

**PRM183**

**ACADEMIC CHANGING CHANGE IN QUALITY OF LIFE: CAN WE DISCUSS DIAGNOSTIC MEDICATIONS AND SCALE RECALIBRATION?**

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**OBJECTIVES:** Treatment effects on health-related quality of life (QoL) often differ depending on whether they are measured prospectively (before and after treatment) or retrospectively (after treatment only). It is not clear which of either evaluations is more valid. Prospective evaluations may be biased by scale recalibration (a changing understanding of the response scale), and retrospective evaluations may be biased by recall bias (a wrong assessment of former QoL). METHODS: Based on an analysis of literature, we present an overview on (a) possible biases in prospective and retrospective measurement of QoL, (b) how these biases are named and defined in literature, and (c) current approaches to distinguish scale recalibration and recall bias. RESULTS: The definitions of different biases are inconsistent. Many authors do not clearly distinguish measurement bias from true change. Furthermore, some consider only scale recalibration or only recall bias. There are different approaches for distinguishing scale recalibration and recall bias. We argue that these make too extensive assumptions to be valid. CONCLUSIONS: Much of the current discussion on the validity of prospective and retrospective QoL measurement suffers from unclear definitions, especially of “response shift” and “recall bias”, or from neglecting one of the possible biases. We suggest more elaborate definitions for different types of bias and recommend more transparent bias assessment when measuring change in QoL. Due to a lack of valid methods, there is not enough evidence on the extent of these biases yet; therefore the best approach for outcomes evaluation might be to include both prospective and retrospective assessments. In the long run, valid methods need to be developed to determine the most valid method of QoL assessment.
**OBJECTIVES:** Patient preferences have implications for treatment decision making, treatment adherence and follow-up care. This study aimed to highlight, using metastatic breast cancer (mBC) as an example, a method to elicit preferences and, of particular novelty, examine individual differences of those preferences.

**METHODS:** Using mixed methods, a qualitative study (n=10) of patients with mBC informed the development of a preference survey, which was validated and administered to women with mBC. Survey participants (N=181) completed a conjoint exercise that included a series of choice questions. Each choice question included a pair of hypothetical treatments that were presented in terms of eight safety attributes, single attributes for effectiveness, dosing regimen, and quality of life. Survey choice data were analyzed using hierarchical Bayesian logistic regression models.

Predicted values from this model were then analyzed to understand individual differences in patient preference. **RESULTS:** Qualitative interviews identified the most relevant side effects to include in the choice task (e.g., alopecia, nausea/vomiting, etc.) and reinforced the importance of quality of life when making treatment decisions. This was especially true when comparing treatments with different cost-effectiveness profiles and different levels of treatment-related toxicity, and with treatment preference, followed by alopecia, fatigue, neutropenia, and quality of life. Predicted values from the choice model enabled preference comparisons across treatment experience subgroups (e.g., 6+ years of chemotherapy vs. less). Preference strength for individual attributes, e.g., side effects was compared with various demographic and health history variables, though only modest associations were detected (Pearson rs<0.25). **CONCLUSIONS:** Understanding patient preferences provides opportunities for improved care and outcomes. Combining qualitative and quantitative methods in this study allowed for specificity of preferences and generalizability (albeit limited). Patient preferences derived across the sample informed predicted values from the choice model that can also be used for comparing patient preferences in subgroups and identifying factors that may be associated with certain preferences.

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**RESEARCH ON METHODS – STATISTICAL METHODS**

**PM186**

**REAL-WORLD VERSUS RANDOMISED CONTROLLED TRIAL DATA: A CASE STUDY ON THE COST-EFFECTIVENESS OF LAPAROSCOPIC SURGERY FOR CHRONIC REFLUX**

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**OBJECTIVES:** Real-world (observational) data has the potential to address the limitations of standardised controlled trials (RCTs) but presents its own challenges given the increased risk of bias. We compared the costs and quality-adjusted life years (QALYs) of patients following random vs preference-based allocation and assessed the performance of different methods to address these challenges. **METHODS:** The RFLEX study compared laparoscopic fundoplication (surgery) with medical management (MM) over 5 years of follow-up. The trial included randomised and non-randomised preference-based allocation. We compared the cost-effectiveness of surgery in the RCT vs preference cohorts as unadjusted raw differences, applying methods to handle biases from selection and confounding (regression adjustment, propensity score matching and instrument variable analysis) and explored the impact of receiving the preferred treatment on the results. **RESULTS:** The preference surgery group accrued greater healthcare costs and QALYs than the randomised surgery group ($3,524 vs $2,852; 3.723 vs 3.612 QALYs). The preference MM group had lower costs but slightly better QALYs than the randomised MM group ($861 vs $1,415; 3.411 vs 3.411 QALYs). The incremental cost-effectiveness ratio (ICER) for the preference cohorts was similar to that obtained in the RCT using the different methods at around $8,000 per QALY gained ($14,632 unadjusted raw differences). Receiving the preferred treatment was significantly associated with lower costs and better QALYs after adjusting for prognostic variables. **CONCLUSIONS:** Real-world data can be used in cost-effectiveness analysis to complement RCT evidence. However, more research is needed on how to choose the most appropriate method to adjust for selection bias and how to account for patient preferences when making recommendations on value for money.

**PM187**

**INTEGRATING HEALTH PSYCHOMETRICS WITH HEALTH ECONOMICS: CAN THE ‘MAPPING’ TOOLBOX BE EXTENDED USING ORDINAL STRUCTURAL EQUATION MODELS?**

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**OBJECTIVES:** Mapping enables the prediction of health-state utility values via health outcomes measures in trial data using algorithms linking those measures available to preference-based measures (PBMs). However, the unusual distributional features of PBMs mean that there is no consensus around the most appropriate statistical methodology for obtaining mapping algorithms. Existing studies have shown that structural equation modelling (SEM) developments open up a range of opportunities for effectively analysing PBMs. This study draws upon some of the methodological developments and structural equation modelling (SEM) developments to enable the inclusion of RWE, especially in the light of the changing nature of RCTs from both a regulatory and reimbursement perspective, is considered here. **METHODS:** RCTs and RWE studies were searched for using standard filters and databases up to, and including, the regulatory approval of Fingolimod by the European Medicines Agency (EMA) in 2011 for Multiple Sclerosis (MS). A number of NMA were then conducted and which included, only RCTs, both RCTs and RWE (accepted at face-value), both RCTs and RWE but including an add-on level in the NMA hierarchical model to represent the different study designs, and finally both RCTs and RWE but adjusting the RWE for potential biases. **RESULTS:** Identification of RWE in addition to RCTs in this MS example significantly increased the number of studies (and comparisons) that were potentially included in the NMA. Whilst the inclusion of the additional RWE led to a reduction in the level of uncertainty surrounding most effect estimates, this reduction on the method for obtaining mapping algorithm, as an example to two versus one, to which biases were adjusted for. **CONCLUSIONS:** This initial evaluation of methods for the inclusion of RWE in NMA indicates that methods of adjustment for the potential biases in RWE can have a significant impact on the level of uncertainty. Consequently, further work, including both empirical evidence for such biases and methods of elicitation on experts on the extent of biases associated with individual RWE studies is warranted.

**PM189**

**FREQUENTIST APPROACH FOR DETECTING HETEROGENEITY IN META-ANALYSIS PAIR-WISE COMPARISONS: ENHANCED Q-TEST USE BY USING IZ H AND H2 STATISTICS**

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**OBJECTIVES:** In meta-analysis, model selection is an important criterion which needs to be tested and validated by strong statistical evidence. The Cochran’s Q-test allows in theory to decide between random-effect and fixed-effect models. Due to the highly conservative nature of this test, three statistics have been built to estimate heterogeneity that lead to the H2, the I2 and the R2. **RESULTS:** We conducted a review of the Q-test utility in diverse scenarios with a comparison of three different methods to estimate the heterogeneity between studies (H2, I2 and R2). **CONCLUSIONS:** Based on the Cochrans Q-test, we proposed to analyse jointly the first error species and the second error species in different scenarios based on the number of studies included in each meta-analysis. The analysis led to determine the reliability of the Q-test in extreme situations and also to give some benchmark for the reliability of this test. We use simulation methods to analyse the three different methods for calculating the between-study variance compared to the real value of heterogeneity. We also compared different arbitrary levels for model selection using these statistics in different scenarios. **RESULTS:** The Cochran’s Q-test is too conservative with a large number of studies and concludes to the presence of heterogeneity whatever the situation is when the number of studies is higher than 18. In comparison, the different statistics have an average value inversely linked with the number of studies in case of non-heterogeneity: the higher the number of studies, the lower the statistics’ average values. **CONCLUSIONS:** The H2 and H2statistics can eventually enhance the use of Cochran’s Q-test by solving conservative issue associated with this test. The first selection decision, eventually, be led by benchmark of these statistics jointly with the Cochran’s Q-test.

**PM190**

**THE USE AND ACCEPTANCE OF NOVEL STATISTICAL ANALYSES TO SUPPORT TECHNOLOGY SUBMISSIONS TO HTA AUTHORITIES**

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**OBJECTIVES:** Indirect comparisons are increasingly accepted to model the clinical- and cost-effectiveness of treatments. The purpose of this study was to (i) assess the literature reporting on the use of novel statistical methods [simulated treatment comparison (STC), and matching-adjusted indirect comparison (MAIC)]; and (ii) assess technology appraisals (TAs) submitted to the National Institute of Health and Care Excellence (NICE) to determine whether these analytical frameworks have been accepted by reimbursement authorities. **METHODS:** Embase, Medline and the Cochrane Library were interrogated to identify publications reporting on the use of MAIC or STC. NICE TAs published from 2011–2014 which reported MAIC or STC were identified using external information. **RESULTS:** Six publications reported on the use of MAIC in six indications. Results from these analyses concluded that MAIC offered several advantages over conventional meta-analytic approach that are of great importance. Findings from the review of NICE TAs indicated that these novel statistical techniques have not been
widerly used in manufacturers' submissions to date. Of the most recent 60 NICE TAs, 41% make use of AUC methodology, in two submissions and a STAC analysis in a single HTA, all in the oncology setting. In all cases the review group identified limitations with the statistical methodology presented, although their use as exploratory analyses supporting results from conventional meta-analysis was appropriate when used in one submission (NICE AA), and randomised data from single treatment arms was highlighted as a potential weak- ness of STAC. CONCLUSIONS: In spite of the increasing published evidence base reporting on the use of AUC methodology, both meta-analyses have been widely used in manufacturer's submission to NICE. Assessment bodies critiquing the technology submissions remain to be convinced of the appropriateness of these novel techniques for the robust assessment of relative efficacy.

PMR191
META-ANALYSIS IN OPEN BUGS: HOW TO ASSESS THE CONVERGENCE OF MCMC CHAIN?
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OBJECTIVES: Meta-analysis is often conducted in OpenBUGS. This software, like all BUGS, is based on MCMC simulations by using Gibbs sampling. One of the main issues in the use of Markov chains in a continuous space is the chain convergence. If the chain does not converge, transient states will be accounted for in our posterior distributions. Since these states are not bound to the empirical data only but with the chain's starting point, the estimated parameters of the posterior distribution will be biased. To help assessing the convergence of MCMC chain, several methods exist. METHODS: Based on the literature, we run several simulation scenarios in order to evaluate different methods to assess convergence. We present the results of the “thin” approach, a fixed-step jumping-data method, for convergence. Then, we focus on the existing diagnoses, their supplementary assumptions and their associated computation costs. To help convergence, we present the use of OpenBUGS objects, we present the R-package coda. RESULTS: The use of jumping-data method leads to power of the thin approach to be used in the use of the thin approach, it is not recommended to obtain a quicker convergence and better posterior distribution estimation. We have also seen that although auto-tuning and trace can be useful for assessing convergence, they can lead to misinterpretation in case of extremely low power of the thin approach. To conclude to convergence, the Geweke diagnose seems, in terms of computation cost and assumptions, recommended for two main advantages: it gives a measure of trust of being in a stationary process and very low computation cost. CONCLUSIONS: We presented methods to assess conver- gence of MCMC chains and argued on their pros and cons. The Geweke diagnose was found to provide best trade-off between computational cost and interpretability.

PMR192
ADJUSTING FOR TREATMENT CROSSOVER IN A TRAMETINIB METASTATIC MELANOMA RCT: IDENTIFYING THE APPROPRIATE METHOD
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OBJECTIVES: Treatment crossover refers to the situation in randomised controlled trials (RCTs) where patients randomised to the control group switch onto the exper- imental treatment, or vice versa. The degree to which crossover biases the estimated effects is obviously dependent upon the extent of crossover. This study investigated the impact of crossover on an RCT comparing trametinib to chemotherapy in patients with BRAF V600E/K- mutation-positive advanced or metastatic melanoma (NCT01245062), and investi- gated which adjustment method best fits this case study. METHODS: The crossover adjustment methods assessed included the Rank Preserving Structured Partitioning Time Model (RPSFSTM), Iterative Parameter Estimation (IPE) algorithm, Inverse Probability of Censoring Weights (IPCW) and a two-stage accelerated failure time model estimation procedure. Suitability of each method is compared by assessing the plausibil- ity of the underlying assumptions of the models in this case study and analysing output and performance indicators associated with each method. RESULTS: In the primary efficacy population (patients without history of brain metastases) 67.4% of chemotherapy patients switched onto trametinib. The intention to treat (ITT) hazard ratio (HR) for overall survival (OS) was 0.72 (95% CI 0.52-1.01). Point-estimates of the adjusted HRs produced by the most plausible applications of the RPSFSTM, IPE, IPCW and two-stage methods varied between 0.43 and 0.49, consistently favouring trametinib. Results were sensitive to the technique used to apply each method. Key issues included recensnoring, the active nature of the comparator, and the choice of covariates included in the analyses. CONCLUSIONS: Each of the crossover treat- ment methods result in a lower HR than the ITT analysis. However, results are uncertain and sensitive to key assumptions. It is important to carefully analyse trial characteristics and model output when identifying which applications of adjust- ment methods are most plausible.

PMR193
ASSESSING BALANCE IN BASELINE CHARACTERISTICS USING DIFFERENT PROPENSITY ADJUSTED METHODS FOR BIPOLAR I MIXED DISORDER PATIENTS INITIATING ASENAPINE VERSUS OTHER ORAL ATYPICAL ANTIPSYCHOTICS
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OBJECTIVES: Asenapine, an oral Atypical Antipsychotic (AA), was initially used for more severe bipolar I mixed disorder. Different propensity score (PS) methods were investigated to achieve balanced baseline characteristics between ASE and four oral AA cohorts for eventual outcomes analyses. METHODS: Adults with ≥ 1 asenapine, aripiprazole, olanzapine, quetiapine, or risperidone prescription fill (Aug 2009 to Dec 2010) and diagnosis of bipolar I mixed disorder ([CD-9-CM: 296.6]) were included (ASE: 230, AIP: 276, ORA: 139, OLA: 305, and OLP: 26). Patients were derived using logistic regression models for ASE and each AA with baseline demographic and clinical characteristics as covariates. PS, inverse probability treatment weight (IPTW: 1/ PS x 100) and 0.1 log transformed PS weights (SMR: 1/PS/0.1~PS AA) distributions were evaluated. ASE: AA un-weighted, IPTW, and SMR baseline characteristics were compared using standardized differences, chi-squares, and reporting of long-term side effects. RESULTS: Un-weighted baseline characteristics of bipolar I mixed disorder patients have not been studied widely in manufacturer's submission to NICE. Assessment bodies critiquing the technology submissions remain to be convinced of the appropriateness of these novel techniques for the robust assessment of relative efficacy.
in a user-friendly environment during a decision-making setting avoiding disadvantages of pre-prepared analyses.

**PRM196**

AN EVALUATION AND COMPARISON OF METHODS USED IN SURVIVAL ANALYSIS TO FIT DISTRIBUTIONAL CURVES TO KAPLAN-MEIER DATA

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OBJECTIVES: HTA bodies increasingly require accurate survival estimates in order to provide reliable recommendations. It is argued that access to individual patient data (IPD) can improve their accuracy. This paper aims to assess to what degree extracting IPD from published Kaplan-Meier curves helps improve extrapolated survival estimates. Some methods currently used for HTA submissions fit a survival curve directly to a published Kaplan-Meier curve, but does this lack accuracy? METHODS: Two methods were used to extract the IPD from Kaplan-Meier curves reviewed in this paper, described in Col and Lumley (2003). The first compared it with two different implementations of the standard 'least squares' method. Comparisons were made for two situations: 1) when numbers at risk are available at different time points throughout the Kaplan-Meier curve and 2) when numbers at risk are only available at the start. RESULTS: The three methods resulted in the long-normal distribution showing the best fit, with all containing the true mean and median within their confidence intervals. However, the Hoyle and Henley method estimates a mean marginally closer to the true mean than the other methods in both situations. When many numbers at risk are provided, the Hoyle and Henley method gives narrower confidence intervals. Both extraction methods slightly outperformed the least squares method. The three methods resulted in the long-normal distribution showing the best fit, with all containing the true mean and median within their confidence intervals. However, these results may not be applicable to other examples. In addition, the extra time taken to run extraction methods could be too large to account for the small improvement in accuracy of results.

**PRM197**

MULTI-LEVEL NETWORK META-ANALYSIS TO ACCOUNT FOR DOSE-RESPONSE AND CLASS EFFECTS

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OBJECTIVES: A frequent challenge in Network Meta-Analysis (NMA) arises from the fact that several interventions may belong to the same class and be given at multiple doses. Models have been proposed for NMA accounting for dose-response, but these models do not also consider class effects at the same time, which are important from a clinical perspective. We aim to develop a framework that extends these previously proposed dose-response NMA methods to account for dose and class effects simultaneously, and explore the ability of these models to explain heterogeneity, improve model fit and increase precision of the estimated treatment effects. METHODS: Using clinical trial data of treatments for acute migraine obtained from Cochrane reviews, we made less plausible assumptions around dose-response had poorer fit than models constrained to be monotonically increasing with dose. Models have been proposed for NMA accounting for dose-response, but these models do not also consider class effects at the same time, which are important from a clinical perspective. We aim to develop a framework that extends these previously proposed dose-response NMA methods to account for dose and class effects simultaneously, and explore the ability of these models to explain heterogeneity, improve model fit and increase precision of the estimated treatment effects. METHODS: Using clinical trial data of treatments for acute migraine obtained from Cochrane reviews, we developed multi-level NMA models to simultaneously account for dose-response and class-effects, in particular defining a ‘dose’, ‘treatment’ and ‘class’ hierarchy within the NMA models. We explored a non-parametric ‘random walk’ model concept constrained to be monotonically increasing with dose. Multi-level NMA models were compared to 1-level (standard) NMA models where interventions were ‘lumped’ at each level separately. The model that explicitly included monotonic dose response and class effects showed the best fit and least heterogeneity, and produced more precise measures of treatment effect than all 1-level models. NMA models that made more plausible assumptions around dose fit than models with monotonic dose-response. CONCLUSIONS: We have developed a framework for simultaneously estimating treatment effects at the dose, ‘treatment’ and class level within the same NMA model. The framework can help decision makers identify the most appropriate class, drug, and dose, however, results of dose-response class models are not straightforward to interpret or implement from a decision making perspective. Careful consideration should be given to dose-response and similarity of interventions when conducting NMA.

**PRM198**

THE LUMLEY-METHOD, A RECOMMENDED NETWORK META-ANALYSIS FOR INDIVIDUAL PATIENT DATA SUMMARIZED FOR PRACTITIONERS

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OBJECTIVES: In recent years we have seen a growth in the use of network meta-analysis as part of the evidence base for Health Technology Assessments, with the Lumley method, published in 2002 being a key reference when considering both indirect and direct comparisons. Unfortunately the program code included in the user manual cannot easily be run, and the given examples cannot be replicated even with corrected code. To give practitioners helpful insight into the method, we start from individual patient data of head to head trials and show how from subgroups of data the Lumley framework can be derived. METHODS: We give more details than in the article of how the proposed variance function aggregates study-heterogeneities and of how effect-sizes and confidence intervals can be derived from the parameter- and variance-estimation. We discuss why dependencies coming from the network structure should be incorporated into confidence interval calculations and of how the model can be extended with an in the article suggested Bayesian approach for modeling the random-effects parameters. RESULTS: We present an example in the article a corrected R version and a translation into SAS. For both we show how aggregated study-data should be structured and dummy-coded before running the program. The Lumley-method was applied to simulated data with known model-parameters and we show for different scenarios how close the estimates come. For selected treatment-comparisons we presented effect-sizes with confidence intervals which we applied also the Bayesian extension and discuss its advantages. CONCLUSIONS: Based on our research we give recommendations of when the Lumley-method should be best applied, and discuss limitations. Haines T. Network meta-analysis for indirect treatment comparisons. Stat. Med. 2002, 21: 2313-2324.

**PRM199**

ANALYSIS OF VOLUME AND STRUCTURE OF ORAL ANTIDIABETIC DRUGS CONSUMPTION IN UKRAINE

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OBJECTIVES: Evaluation and comparison of oral antidiabetic drugs (OAD) consumption at state level are an important element at control of 2nd type DM patients treatment quality. The objective of the study is to determine the volumes and structure of OAD consumption in Ukraine in comparison with other countries. METHODS: ATC/DDD methodology with application of DDD/1000/day (DID). The evaluation is based on consumption volume, provided by “PharmXplorer/Pharmstandard” analytical system of market research. RESULTS: In year 2008, OAD consumption was 5.78 DID and it increased to 8.13 DID per 1,000 inhabitants in year 2013. In year 2011, OAD consumption was 54.28 DID in France, 44.58 - in Germany (S. Pichetti, C. Sermet, S. van der Erf, 2013), 33.25 - in Estonia, 29.87 - in Latvia (Baltic Statistics on Medicines 2010-2012), showing that OAD consumption in Ukraine was very low. Structure of OAD consumption in Ukraine shows that 98.95% of the total consumption volume is distributed to 2 groups: sulfonylureas (73.84%) and biguanides (25%) and only 1.05% to glitazones, glinides and glifamides. The total share of prescribed doses of sulfonylureas and biguanides group in the total consumption structure in France and Germany was 71.8% and 80.1% respectively of the total consumption OAD. In year 2013, OAD of the II generation - gliclazide (5.01 DID) and glibenclamide (2.09 DID) had lower consumption in comparison with preparations of III generation - gliperamide (2.09 DID) had lesser consumption rate. Out of 61 OAD trade names (TN), presented in the pharmaceutical market of Ukraine, 8 TN accounted for 85% of the total consumption volume. CONCLUSIONS: Very low rate of OAD consumption in Ukraine shows the necessity of its increase. Analysis of OAD consumption structure evidences the application of relatively cheap and long-used medical preparations for treatment of 2nd type DM, which is largely due to financial capacitors of payers.

**PRM200**

DEVELOPMENT OF A WEB-BASED TOOL TO ELICIT THE OPINION OF REGIONALLY DISPERSED HEALTH CARE PROFESSIONALS RESPONSIBLE FOR MEDICAL DEVICE VIGILANCE

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OBJECTIVES: In the context of uncertainty due to the lack of sound data, expert opinion is considered as a legitimate source of information for decision-makers. The use of experts’ opinion requires to quantifying their uncertainty about a specific event by eliciting a probability distribution of the event. The objectives of this study were to develop a web-based tool enabling users to remotely elicit the opinion of a group of geographically dispersed experts and to evaluate the measurement properties of this tool. METHODS: The web-based tool allowed first to eliciting univariable probability distributions separately from each expert and secondly to calculate an aggregated distribution. The method was compared to the four-limit method that had to be judged more appropriate for non-statistician experts due to its clarity of use. As recommended to limit biases, the elicitation questionnaire included a training exercise and a graphical representation of what the experts could validate their distribution. A pilot survey was conducted among all the French regional medical device vigilance correspondents (n=24) about the risk of failure (%) of an implantable medical device. RESULTS: Twenty-two correspondents (92%) completed the survey. An aggregated distribution was calculated from the elicited individual distributions and a beta distribution was fitted reflecting the group uncertainty about the risk of failure. Feasibility was judged in view of the users’ feedback and time to completion. Validity and reliability were assessed on comparison with an expert consensus, internal coherence and test-retest reliability. CONCLUSIONS: The proposed web-based tool was feasible, valid and reliable. It should be useful in making expert elicitation easier and more practical.
to promote awareness on the medications, balanced diet and physical activity to improve the quality of life of an individual.

PRM202 SIMULATING INDIVIDUAL PATIENT LEVEL DATA TO ADDRESS TREATMENT EFFECT ON PATIENTS WITHOUT SUMMARY DATA ARE AVAILABLE

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OBJECTIVES: Treatment switching commonly occurs in the pivotal HTA evidence for advanced or metastatic cancer treatments submitted to reimbursement agencies. Simple approaches, such as Intention-to-treat (ITT) analysis, have typically been used to analyse data with treatment switching, despite simulation studies showing these to drastically underestimate the underlying treatment effect. With more manufacturers conducting indirect comparisons (ICs) to compare treatments, summary data are being used more in analysis. The method outlined addresses treatment switching in small sample size summary data when there is uncertain treatment effects for sequential therapies. The objective is to correctly estimate the treatment effect when the data is then used in an IC. METHODS: Using digitised survival curves, multiple datasets that are representative of the original individual patient data (FPG) are simulated. Treatment switching is conducted with each simulated dataset survival, and then established methods which adjust appropriately for treatment switching used to analyse the simulated data. This approach is applied to an example of a technology appraisal (TA) submitted to National Institute for Health and Care Excellence (NICE), and the ITT hazard ratio and median survival obtained and compared with those reported, before analysis using a Rank Preserving Structural Failure Time Model (RPSFTM). RESULTS: Averaging over 2000 datasets, the replicated survival curves were similar to those reported. Both median survival times were within 1 month of those stated in the TA and the hazard ratio less than 0.05 different. Subsequent analysis using an RPSFTM shows the new treatment to be more effective and inappropriate adjusting for crossover to have underestimated the treatment effect. CONCLUSIONS: Adjusting summary data is important as otherwise, subsequent analysis conducted will give inappropriate results. The simulated datasets with treatment switching present the original data and average similar results to those reported. Hence, the further analysis to address treatment switching issues gives more appropriate treatment effect estimates.

PRM203 MODELING THE EFFECT OF COMBING ALOGLIPTIN WITH DUAL THERAPY IN TYPE 2 DIABETES

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OBJECTIVES: To estimate the impact of combining the dipeptidyl peptidase-4 (DPP-4) inhibitor, alogliptin, with metformin and sulfonylurea (alogliptin triple therapy) to achieve glycemic control in patients with type 2 diabetes. We modelled the clinical trial of alogliptin triple therapy has been conducted, the effect of adding alogliptin to dual therapy (metformin + sulfonylurea) was modeled using novel additive effect methodology, utilizing data from a previous mixed treatment comparisons (MTC). The following assumptions were made: the efficacy of triple therapy can be estimated as a function of its constituent parts, and the efficacies of the constituent parts are equal. Fused data for the absolute change from baseline in glycoylated hemoglobin (HbA1c) from trials of sitagliptin, linagliptin, and vildagliptin triple therapy, and for their constituent parts, informed the model. A weighting factor, β, coefficient, derived from DPP-4 mono, dual, and triple therapy trials, was used to estimate the effect size for triple therapy using the sum of the constituent parts. The estimated mean β value was validated against the observed effect size of alogliptin +pioglitazone+metformin, using the pooled effect from the MTC. RESULTS: An estimated μ value of 0.83 represented the DPP-4 inhibitor class. Validation of the approach resulted in a similar β coefficient for pioglitazone triple therapy (0.82). Absolute change in HbA1c, from baseline for alogliptin triple therapy was estimated as -0.77% (95% CI -1.16, -0.39). Similar values were observed in the MTC for sitagliptin -0.94% (95% CI -3.94, 3.40), linagliptin -0.62 (95% CI -6.87, 5.60), and vildagliptin -0.80% (95% CI -7.00, 5.43). CONCLUSIONS: The wide confidence interval is consistent with expectations in the literature and is a limitation of the method employed, in that it requires the variance of the individual studies be summated. Nevertheless, the method demonstrates the value of modeling when clinical trial evidence is not available.

PRM204 UNCERTAINTY AND PROBABILISTIC METHODS IN MULTI-CRITERIA DECISION ANALYSIS

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OBJECTIVES: Multi-Criteria Decision Analysis (MCDA) is a collection of techniques for choosing optimal decisions when two or more criteria need to be taken into account in the decision process. Most MCDA techniques require the specification of a number of parameters; criteria weights, utility functions or indifference thresholds. We wish to account for the uncertainty in these parameters which may arise due to the uncertainty in the decision model or the lack of data. The Decision Models and Analysis (Dma) framework represents the relationship between a group of decision makers or population group, or the abstract nature of the parameters. METHODS: We implement some MCDA models from a Bayesian perspective when the context of a problem is a combination of probabilities distributions representing the combination of available knowledge on the parameters. Such knowledge can come from empirical data, expert elicitation, survey data, decision-making committees, or some combination of these. RESULTS: Depending on the method used, the explicit model is used to identify the expected utility function, which will be used to rank benefit score for each action, or a rankogram which depicts the uncertainty in the ranking of actions. CONCLUSIONS: Knowledge about this uncertainty allows decision makers to make more informed decisions. A decision action may be clear when uncertainty is sufficiently low, or it may be necessary to request more information or to reframe the decision formulation if uncertainty is high, potentially leading to improved decision-making.

PRM205 SYSTEMATIC REVIEW AND CRITICAL APPRAISAL OF THE STATISTICAL METHODS USED IN PUBLICATION LEVEL ANTICOAGULANT (NOACs) WITH WARFARIN FOR THE PREVENTION OF STROKE IN PATIENTS WITH ATRIAL FIBRILLATION (AF)

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INTRODUCTION: The three main novel anticoagulants (NOACs) currently licensed in Europe, apixaban, dabigatran and rivaroxaban, have all been directly compared against warfarin in randomized controlled trials. However, none of the three drugs have been directly compared against each other. Thus, there has been an increase in the number of meta-analyses and indirect comparisons published comparing the NOACs to each other and warfarin via a common comparator. OBJECTIVES: Systematically review all meta-analyses and indirect comparisons evaluating the NOACs for prevention of stroke in patients with AF and critically appraise the statistical methods used to do so. METHODS: Systematic searches of EMBASE, Medline, EBM Reviews, Econstit as well as manual searches of ClinicalTrials. gov, the Cochrane Library, CADTH, NICE, NHSEED and HTA were conducted. Data was abstracted from any citation applying statistical methods to compare the efficacy and safety of NOACs for the prevention of AF-related stroke. Information regarding the statistical approach, model assumptions, data presentation, interpretation of the evidence, and discussions of internal and external validity was used to quality rate each study. RESULTS: The limited number of RCTs available comparing the NOACs to standard therapy, creates considerable uncertainty in the indirect comparative efficacy and safety of these anticoagulants. In order to establish which individual NOAC is most likely to benefit a given patient population, indirect comparisons and meta-analyses are increasingly used. However, the quality of indirect comparison studies are variable and results should be interpreted with care.
in type 2 diabetes mellitus. Comparison of the checklist was based on qualitative assessment of each analyst. A measure of the inter-analyst agreement was estimated to ensure the reliability of the checklist. **RESULTS:** Checklists identified from the literature included the checklist developed by the NICE Decision Support Unit and the one developed by the ISPOR task force. These two checklists were used by the randomised Blind Start design for review NMA. However, they seem to lack clarity for non-statisticians. We developed a new checklist, which included the following items: definition of the study question (list of comparisons and outcomes), methods for data extraction, statistical model, selection of fixed versus random effects model, assumptions for the base case, heterogeneity and inconsistency assessment and sensitivity analyses, reporting of results (network and source data, median or mean and 95% credibility interval) and interpretation of results. Our checklist can be used by analysts not trained in statistics to prepare or review NMA to be submitted to NICE and/or to populate cost-effectiveness models.

**Conclusion:**

The developed checklist will be useful for improving the quality of economic evaluations and will be an essential tool in the future for the development of guidelines and quality standards. The checklist will support analysts and reviewers in ensuring the quality and transparency of economic evaluations.

**Method:**

The checklist was developed through a systematic review of existing checklists and guidelines, followed by a Delphi process involving a group of experts in modelling and economic evaluation. The final checklist was refined through feedback from stakeholders and expert groups.

**Conclusions:**

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the algorithms’ PPV. **CONCLUSIONS:** We have demonstrated that MC/PPV algorithms can be used to identify PsO patients with a high degree of accuracy, while PsO-AC accuracy requires further investigation. Such methods allow researchers to conduct retrospective studies in databases where diagnosis codes are absent.

**PMR215**

**ASSESSING THE EFFECTIVENESS OF COUNTER MATCHING FOR IMPROVING THE EFFICIENCY OF THE NESTED CASE-CONTROL DESIGN IN OBSERVATIONAL STUDIES**

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**OBJECTIVES:** The nested case-control (NCC) design offers a simple method for avoiding unreasonable assumptions in the evaluation of time-dependent treatment effect. Its results are easy to interpret. Its strength rests largely on the appropriateness of the controls which are matched to the cases—suggesting a matching strategy will be required. A technical determination is needed: how many discordant case-control pairs may be more efficient since effect estimation is based entirely on the off-diagonal data of the resulting 2x2 tables in the conditional logistic regression. In theory, the more off-diagonal pairs that are generated by the random sampling scheme, the more improvement we can expect on efficiency. The objective of this study is to assess the efficiency of counter-matching on treatment compared with the classical matching approach in the NCC design based on results from the cohort design using simulated data. **METHODS:** In each simulation of 1000 patients at 100 replications per run, we assumed an underlying event hazard of Weibull distribution using input values for the scale and shape parameters, treatment, age and sex as the factors. Each run involved distinct treatment prevalence of between 10%-50% with event rate varying from a control rate of 10% to a control rate of 0%. Each matched pairs at 1 control per case used in the analyses of the resulting data between the classical and counter matching strategies. **RESULTS:** The counter-matched strategy was overall more efficient than the classical approach. The number of matched pairs selected was on average over ten times more and it also gave mean effect estimates which were more consistent with the full cohort values, particularly for low treatment exposure. **CONCLUSIONS:** Our study suggests that counter matching is more efficient and more accurate estimates than classical matching in nested case-control design. These benefits may be particularly important for studies involving rare events or low treatment exposure.

**PMR216**

**ASSESSMENT OF THE METHODOLOGICAL QUALITY OF RANDOMIZED CONTROLLED TRIALS PUBLISHED IN “RUSSIAN ALLELOGEOGRAPHY JOURNAL.” IN 2009-2013**

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**OBJECTIVES:** To assess the methodological quality of randomized controlled trials (RCTs) published in “Russian Allelogoaphy Journal” in 2009-2013. **METHODS:** Retrospective analysis of 96 original publications was carried out. For 8 RCT the risks of bias were assessed using the methodology of the Cochrane Collaboration. Assessment of the risk of bias in studies that have been published in the Russian journal’s requirements, made in accordance with best international practice. **RESULTS:** 96 articles were analysed, 8 (8%) of them were identified as RCTs. All the RCTs were studies on the research drug, but 40% of the trials had major mistakes in the statistical analysis. **CONCLUSIONS:** The methodological quality of RCTs is insufficient and needs to be improved. We consider that the most important role should play improvement of trials planning. Collaboration with the experts in clinical trials’ methodology is strongly recommended. The analysis empowers researchers to consider exist-
analyses reduce the probability of finding significant results due to chance while large numbers of our events reduce the overestimation of treatment effects. Our analysis finds that a statistically significant gain in OS is an important decision driver for even the most critical HTA agencies, although the treatment effect may still be questioned when the trial is unblinded early. HTA agencies appreciate to receive the latest available evidence that is generated within a short time. They may reject the use of oncology drugs when there is too much uncertainty around OS estimates to justify the proposed price. It is generally useful to continue data collection of the primary outcome of interest. Conclusions: HTA agencies should request more reliable OS estimates for modeling purposes (UK and Australia) or long-term risk-benefit evaluation (France).

**CONCLUSIONS:** Payers are aware of the overestimation of effect size due to early trial termination and may reject drugs for high uncertainty around OS estimates. While non-blinding is often a requirement for more reliable data, it is advised to continue data collection and follow-up patients.

**PM221**

**THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME (IBS) IN ENGLAND:** A REAL WORLD STUDY IN PRIMARY CARE CLINICAL PRACTICE

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**OBJECTIVES:** IBS is often a diagnosis of exclusion, with poor diagnosis coding in primary care and identification of eligible research participants challenging. We present the methodology of an on-going multi-centre, observational, retrospective research study, designed to overcome the challenges of IBS patient identification.

**METHODS:** FARSITE, a software tool for identification of research participants developed by the Greater Manchester Comprehensive Local Research Network North West eHealth, was used to screen anonymised primary care records for potentially eligible patients. Ethical approval reference 13/LO/0692. Search criteria: patients aged 16 + with at least 2 episodes in 6 months with symptoms indicative of IBS and prescription of IBS medications 01/09/2011–31/12/2012. GPs at 18 participating practices in Salford & Greater Manchester reviewed clinical records of the FARSITE-generated list of patients to identify an eligibility criteria specific for IBS. Inclusion criteria: medical diagnosis of IBS or meeting ROME III criteria, provision of consent. Exclusion Criteria: diagnosis excluding IBS, IBS symptoms secondary to other condition, IBS medications only for non-GI symptoms. **RESULTS:** FARSITE identified 1093 patients with IBS diagnosis (14% of the total). Of those, 1297 (27.3%) were eligible. 97 patients consented to participation (79% female). Main reasons for non-eligibility were not meeting ROME III criteria or IBS excluded by medical opinion. Patients were mostly commonly coded as irritable colon (37%), difficulty defecating (31%), abdominal pain (18%), diarrhoea symptoms (14%). Four (4%) patients had a read code specific for IBS. The median (IQR) time from 1st presentation with abdominal symptoms to study eligibility was 3.38 (0.00-9.04) years. **CONCLUSIONS:** Identification of patients with IBS using read coding alone has limited effectiveness. A combination of read codes with a symptom and prescription data via FARSITE has enabled potential patients to be identified with a reasonable screening failure rate. FARSITE is a valuable research tool aiding study feasibility by reducing the need for manual patient identification.

**PM222**

**THE EFFECT OF A LIKELY OVEREMPHASIS ON FICIONIETY-RELATED TEST ATTRIBUTES ON ACG RECOMMENDATIONS AND ACCESS TO NEWBORN SCREENING (NBS)**

*Bettssoune B*

*MethOds:** Patient access to NBS has been greatly influenced by the 2006 American College of Medical Genetics (ACMG) recommended expansion of NBS. ACMG relied largely on a stakeholder survey on 19 attributes of 84 rare conditions. The presence or absence of a condition’s presence for a given test was determined by an expert panel, along with its weight, determined attribute score. Sums of scores determined the entry point to an algorithm for final recommendations. This research examines 6 attributes that appear to be associated with the same concept and asks whether these are really one (over-weighted) concept. **METHODS:** The ACMG report provided attribute scores. Six questions addressed test efficiency (simplicity, high throughput, cost <$1), condition, multiple analytes/test run, other conditions identified/analyte, multiple conditions detected/test. We examined correlations between the 6 answers for a given condition across conditions and associations with recommendations. **RESULTS:** After eliminating conditions with missing data, 78 remained. Pairwise correlations between the 6 answers were high (mean: -85; range: 72-96). Of those conditions (37) scoring at least 75% of the possible points on one question (“high throughput”), 79% were recommended as Core conditions to be screened and only 8% were Not Recommended. The mean total scores for the 6 similar questions was 339 (500 possible). Of those (19) scoring 25% or fewer of the possible points for that one question, only 3% were Core, 72% Not Recommended (mean score: 89). **CONCLUSIONS:** The high correlations support the idea that the 6 similar questions were answered as if they were the same concept, weighting the common general attribute very highly. A more systematic approach, say MCDA, would likely have eliminated some of these questions with significant consequences for ACGM recommendations.

**PM223**

**WORKFLOW MAPPING FOR PAEDIATRIC VACCINATION PROCESS IN THE UNITED KINGDOM (UK): A PRECURSOR OF A TIME AND MOTION (T&M) STUDY**

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**OBJECTIVES:** Time and Motion (T&M) methodology allows quantifying time-related outcomes for a health care delivery process by disaggregating the process in its constituent parts to measure task durations. The design of a T&M study requires early process mapping to define the time outcomes to be measured.

**METHODS:** The mapping of paediatric vaccination process in the United Kingdom (UK), as a precursor to a T&M study. Methodologically, publicly available information was conducted to gain comprehensive understanding of the paediatric vaccination process in the UK. A survey was designed eliciting the chronology of vaccination process prior to and on vaccination day, including estimates of time taken for professional involvement. Face-to-face interviews with a nurse were conducted at three general practitioner surgeries routinely performing vaccinations. A subsequent follow-up call with each nurse was also arranged to get descriptive and quantitative professional involvement. Calculation and presentation of the data made. **RESULTS:** Paediatric vaccination process can be broken down in 6 and 8 clearly discernible steps prior to and on vaccination day, respectively. Activities prior to vaccination day include, among others, inventory, ordering, cold-chain management and are typically for multiple subjects. Mean time for those activities, recalculated per single vaccination visit, was 6.7 minutes, of which 61% dedicated to administrative duties. Activities on vaccination day include, among others, room preparation, consultation, vaccination and administration. Estimated total time visit totaled 25.4 minutes. Estimated total cost per single vaccine administration, with nurse salary cost from PSSRU, was £10.4. Costs may vary substantially depending on the level of “on-costs” to nurse’s gross salary. **CONCLUSIONS:** The detailed description of the vaccine administration process, as well as the time and cost estimates, factors impacting variability of time outcomes, and early cost estimates. This forms the basis of a real-world T&M study aiming to generate robust time and cost outcomes.

**PM224**

**COMPARATIVE EFFECTIVENESS RESEARCH OF MEDICAL DEVICES – NEW METHODS NEEDED?**

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**OBJECTIVES:** Guidelines for Health Technology Assessment (HTA) and Comparative Effectiveness Research (CER) for Medical Devices are being developed. This study critically consider other health care technologies. CER of medical devices (MD) faces some challenges that raise questions about how adequate current CER methods account for the specific features of MD and how well MD fit in the paradigm of drug HTA. Our aim is to identify in methodological review of CER of MD. Our comprehensive framework for the evaluation of clinical effectiveness of MD includes recommendations for generation of primary data and analyzing and synthesizing of systematic reviews of CER of MD. We performed a targeted literature review for CER methods and specific features of MD. An electronic database search was combined with systematic screening of tables of content of selected journals in the fields of epidemiology, HTA, statistics, and evidence-based methods. CER methods which have a strong methodological footprint of MD were included and the reference lists of the most relevant papers. **RESULTS:** More than 200 publications about the general evaluation of MD and about specific CER methods were included. The MD’s physical mechanism of action, the dynamic development and regulatory evidence requirements are the driving features that suggest the increased use of certain methods for the evidence generation, finding of information for HTA, data analysis and synthesis, and interpretation of results. Rather than following the paradigm of drug evaluation, MD resemble more the notion of complex interventions. Our methodological framework is compatible with the EUnetHTA core model and integrates existing recommendations for other complex interventions. The consideration of operator-characteristic data, comparative effectiveness study, and decision-analytic modeling are of special importance, as well as the application of Bayesian methods. **CONCLUSIONS:** The assessment of the clinical effectiveness of MD does require specific, although not necessarily new methods.
the use of e-health interventions. Both B. F. M. Wijnen and L. A. M. Leenen contributed equally to this work.

PRM226 IMPLEMENTATION OF INTERNATIONAL CHART REVIEW STUDIES: AN ABSTRACTION OF STUDIES AND REGULATORY CONSIDERATIONS Jean-Mary 1, Stein 2, Yeomans 2,5, Payne KA 1

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OBJECTIVES: In the absence of secondary sources of health care data, chart review studies can result in patient level data repositories including patient characteristics, care patterns, treatment effectiveness and clinical and safety outcomes. Data can be used to populate economic evaluations, and value dossiers, and inform drug safety assessments. For successful implementation, however, knowledge of country-specific ethics and regulatory approval processes is paramount. METHODS: Open access databases, country specific rules and regulations as well as study protocols to ensure study success have been summarized in the context of eleven recent multi-national chart review case studies. RESULTS: Two of 11 studies also collected data prospectively, two studies were categorized as post authorization safety studies and three studies were categorized as post-marketing observational studies. The majority of studies (9) were oncology focused, with two studies focused on infectious diseases and opioid-induced constipation. Sample sizes varied from 20 to 500 patients, the number of countries from 1 to 8, and the number of sites from 4 to 61. All studies included at least one European country. Across studies, key operational considerations included obtaining consent for release of data, data handling procedures, data quality control and data storage requirements. Study duration, disease category, and different hypotheses for LFU rates.

PRM227 COST PER PATIENT IN NON INTERVENTIONAL STUDIES AND ADDITIONAL VALUE OF DIRECT TO PATIENT CONTACT SERVICE Fournier X

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OBJECTIVES: In addition to study outcome concerns arising from patients lost to follow-up (LFU) in pharmacoepidemiology and pharmacovigilance studies, the financial impact of LFU can be significant. Our objectives were to estimate cost per patient in non-interventional studies, to identify variables that may affect this patient cost, to estimate cost of patient lost to follow-up (LFU), and financial benefits that can be expected from LFU minimization through Direct to Patient Contact service (DPC). METHODS: Analysis of 2013 proposals and budgets submitted to study sponsors. Selection criteria: non intervention prospective, longitudinal patient follow-up, full CRO services. Analysis were performed according to patient sample size, study duration, disease category, and different hypothesis for LFU rates. RESULTS: 1) 20 studies included (Regional or Global) met all inclusion criteria. 2) Annual cost per patient - ranging from €1,068 to €4,370 - decreases as the study duration increases (set-up cost is more diluted in the patient annual cost). But the longer the study, the more expensive the overall cost per patient. 3) Mean annual patient cost signals the need for CRO services depending on the prioritization of patient loss to LFU. 4) For studies in oncology, data quality can positively impact data quality. 5) In a clinical study on the primary prevention of cardiovascular disease using improved versus standard risk prediction we calculated the EVPI with selection of the best risk prediction strategy concerning a trade-off between budget effectiveness and budget impact. RESULTS: In our simulation study we found EVPI estimates per patient based only on cost-effectiveness were up to €586 lower and €459 higher compared to EVPI estimates also acknowledging the safety criterion, depending on its weight. In our clinical study, the EVPI estimates based only on cost-effectiveness were consistently lower, up to €540 per patient, compared to EVPI estimates also acknowledging the budget impact criterion. CONCLUSIONS: When decisions are based not only on cost-effectiveness and safety criteria as well, some of which also relate to costs or health effects, standard VOI estimates are no longer valid. However, separate application of VOI methods to each of the relevant decision criteria is straightforward and can facilitate transparent research prioritization in a complex MCA context.

PRM230 A STATISTICAL MODELING FRAMEWORK TO CHARACTERIZE THE IMPACT OF PROGRESSION ON SURVIVAL IN ONCOLOGY Elbak K

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The recent development of new cancer treatments often focus on the overall survival (OS) gains that patients may derive. Trials are typically not long enough to allow detailed understanding of OS, and potential benefits must be inferred from benefits on progression-free survival (PFS). This raises questions such as whether early or later progression impacts survival, whether the increase in mortality following progression is sustained or gradually diffused, and whether a benefit observed on PFS implies a benefit in OS. Answering these questions requires an analytical framework in which progression and survival can be analyzed together and parameterized to address key questions. We propose a statistical modeling framework based on Cox regression and time-dependent predictors and effects. A simple formulation of this model would include a time-dependent indicator for progression, whose coefficient would measure the increase in risk of death following the event. This is very limiting, however; it assumes that the timing of progression does not matter and that the increase in risk of death is sustained indefinitely. A more flexible formulation can be built using two descriptors of event: the timing of progression (TP) and time since progression (TSP). These can be continuous measures or categorized (e.g., early vs. late TP), as appropriate. The coefficient for TP reveals whether later progression is associated with higher/lower subsequent mortality, while the coefficient for TSP reflects whether and for how long the increase/decrease in mortality is sustained and whether it ever returns to the level of patients who had not progressed. The impact of treatment can be captured on each of these parameters separately. The proposed framework will be illustrated with an example, and extension of the approach to other applications (e.g., measuring the impact of a stroke on survival) will be discussed.
tred care and integration of the patient perspective in health care policy decisions. A major challenge for the integration of evidence on patient preferences is that research on patient preferences is performed by various disciplines (e.g. psychology and economics) that do not share a common language. It has been recommended to perform conceptual and taxonomic work on the definition and conceptualisation of ‘preference’ and related terms. The aim of this study was to develop a taxonomy of preference-related terms. The taxonomy was developed in three steps: 1) the identification of preference-related terms; 2) providing all identified terms with a definition from the dictionary; and 3) the identification of dominant theories or models from (health) economics and psychology that deal with the preference-related terms. The proposed taxonomy consists of several building blocks that hold all identified preference-related terms and demonstrate the relation between terms. The building blocks are centred around a factual event. Ex ante to this factual event, building block 1, “decision making” holding terms like “choice” and “decision”, which are post-factum building block 2, “evaluation process” and building block 3 “outcome evaluation”. Resulting building blocks 3. Building blocks terms like “utility”, “quality of life” and “satisfaction”. Building blocks 1-3 are influenced by building block 4 “the value system”. This value system is divided in cognition, affect and conation and holds terms like “beliefs”, “expectation”, “attitudes”, “desires” and “intention”. In this taxonomy, the neutrality of preferences can be considered as a part of the value system. The proposed taxonomy is a first step towards conceptual clarity to facilitate the integration of research evidence in health care policy decisions.

PMR232
WHEN IT MAY NOT BE NECESSARY TO MODEL OVERALL SURVIVAL. FOR ECONOMIC EVALUATIONS OF ANTI-CANCER DRUGS

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Overall survival (OS) is traditionally modelled in economic evaluations of anti-cancer drugs. OS is generally associated with endpoints such as patient survival data, or confounding due to treatment switching or use of inappropriate treatments after progression. Fortunately, analysis of historical trials reveals that there is good evidence that OS will not be affected by progression in post-marketing surveillance (PPS). OS is equal between treatment arms, i.e. ΔPPS = 0. Therefore, we recommend that the default position is to assume equal mean times post-progression. If there is no a priori biological reason to suppose that the PPS times are likely to differ between treatment arms, e.g. due to differences in cross-resistance between treatments, our recommendation is that it should be assumed that the mean time in progressive disease is equal between treatment arms if any of the following apply: OS is very immature; treatment switching progression are subsequently unbiased; different treatment arms; in particular, treatment switching has occurred at progression; treatment post-progression are different to those routinely given in clinical practice; only single arm trials are available. If none of the above apply, or if there are a prioritons reasons to suppose that the PPS times will be different, then there is a recommendation to model OS and PPS in the traditional way. For chronic cancers, it is recommended that analyses should either assume equal times post initial treatment or equal time post progression. The assumption that ΔPPS = 0 substantially simplifies the economic analysis because cost-effectiveness becomes insensitive to OS. The methodology has been endorsed twice by NICE appraisal committees in assessments of drugs for chronic myeloid leukaemia. The cost-effectiveness of several drugs recently assessed by NICE are re-calculated using the methods proposed. Next, we give simplified formulae for the maximum drug price acceptable for reimbursement under the methodology.

PMR234
FEASIBILITY OF CONDUCTING RETROSPECTIVE STUDIES USING HASHTAGS AND SOCIAL MEDIA DATA FROM FACEBOOK AND TWITTER

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Various online services such as Socialbakers, Keyhole, Gnip offer tools to analyze, fetch and collect data from social media. This data is often presented in a form of interactive web based dashboards, displaying various trends: number of posts, mentions, shares, likes over time. Facebook and Twitter have an API to access data within functional constraints. Finally, our alternate methodology may be used to generate efficacy estimates at intermediate time points, which can be evaluated using an iterative time point data. Bases of published studies of esosome and tolterodine. CONCLUSIONS: The endpoint results obtained from the alternate methodology were comparable to those obtained from an endpoint ITT. This novel methodology has the additional advantage of utilizing available time point data within a single publication. It may be used to generate efficacy estimates at intermediate time points, which may be utilized within economic models. Limitations include unavailable of estimates from the %red variable and difficulty of estimating combinations of parameters within functional constraints. Finally, our alternate methodology may be used for any longitudinal data exhibiting a monotonic increase or decrease and may be expanded to include a network with multiple treatments.

PMR235
A FRAMEWORK FOR THE ECONOMIC EVALUATION OF SEQUENTIAL THERAPIES FOR CHRONIC CONDITIONS

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Cost-effectiveness models often require the consideration of a sequence of treatments. This evaluation of alternative sequences to be captured, and alternative sequences to be compared. However, when many treatments are available, the number of feasible sequences can be large. Also, if the objective is to maximise net benefit for a given ICER threshold, then a comparative analysis to identify the optimal sequence is not possible. Further complicating, when not using patient simulation (IPS), because of the increased computational burden compared with cohort approaches. The aim of this study was to undertake a systematic review of methods that are applicable to a treatment sequencing IPS model. 28 key papers were identified across a range of academic subjects. Metaheuristics including simulated annealing, tabu search and genetic algorithms have been applied to simulation-optimisation problems and a bespoke review framework was applied to determine their appropriateness. Based on the review, a framework for the economic evaluation of treatment sequences was developed. The framework considers the requirements of a cost-effectiveness model to efficiently evaluate sequences and application of the metaheuristics to determine the optimal sequence, and the consideration of these results within a decision-making context. This will be applied to a case study in rheumatoid arthritis. Alternative metaheuristic algorithms will be applied in an attempt to estimate a (near) optimal treatment sequence. Results of these experiments will be available in time for the November 2014 ISPOR conference. If these methods prove successful and feasible, then the framework may have potential applicability to sequencing models in many diseases. Whether there is the capability for it to be applicable within the current process for decision-making organisations such as NICE remains an open question, however, identifying an optimal sequence in a decision problem is of interest to decision makers.

PMR236
NOVEL INDIRECT COMPARISON METHODOLOGY FOR ESTIMATING TIME-DEPENDENT RESPONSE TO ANTICANCER DRUGS IN THE TREATMENT OF OAB

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BACKGROUND: Common indirect treatment comparison (ITC) methodology in over- active bladder involves combining absolute reduction in urine urgency incontinence (UUI) episodes at study endpoint (e.g., week 12) to estimate the overall treatment effect. Trials with differing endpoints must assume equivalence to be included in the network. Further, analyses of endpoint data are not sufficient to predict efficacy at intermediate time points (e.g. 4 or 6 weeks). We developed and tested an alternate methodology to utilize available intermediate time point data of published studies of fesoterodine and tolterodine. METHODOLOGY: Study level mean UUI reduction over time can be represented as the percent reduction from baseline, which can be modeled as a monotonically-increasing function with a theoretical maximum at 100%. This function is expressed by two parameters: %red = b*time/ (c1 + time), where b is the maximum possible reduction for treatment i, and c1 is the time required to reach half the maximum reduction. The inverse %red is a linear function of 1/time that can be used within a Bayesian ITC framework to generate a placebo-adjusted indirect comparison of efficacy. CONCLUSIONS: The endpoint results obtained from the alternate methodology were comparable to those obtained from an endpoint ITC. This novel methodology has the additional advantage of utilizing available time point data within a single publication. It may be used to generate efficacy estimates at intermediate time points, which may be utilized within economic models. Limitations include unavailability of estimates from the %red variable and difficulty of estimating combinations of parameters within functional constraints. Finally, our alternate methodology may be used for any longitudinal data exhibiting a monotonic increase or decrease and may be expanded to include a network with multiple treatments.

PMR237
BAYESIAN MODELS FOR COST-EFFECTIVENESS ANALYSIS IN THE PRESENCE OF STRUCTURAL ZERO COSTS

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Bayesian modelling for cost-effectiveness data has received much attention in both the health economics and the statistical literature, in recent years. Cost-effectiveness data are characterised by a relatively complex structure of relationships linking a suitable measure of clinical benefit (e.g. QALYs) and the associated costs. Simplifying assumptions, such as (h)variance normality of the underlying distributions are usually not granted, particularly for the cost variable, which is characterised by markedly skewed distributions. In addition, individual-level datasets are often characterised by the presence of structural zeros in the cost variable. hurdle models can be used to account for the presence of zero costs in a distribution and have been applied in the context of cost data. We extend their application to cost-effectiveness data, defining a full Bayesian specification which consists of a pattern model for the individual probability of null costs, a marginal model for the costs and a conditional model for the measure of effectiveness (given the observed costs). The model is presented using a working example to describe its main features. In addition, we present a R package that directly implements this framework and can be used to run a full Bayesian cost-effectiveness analysis of individual data in the presence of structural zero costs for some subjects.

PMR238
EFFECTIVE PRIORITISATION OF NATIONAL HEALTH TECHNOLOGY ASSESSMENTS

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Prioritisation of assessment topics is an essential activity within HTA. Failure to successfully identify technologies that are likely to have the greatest impact on the health system carries an opportunity cost that is measured in poorer decision
making, reduced patient benefits and less efficient use of public resources. Within individual agencies, prioritization is also a business function that must balance the need to plan for and manage the allocation of resources with the need to provide expedient advice to decision makers and adapt quickly to changing circumstances. This research describes a transparent and responsive framework for selecting health technology and prioritizing the potential health benefits exhibited by candidate therapies. It identifies the outcomes to be measured and provides a useful resource for HTA agencies facing similar issues.

Topics are identified through a mix of routine horizon scanning, a formally convened advisory group consisting of the major decision makers from within the publicly funded health system and informal business intelligence gathering. Screening is carried out to eliminate technologies that are clearly unsuitable and provisionally grade all remaining candidates according to three principal criteria: 1) clinical importance (potential impact on health care use and health consequences of all competing decision alternatives). Whilst models are required because a single source of evidence, such as a randomised controlled trial, is rarely sufficient to provide all relevant information about the expected costs and health consequences of all competing decision alternatives. Whilst models are used to synthesise all relevant evidence, they also contain assumptions, abstractions and simplifications. By their very nature, all models are therefore "wrong." Whilst the presence of imperfect evidence provides the impetus for developing models, it is also the reason why we can never fully validate them. As such, the interpretation of the cost-effectiveness of health technologies requires careful judgements about the degree of confidence that can be placed in the models from which they are drawn. The presence of a single error or inappropriate judgement within a model may lead to inappropriate decisions, an inefficient allocation of health care resources and ultimately suboptimal outcomes for patients. This study tests out a taxonomy of threats to the credibility of health economic models. The taxonomy segregates threat types to model credibility into three broad categories (1) unverifiable errors, (2) violations and (3) matters of judgement, and maps these across the main elements of the model development process. These three categories of threat to model credibility are defined as follows: (1) unverifiable error: the existence of a range of criteria for judging correctness, the degree of force with which such criteria can be applied, and the means by which potential threats can be handled. A range of suggested processes and techniques for avoiding and identifying these threats is put forward with the intention of prospectively increasing the credibility of any given model.
The concept of “efficacy-effectiveness gap” (EEG) has gained awareness in the scientific community and started to erode the confidence in decisions taken on drugs: authorization, appraisal, and medical choice between alternatives. This is due to an increased need and recognition of the importance of balancing prognostic scoring under several different scenarios including homogeneous and heterogeneous treatment effects. Mean square error, bias, coverage probability for the treatment effect, and prediction accuracy of personalized treatment contrast (for scenarios with heterogeneous treatment effect) were assessed. We will present some guidelines for estimating treatment effects with observational data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

### PRM245

**HEALTH TECHNOLOGY ASSESSMENT AND ENVIRONMENTAL COSTS: TIME FOR HEALTH CARE TO CATCH UP?**

**Objectives:**
- To develop a new method that naturally extends the UK NICE way of single-threshold for incremental cost-effectiveness ratio (ICER).
- To provide a common decision criteria for assessing an ICER of expensive health technologies such as molecular-targeted cancer drugs and regenerative medicine products.

**Methods:**
- We adopted a model-based approach to evaluate the cost-effectiveness of cancer drugs and regenerative medicine products across different decision scenarios.
- We conducted a focused literature review to gain clarity and perspectives on the use of environmental data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Results:**
- We present some guidelines for estimating treatment effects with observational data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Conclusions:**
- There are two lines of reasoning for incorporating environmental impacts into HTA. 1) Directly including environmental impacts that could affect the health of individuals, and 2) Health decision makers’ objectives are broader and are informed by other policy goals, such as the CO2 targets adopted by the NHS in the UK. We also identified two types of methodological challenges for incorporating environmental impacts into the HTA method: (1) the need to develop operational solutions for evaluating these technologies.

**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**

### PRM246

**MULTIPLE DECISION CRITERIA FOR ASSESSING AN INCREMENTAL COST-EFFECTIVENESS RATIO OF EXPENSIVE HEALTH TECHNOLOGIES**

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**Objectives:**
- To develop a new method that naturally extends the UK NICE way of single-threshold for incremental cost-effectiveness ratio (ICER).
- To provide a common decision criteria for assessing an ICER of expensive health technologies such as molecular-targeted cancer drugs and regenerative medicine products.

**Methods:**
- We adopted a model-based approach to evaluate the cost-effectiveness of cancer drugs and regenerative medicine products across different decision scenarios.
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**Results:**
- We present some guidelines for estimating treatment effects with observational data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Conclusions:**
- There are two lines of reasoning for incorporating environmental impacts into HTA. 1) Directly including environmental impacts that could affect the health of individuals, and 2) Health decision makers’ objectives are broader and are informed by other policy goals, such as the CO2 targets adopted by the NHS in the UK. We also identified two types of methodological challenges for incorporating environmental impacts into the HTA method: (1) the need to develop operational solutions for evaluating these technologies.

**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**

### PRM247

**Efficacy, Effectiveness and the “Efficacy-to-Effectiveness Gap”: Review of the Current State of Play and Perspectives. First Results from the IMF GetReal Project**

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**Background:**
- The concept of “efficacy-effectiveness gap” (EEG) has gained awareness in the scientific community and started to erode the confidence in decisions taken on drugs: authorization, appraisal, and medical choice between alternatives. This is due to an increased need and recognition of the importance of balancing prognostic scoring under several different scenarios including homogeneous and heterogeneous treatment effects. Mean square error, bias, coverage probability for the treatment effect, and prediction accuracy of personalized treatment contrast (for scenarios with heterogeneous treatment effect) were assessed. We will present some guidelines for estimating treatment effects with observational data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Objectives:**
- To develop a new method that naturally extends the UK NICE way of single-threshold for incremental cost-effectiveness ratio (ICER).
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- There are two lines of reasoning for incorporating environmental impacts into HTA. 1) Directly including environmental impacts that could affect the health of individuals, and 2) Health decision makers’ objectives are broader and are informed by other policy goals, such as the CO2 targets adopted by the NHS in the UK. We also identified two types of methodological challenges for incorporating environmental impacts into the HTA method: (1) the need to develop operational solutions for evaluating these technologies.

**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**

### PRM248

**HEALTH TECHNOLOGY ASSESSMENTS FOR PERSONALISED MEDICATIONS: ARE CURRENT METHODOLOGIES SUITABLE FOR THE ASSESSMENT OF PERSONALISED THERAPIES?**

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**Objectives:**
- To develop a new method that naturally extends the UK NICE way of single-threshold for incremental cost-effectiveness ratio (ICER).
- To provide a common decision criteria for assessing an ICER of expensive health technologies such as molecular-targeted cancer drugs and regenerative medicine products.

**Methods:**
- We adopted a model-based approach to evaluate the cost-effectiveness of cancer drugs and regenerative medicine products across different decision scenarios.
- We conducted a focused literature review to gain clarity and perspectives on the use of environmental data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Results:**
- We present some guidelines for estimating treatment effects with observational data and strategies that are appropriate with respect to (i) tree-structured treatment (ii) polynomial outcome model with interactions (iii) presence of noise covariates.

**Conclusions:**
- There are two lines of reasoning for incorporating environmental impacts into HTA. 1) Directly including environmental impacts that could affect the health of individuals, and 2) Health decision makers’ objectives are broader and are informed by other policy goals, such as the CO2 targets adopted by the NHS in the UK. We also identified two types of methodological challenges for incorporating environmental impacts into the HTA method: (1) the need to develop operational solutions for evaluating these technologies.

**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**

### PRM249

**CHALLENGES IN MEETING EVIDENCE NEEDS OF PAYER, PHYSICIAN, PATIENT AND INDUSTRY STAKEHOLDERS FOR NOVEL THERAPEUTICS**

**Peer L.**

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**Objectives:**
- To develop a new method that naturally extends the UK NICE way of single-threshold for incremental cost-effectiveness ratio (ICER).
- To provide a common decision criteria for assessing an ICER of expensive health technologies such as molecular-targeted cancer drugs and regenerative medicine products.

**Methods:**
- We adopted a model-based approach to evaluate the cost-effectiveness of cancer drugs and regenerative medicine products across different decision scenarios.
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**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**

### PRM250

**PERSONALISED THERAPIES?**

**CONCLUSIONS:**
- The United Nations recently published its most definitive report, calling for greater action on climate change. Historically, however, health technology assessment (HTA) has had a more narrow focus with emphasis on the health of patients and health inequalities. Recently some health care decision makers have extended the focus to include the environment, e.g. the Swedish Government is considering a Green Premium for generic drugs, and the UK NHS has CO2 emissions targets. We consider the case for incorporating environmental impacts into HTA, and the associated methodological challenges. **METHODS:**
- We reviewed the current state of environmental impact assessments considered and - a summary will be provided in the paper. We then convened a workshop with key opinion leaders. **RESULTS:**
- There are two lines of reasoning for incorporating environmental impacts into HTA. 1) Directly including environmental impacts that could affect the health of individuals, and 2) Health decision makers’ objectives are broader and are informed by other policy goals, such as the CO2 targets adopted by the NHS in the UK. We also identified two types of methodological challenges for incorporating environmental impacts into the HTA method: (1) the need to develop operational solutions for evaluating these technologies.

**Further work is needed to track decision makers’ demand for evidence on environmental impacts. Robust methods also are needed for capturing and incorporating environmental data as part of HTA as more decision makers begin incorporating environmental impacts.**
BACKGROUND: While the orphan drug supply program is in progress, development, decision-making rules for approving orphan drug for supply programs of Russian Federation becomes very actual. Real world data provides evidence, that routine approaches for approving such kind of drugs, e.g. pharmacoeconomic conclusions, are not applicable. Than the need in more appropriate approaches is existed. Multi-criteria decision analysis is one such approaches (MCDA). OBJECTIVE: To evaluate prospective of implementation of MCDA in health care system of Russian Federation and to develop road map of MCDA in Russia. METHODS: Literature review, expert opinion, interview with experts (qualitative) to implement MCDA is to test various MCDA methods to find out optimal one for Russian Federation: it is expected to select the most relevant criteria from the wide range of them. First of all, MCDA is considered to be the instrument to improve the transparency, to underline different point of view and ranges. First of all, MCDA is considered to be the instrument to improve the transparency, to underline different point of view and ranges. First of all, MCDA is considered to be the instrument to improve the transparency, to underline different point of view and ranges. Where as the literature has suggested that these propensity-based methods do not naturally extended to the multi-level treatment case, we show, using the concept of weak unconfoundedness, that adjusting for or matching on a scalar function of the covariates removes biases associated with observed covariates. We focused on subclassification and matching approaches as these have found to be effective for two treatments and are among the most popular methods in that setting. We apply the proposed methods to an analysis of the effectiveness of treatments for fibromyalgia from a prospective observational study. We also carried out a simulation study to assess the performance of those methods relative to such approaches like: pairwise propensity score matching; matching on the Mahalanobis distance of all covariates; matching on the set of propensity scores (with the number of scores equal to the number of distinct treatment lev- els multiplied by the number of covariates); weighting on the propensity scores (McCaffrey, 2013). The simulation study suggested that the proposed methods are simple and viable options for comparing the effectiveness of three or more treatments. RASSEN et al. Matching by propensity score in cohort studies in the presence of continuous covariates, a first step to obtain limited regulatory approval. Following this, data from the pragmatic trial are often viewed as the only sources of evidence for regulatory authorities. Instead, we focus on the comparison of two branches of therapy: investigational therapy or placebo. Either in parallel with or follow- ing the phase 3 study, a second patient cohort would be randomized under pragmatic clinical trial conditions with the aim of comparing the investigational therapy with placebo and a limited number of active comparator treatments. Lastly, a third (observational) cohort would be enrolled and allocated to a wider range of disease states. The pragmatic trials are only intended to obtain limited regulatory approval. Following this, data from the pragmatic cohort, once available, would then be formally combined using standard statistical techniques with data from the RCT cohort in order to obtain a wider regulatory approval and possibly some form of conditional reimbursement. The pragmatic and observational cohorts would then provide the comparative effectiveness data to allow for reimbursement across different patient groups. We outline the strengths and weaknesses of this approach, and discuss its operational considerations.
concerning the long-term safety and effectiveness of the drugs when used on larger populations. Pharmaceutical companies face big challenges for the coming years. This is especially in EU and there is an increase need for local regulatory knowledge. There’s still need to increase awareness for the importance of real world studies and the impact it has on the patient’s life.

PMRG56

PUBLIC MANUAL OF BUDGET IMPACT ANALYSIS (BIA) BY THE DEPARTMENT OF SCIENCE AND TECHNOLOGY OF THE MINISTRY OF HEALTH (DEICT)

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The epidemiological and economic methods applied to health technologies evaluations had a significant development in the last two decades. The need to balance the introduction of new health technologies in health systems and limited resources has promoted the construction and application of instruments supporting the decision making of health technology. The requirement Budget Impact Analysis formally stated in Law 12.401/2011 establishing the incorporation process technologies in SNIIR-AM, the National Agency of Sanitary Surveillance (ANVISA) and DEICT, in partnership Institute for Health Technology Assessment (IATS) for drawing up of this guideline. In the first stage of development were used international recommendations of Canada, Australia, the UK and Poland, the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the methods used in studies of budgetary impact that had already been published. Afterwards, drafted a preliminary version of the Guideline is a standard tool - Excel worksheets - to estimate the uptake of monetary resources required for adoption of new technologies. Revisions were carried out by technicians DEICT and health agencies, and the proposal was submitted to the World Group of University Development of Methodology KEBRAT, composed of experts and academic researchers from several Brazilian states. Were also carried out workshops for the application of spreadsheets. In 2012, the first edition of the Guidelines was published two thousand copies in Portuguese in order to provide best practice recommendations for studies of budget impact.

DISEASE - SPECIFIC STUDIES

RESPIRATORY-RELATED DISORDERS - Clinical Outcome Studies

PR51

PROSPECTIVE STUDY ON COST-EFFECTIVENESS OF NURSE INTERVIEW INTRODUCING RETESTING WITH IN VITRO DIAGNOSTICS (IVD) TO PARENTS OF CHILDREN WITH SUSPECTED FOOD ALLERGY IN FINLAND

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OBJECTIVES: According to Finnish Allergy Program 2008-2018, to decrease food avoidance diets by 50%. Focus in algorithm was patient history: IVIg in school children with suspected food allergy and reason for declining re-diagnosis. NICE clinical guideline (Food Allergy Diagnoses, 2013) suggested further work made on effect of diagnosing allergies in realistic population and cost effectiveness of retesting. METHODS: Retrospective study with patients from Finnish primary care database (2885 school children). School kitchen had allergy restricted diets for 179 children. In the pilot phase, 179 families were contacted by letter. Of the 24 who were not allergic in pilot 17 were not allergic (70%). In this study families were invited to retested by telephone. Of 156 families 107 agreed to participate in this study and 47 children will be diagnosed by component resolved diagnostics (CRD) and 60 avoided diets. Viewed by telephone. Of 156 families 107 agreed to participate in this study and 47 children will be diagnosed by component resolved diagnostics (CRD) and 60 avoided diets.

RESULTS: Prevalence of food avoidance diets: 6.2%. Reasons for declining re-testing were not allergic, 9 were busy, 9 have own physician, 3 did not believe allergy tests, 8 scared of needles, 7 already tested, 4 tested often due to health problems, in 2 pilot study and 7 did not recognize a benefit. CONCLUSIONS: Telephone consultation by nurse decreased special diets for 23 children (13%) and 39 (22%) had non-medical reasons to decline retesting. Nurse consultation to introduce retesting with IVD can be considered as cost effective approach in decreasing food avoidance diets in children.

PR52

EFFECTIVENESS OF MONTELUKAST ON ASThma CONTROL IN INFANTS: A CLAIMS DATA STUDY

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OBJECTIVES: Montelukast-4mg (ML)-is an add-on therapy for asthmatic infants. Given the quality and exhaustivity of the data, French claims data (SNIIR-AM) is a relevant tool to investigate MTL-4 effectiveness in infants. The objective was to compare the effectiveness of MTL-4, associated or not with ICS, vs. ICS without MTL-4, on relevant tool to investigate MTL-4 effectiveness in infants.

RESULTS: Among 115,489 infants (mean age: 13.9 months; 62.9% boys), 4,477 infants of the MTL-4 group were matched with 13,386 infants of the ICS group. In multivariate analysis, the risk of a new exacerbation was lower in infants of MTL-4 group compared to infants of ICS group (HR=0.91, 95% CI: 0.81-0.91). The objective did not differ between the 2 groups during the 6-month follow-up (p=0.8617), neither the cost of asthma management (344€ for MTL-4 group vs. 308€ for ICS group, p=0.31). CONCLUSIONS: PR52 appears to be comparable therapeutic strategies, with similar effects on exacerbation and equivalent costs. The SNIIR-AM allows conducting comparative effectiveness research.

PR53

CLINICAL TRIAL-BASED COST-EFFECTIVENESS ANALYSIS OF INDACETEROL (ONBREZ® 150 MCC) VERSUS TISOTRIPY (SPIRITIV®) IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN TURKEY

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OBJECTIVES: COPD is a disease that is characterized by chronic and progressive restriction of the airflow. The cost of COPD medications can be reduced signifi-

1cantly by implementing a treatment algorithm that is consistent with the GOLD guidelines. Indacaterol and tiotropium administered by inhalation are indicated for maintenance treatment of COPD in Turkey. We aimed to compare, from the perspec-

tive of the Turkish social security institution, the cost-effectiveness of indaceterol 150 mcg once daily and long-acting tiotropium 18 mcg once daily at months 3 and 6 in patients with moderate to severe COPD aged 30 years and above. METHODS: From a Turkish, retrospective, a guided and analyzed analysis based on two separate clinical trials (INTENSITY-once daily indacaterol and tiotropium vs. placebo and INHANCE-indacaterol vs tiotropium) was performed. The primary endpoints of the clinical trials were FEV1, Transient Dyspnea Index (TDI) and St George’s Respiratory Questionnaire (SGRQ) were included in the cost-effectiveness analysis. Incremental cost effectiveness ratio (ICER) of indacaterol vs. tiotropium for different treatment success rates were calculated (week 12 FEV1 increase, increase in infants, 34%, 12% decrease in SGRQ score) were compared. Incremental cost effectiveness ratios were calculated over incremental differences versus placebo. Probabilistic sensitivity analysis was performed using the Bootstrap method. RESULTS: FEV1 success rates at month 3 of indacaterol and tiotropium were 26.5% and 26.8%, respectively. At month 3, ICERS of indacaterol versus ipratropium were -1002TL for FEV1, -431TL for TDI and -878TL for SGRQ. At month 6, FEV1 success rates were 58% and 47%, TDI success rates were 54.7% and 46% and SGRQ success rates were 81.8% and 77.1%, respectively. ICERS of indacaterol versus ipratropium at month 6 were -616TL for FEV1, -1049TL for TDI and -1014TL for SGRQ. CONCLUSIONS: Based on this clinical trial-based analysis, indacaterol was cost effective treatment and cost reducing choice vs. tiotropium in COPD treatment.
OBJECTIVES: To assess the relative efficacy of umclidinium bromide 62.5 mcg OD (U) versus tiotropium bromide 18 mcg OD (TIO), aclidinium bromide 400 mcg OD (AB) and glycopyrronium bromide 50 mcg OD (GLYCO). METHODS: A systematic literature review was performed to identify RCTs ≥ 12 weeks duration comparing TIO, AB, GLYCO or UMEC to placebo in adult patients with COPD. Random effects meta-analysis was performed pooling results of each treatment with respect to baseline risk (before omalizumab: 0.32–4.45) and the treatment effect (RR: 0.05–0.39). In terms of hospitalization rates, a limited difference in change from baseline in SGRQ total score between UMEC, TIO, AB and GLYCO. CONCLUSIONS: UMEC showed comparable efficacy to TIO, AB and GLYCO. UMEC resulted in numerically lower (better) change from baseline at 12 weeks in SGRQ total score compared with TIO (-2.65, 95% CI: -7.09, p = 0.245); AB (-2.68, 95% CI: -7.12, 1.75, p = 0.230) and GLYCO (-2.15, 95% CI: -6.60, 2.31, p = 0.345). At 24 weeks there was no statistically significant difference in change from baseline in SGRQ total score between UMEC, TIO, AB, and GLYCO. PRS5

SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES AND RCTS OF OMALIZUMAB IN SEVERE PERSISTENT ALLERGIC ASTHMA AND META-ANALYSIS FEASIBILITY ASSESSMENT

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OBJECTIVES: To compare the effectiveness of omalizumab versus standard of care (SOC) based on randomized controlled trials (RCTs) compared with ‘real-world’, single cohort, observational studies that assess patients ‘before and after the use of omalizumab’.

METHODS: A systematic literature review was conducted to identify RCTs and observational studies that assessed omalizumab in patients with severe persistent allergic asthma. Study and patient characteristics, outcome definitions, and differences in baseline risk and observed effects were compared in terms of exacerbations and hospitalizations across the RCTs and observational studies.

RESULTS: 11 RCTs and 24 observational studies were identified. A wide range of clinically significant exacerbation rates was observed across RCTs in terms of baseline risk (SOC: 0.42–2.40) and the treatment effect (rate ratio [RR]: 0.39–0.75). This differed from observational studies in terms of baseline risk (before omalizumab: 3.48–6.00) and the treatment effect (RRs: 0.12–0.46). A limited range of severe exacerbation rates was observed in RCTs regarding baseline risk (SOC: 0.42–2.40) and the treatment effect (RR: 0.50–0.56). However, considerable differences were identified in observational studies in terms of baseline risk (before omalizumab: 2.20–4.50) and the treatment effect (RR: 0.56–0.59). In terms of hospitalization rates, a limited range was observed for RCTs with respect to baseline risk (SOC: 0.12–0.17) and the treatment effect (RR: 0.47–0.56). This difference in change from baseline in SGRQ total score between UMEC, TIO, AB and GLYCO. RESULTS: UMEC showed comparable efficacy to TIO, AB and GLYCO. UMEC resulted in numerically lower (better) change from baseline at 12 weeks in SGRQ total score compared with TIO (-2.65, 95% CI: -7.09, p = 0.245); AB (-2.68, 95% CI: -7.12, 1.75, p = 0.230) and GLYCO (-2.15, 95% CI: -6.60, 2.31, p = 0.345). At 24 weeks there was no statistically significant difference in change from baseline in SGRQ total score between UMEC, TIO, AB, and GLYCO. PRS5

IMPACT OF OMALIZUMAB ON POOR ASTHMA CONTROL EVENTS AND MEDICATION UPTILIZATION IN PATIENTS WITH MODERATE OR SEVERE PERSISTENT ASTHMA

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OBJECTIVES: To estimate the number of users of Theophylline (ATC: R03DA04) and Doxofylline (ATC: R03DA11) for the treatment of chronic asthma in adults, in the Marche Region. Moreover, we wanted to estimate the cost of the two treatments. METHODS: The drug prescriptions were extracted from the Information System of the Pharmaceutical Prescriptions of the Marche Region (PHARM), containing all the recipes sent by pharmacies within the region and reimbursed by the National Health System. The number of prescriptions per year has been obtained by selecting all the recipes for each ATC code in the years 2008-2012, while the number of users has been estimated by identifying the subjects who received at least one prescription of the ATC codes of interest. The number of concomitant prescriptions was estimated by selecting all the recipes for potentially associated ATC, dispersed between 5 days before and 5 days following the prescription of ATC code. RESULTS: The number of prescriptions contained in the PHARM record. RESULTS: For both drugs, the users are approximately 5,000 per year in the study period. Theophylline had a mean base price lower than Dofylline (4.84€ vs 6.37€). However, the mean price paid for Theophylline was more associated with Dofylline (34.4€ vs 23.7€) with other drugs.

CONCLUSIONS: The total cost treatment for Theophylline was equal to 33.65€ vs a total cost for Dofylline equal to 22.49€ (49.6%). The PHARM allows the estimation of drugs’ utilization, taking into account the overall patient’s treatment plan.

In our study, the prescription of the first ATC code is more associated with prescriptions of other drugs, and this implies an increasing in the cost of the treatment plan despite a lower average initial price.

A DATABASE STUDY TO INVESTIGATE THE INCIDENCE OF ANAPHYLAXIS AND THE PRESCRIPTION RATE OF SELF-INJECTION EPEPHINE IN JAPAN

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OBJECTIVES: To assess the incidence of anaphylaxis in Japan and the prescription rate of self-injection epinephrine in patients with moderate or severe persistent asthma. Here we evaluate the impact of omalizumab on poor asthma control events (PACE) and medication utilisation (MU) in a case-crossover study of US patients with moderate or severe persistent asthma.

METHODS: Truven MarketScan database was used to compare PACE (hospitalisation, ER visit, corticosteroid [CS] burst or ≥ 340, Severe asthma exacerbation, OCS fill) and MU (≥ 7 SABA fills in the Moderate group and ≥ 21 SABA fills in the Severe group) among patients with moderate or severe persistent asthma that used omalizumab on poor asthma control events (PACE) and medication utilisation (hospitalisation, ER visit, corticosteroid [CS] burst or ≥ 340, Severe asthma exacerbation, OCS fill) and among those without omalizumab. RESULTS: After screening 278 full-text articles, we identified 19 clinical trials that total 19,741 COPD patients were participated. 3 trials of aclidinium 200µg and 400µg BID and 16 trials of tiotropium 18µg QD tiotropium 18µg was associated with a significant reduction in exacerbation compared with placebo (OR: 0.90; 95% CI 0.84 to 0.96). Other two anticholinergic agents showed comparable effects in reducing exacerbation compared with placebo: aclidinium 200µg (OR: 0.97; 95% CI 0.93 to 1.01) and aclidinium 400µg (OR: 0.72; 95% CI 0.52 to 1.00). Aclidinium 200µg (OR: 0.84; 95% CI 0.63-1.17) and aclidinium 400µg (OR: 0.93; 95% CI 0.92-1.156) showed the similar efficacy to tiotropium 18µg QD. The results of the study substantiates that tiotropium 18µg QD provides superior effects on lowering the risk of exacerbation compared with placebo but there was no significant difference in the frequency of exacerbations between aclidinium and tiotropium.

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TREATMENT PLAN COMPARISON: AN OBSERVATIONAL STUDY OF THE MARCHE REGION

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OBJECTIVES: To estimate the number of users of Theophylline (ATC: R03DA04) and Dofylline (ATC: R03DA11) for the treatment of chronic asthma in adults, in the Marche Region. Moreover, we wanted to estimate the cost of the two treatments. RESULTS: The number of prescriptions contained in the PHARM record. RESULTS: For both drugs, the users are approximately 5,000 per year in the study period. Theophylline had a mean base price lower than Dofylline (4.84€ vs 6.37€). However, the mean price paid for Theophylline was more associated with Dofylline (34.4€ vs 23.7€) with other drugs.

CONCLUSIONS: The total cost treatment for Theophylline was equal to 33.65€ vs a total cost for Dofylline equal to 22.49€ (49.6%). The PHARM allows the estimation of drugs’ utilization, taking into account the overall patient’s treatment plan.

In our study, the prescription of the first ATC code is more associated with prescriptions of other drugs, and this implies an increasing in the cost of the treatment plan despite a lower average initial price.
of 813,800 individuals 40 years of age the five-year (2008-2012) incidence (95% CI) of COPD among patients aged 40 years were identified in the population-based Clinical Practice Research Datalink. Point prevalence was calculated on December 31, 2013. Incidence was estimated using newly diagnosed patients between 2009-2013. Rates were standardized using 2011 UK population age and gender: % predicted FEV1, modified British Medical Research Council grade and exacerbations defined by Read codes and pre-scriptions were used to classify patients by GOLD categories. Patient characteristics were reported. RESULTS: 49,286 prevalent patients were diagnosed with COPD with mean age 70.7 (SD±7.0), 51% were male. Median time since diagnosis was 5 years. Overall prevalence was 33.0 per 1,000 people (95% CI 32.7-33.4). Of these, 66.4% were classified as GOLD A/B and 33.6% as GOLD C/D. 27,224 newly diagnosed patients were identified with an incidence of 77.5 per 1,000 people (95% CI 77.0-78.0) and 7,006 (18.7%) developed COPD at 2 years. We predicted smoking prevalences for 2012-2024 and explored a different classification of patients. COPD patients are considered high-risk according to the 2013 GOLD categories. Classification of patients is key to identifying appropriate treatment options to reduce symptoms and the frequency of COPD exacerbations.

INCIDENCE AND PREVALENCE OF COPD BY GOLD 2013 CLASSIFICATION IN THE NETHERLANDS
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OBJECTIVES: To quantify the five-year incidence (2008-2013) and 2012 prevalence of COPD in The Netherlands by the Global initiative for chronic Obstructive Lung Disease (GOLD) 2013 combined assessment categories. METHODS: Using the General Practitioners Database of the PHARMO Database Network, the five-year incidence (2008-2013) and prevalence (2012) of COPD (ICPC code R89) by GOLD 2013 combined assessment categories among individuals ≥40 years of age was assessed. Based on degree of airflow limitation (using post-bronchodilator FEV1) and risk of exacerbations (based on medication or as recorded by the GP) patients were classified as low-risk COPD (FEV1 ≥50% and/or ≤1 exacerbations) or high-risk COPD (FEV1 <50% and/or ≥2 exacerbations). RESULTS: Using a source population of 813,800 individuals ≥40 years of age the five-year (2008-2013) incidence (95% CI) of COPD among patients ≥40 years of age was 5.0 (0.4-9.0) per 100 people years; this was 0.54 (0.53-0.55) among males and 0.45 (0.44-0.46) among females. The 2012 prevalence of COPD in a source population of 805,112 individuals ≥40 years of age was 3.7 (3.6-3.8) per 100 people years; this was 3.4 (3.3-3.4) among females. Mean (±sd) age of incident and prevalent COPD patients was 65 ± 12 and 67 ± 12 years, respectively. The distribution of low-risk COPD and high-risk COPD was 90% versus 10%. For patients treated by their GP this distribution of low-risk and high-risk COPD was similar, while patients treated by a specialist had a distribution of 82% versus 18%. CONCLUSIONS: This study describes the epidemiology of COPD in the Netherlands. Results on the distribution of low-risk and high-risk COPD depend on the population studied and the definitions used. Additional information on smoking would allow a more detailed classification of patients.

ESTIMATING SMOKING CESSION RATES AND SMOKING PREVALENCE USING PUBLIC DATA AND A PUBLISHED DYNAMIC MODEL
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OBJECTIVES: Mendez et al developed a dynamic forecasting model to predict the prevalence of smoking using incidence and prevalence rates (data from 1965-1993) and estimate cessation rates for that period. Further, they assume the persistence of the cessation rates and predict future prevalence of smoking. We re-created the Mendez et al model in order to estimate smoking cessation rates (r) and updated cessation rates for 2000-2012 using newly available data on smoking prevalence (R). Smoking prevalences for the decade 2012-2024 were predicted based on a couple of alternate hypotheses of smoking initiation.

CURRENT ANNUAL COST CALCULATION IS THE BEST PREDICTOR OF MORTALITY AT THREE YEARS IN COPD
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OBJECTIVES: Chronic Obstructive Pulmonary Disease (COPD) is a progressive condition that is characterized by a dramatic socio-economic impact. Sensitivity of clinical signs and lung function in predicting death is variable in different COPD phenotypes. AIM: To assess the predictive value of COPD annual cost on mortality. METHODOLOGY: A prospective cohort study of patients with COPD in 10 Swedish county and 11 general hospital clinics in Stockholm county between 2007 and 2011. Clinical data and lung function were assessed in 321 consecutive COPD patients aged ≥40 years together with the annual cost calculated over the last twelve months. STATISTICS: t test for comparing means ± sd, linear regression for checking any relationship between each variable and mortality (p<0.05 was accepted). RESULTS: The total mortality was 40.4% over three years (n=12; 47, and 52 subjects, respectively). Subjects still survived after three years (n=116) proved originally different from those (n=111) who died in the first year (mean age; FEV1 in %; BW; TLC; COVA1; 6' walking test; SO2 and pleth index; and Charlson index (all p<0.001), but not of FEV1% pred. and FEV1/FVC (p=ns). Mean total couple of different scenarios of smoking initiation. Birth and death rates of the simulated population were set equal in all simulations and the average birth rate was 0.5% (after the insurance started to cover the service in 2011/9).

CONCLUSIONS: Smoking prevalence in 2024 is estimated to be 18.5%, even with alternate hypotheses around smoking initiation in the 2012-2022 decade. CONCLUSIONS: Smoking ofager population will play a role in reducing prevalence of smokers. Existing dynamic forecasting models were re-created and used to estimate smoking prevalence using recent data.

Objectives:
COPD cost was £3,290.7 [95% CI: 2539.9, 4051.2], but £1161.0 [95% CI: 968.4, 1353.6] in survivors and £6,158.9 [95% CI: 5,508.0, 6,808.9] in those who died, respectively. p<0.001. The hospitalization cost impacted for 78.2% of the total annual cost in subjects who died, the absolute value being sixfold higher than in survivors. All economic components of cost were discriminant at three years, independently of gender. The change in clinical and lung function variables contribute to predict mortality in COPD; 2) identification of COPD phenotypes is crucial, but multiple indices are required; 3) total annual cost proved the most sensitive predictor of mortality at three years; 4) annual cost is much cheaper and easier to obtain over twelve months; 5) data are supporting the high pricing value and the convenience of COPD “economic phenotyping”.

RESPIRATORY-RELATED DISORDERS – Cost Studies

PRS17 BUDGETARY IMPLICATIONS OF INTRODUCING FLUTICASONE FAUROATE/VI兰TEROL FOR COPD IN THE UK

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OBJECTIVES: Fluticasone furoate/vilanterol (FF/VI) 92/22 mcg is a once-daily, fixed-dose combination inhaled corticosteroid + bronchodilator licensed for the treatment of COPD in the UK. A budget impact model (BIM) was designed to explore the cost implications of prescribing FF/VI 92/22 in adult patients who continue to exacerbate or are currently receiving an off-license therapy versus alternative ICS/LABA therapies, in line with clinical guidelines. METHODS: A one-year BIM was constructed to explore the financial outcomes of prescribing FF/VI 92/22 as an alternative FDC compared to currently prescribed therapies based on market shares. The BIM is based on UK prescription analysis, epidemiological and resource data. The model explores three routes for prescribing patients: 1) exacerbating patients currently on LAMA or LABA monotherapy progressing onto ICS/LABA combination therapy; 2) exacerbating patients currently on ICS/LABA combination therapy progressing onto triple therapy; 3) patients currently on off-license therapies moved onto licensed COPD products. The model does not explore differences in patient outcomes, efficacy or safety; it explores drug acquisition cost alone. RESULTS: The BIM estimates that the average health economy (e. g. clinical commissioning group; local health board) in year 1, 2016 has 3066 COPD patients of whom 2138 continue to exacerbate or are prescribed off licenced therapies in year 1, 2016, if these patients are moved onto FF/VI 92/22. CONCLUSIONS: The introduction of FF/VI 92/22 in COPD has the potential to reduce the budget impact and total spend on ICS/LABA in the average UK health economy compared to current patterns of prescribing.

PRS18 BUDGETARY IMPLICATIONS OF INTRODUCING FLUTICASONE FAUROATE/VI兰TEROL FOR ASTHMA IN THE UK

Dudley S, Armstrong S, Bowditch S
GSK, Uxbridge, UK

OBJECTIVES: Fluticasone furoate/vilanterol (FF/VI) is a once-daily, fixed-dose combination inhaled corticosteroid + bronchodilator licensed for the treatment of asthma in the UK. A budget impact model (BIM) was designed to explore the cost implications of initiating FF/VI patients ≥12 years not adequately controlled on ICS therapy (and as needed SABA) versus alternative ICS/LABA therapies, in line with BTS SIGN guidelines on inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) therapy. METHODS: A fixed-dose combination in COPD patients. RESULTS: The BIM estimates that the average health economy (e. g. clinical commissioning group; local health board) in the UK has 7326 patients on ICS therapy of whom 3736 are inadequately controlled and appropriate for step-up to an ICS/LABA combination therapy. In year 1, presuming a 55% implementation rate, stepping up these patients onto alternative ICS/LABA combinations at current usage rates results in a budget impact of £342,413 compared with a budget impact of £331,167 if these patients initiate FF/VI therapy. CONCLUSIONS: The introduction of FF/VI in patients with persistent asthma and chronic obstructive pulmonary disease technique, due to the innovative characteristics of the Spiromax® inhaler, was also investigated. METHODS: The eligible adult patient population was based on current confirmed UK asthma and COPD diagnosis rates, with the proportion of patients receiving ICS/LABA in the UK based on current confirmed UK asthma and COPD diagnosis rates, with the proportion of patients receiving ICS/LABA in the UK. RESULTS: An estimated 409,445 adult patients used Symbicort® Turhaler® annually in the UK and were therefore eligible for treatment with DuoResp® Spiromax® with Symbicort® Turhaler® was based on a conservative assumption. RESULTS: An estimated 409,445 adult patients used Symbicort® Turhaler® annually in the UK and were therefore eligible for treatment with DuoResp® Spiromax®, with 178,108 of these being new inhaler users. Assuming a hypothetical uptake of DuoResp® Spiromax® reaching 25% in year 4 and 5, and its anticipated price, the model predicted drug cost savings totalling £63.09 million. Furthermore, 39,266 unscheduled health care events could be avoided due to the predicted improvement in asthma control with DuoResp® Spiromax® compared with Symbicort® Turhaler®, resulting in further savings of £3.50 million. CONCLUSIONS: DuoResp® Spiromax® is likely to offer budgetary savings compared with Symbicort® Turhaler®, with further cost savings potentially resulting from improved inhalation technique.

PRS19 THE ECONOMIC IMPACT OF THERAPY OPTIMIZATION IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN PORTUGAL

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is an obstructive lung disease characterized by an airflow limitation that is not fully reversible. COPD is an important humanistic burden, representing the 5th leading cause of death in Portugal. The prevalence of Portuguese population with more than 40 years is 14.2%. COPD symptoms are similar to other respiratory diseases, making harder its diagnosis. Further, the unnecessary use of respiratory medications is associated with an economic burden. This analysis aimed to estimate the economic impact of inappropriate use of inhaled corticosteroid/long-acting beta agonist (ICS/LABA) fixed-dosed combination in COPD patients. METHODS: GOLD 2013 treatment algorithm establish that ICS therapy should only be considered in high risk population (patients classified within GOLD groups C and D), presenting FEV1 <50%, forced expiratory volume at 1 second) and/or 2 or more exacerbations per year. Based on data analysis, there are 1% of patients in group C and 29% in group D. According to GOLD study, only 31% of patients in group C and 37% in group D are eligible for ICS therapy. Based on these assumptions, we estimated the overtreatment of ICS/LABA in Portugal according with local COPD prevalence and number of ICS/LABA fixed-dosed combinations prescribed. It was also calculated the economic impact associated with therapy switch of over treated patients from ICS/LABA to glycopyrronium or indacaterol, according to GOLD 2013. RESULTS: The budget analysis with ICS/LABA was estimated to be approximately 1.6 times greater than expected. Considering the number of patients over treated with ICS/LABA, the therapy switch for indacaterol or glycopyrronium would result in a potential saving of 4,314,390€ or 5,000,000€ per year, respectively. CONCLUSIONS: Therapy switch from ICS/LABA to other LAMA therapy also increased the NHS economic burden in the 12 month time horizon. Costs included were costs of medication; costs of patient care, including hospital care, costs of GP visits and costs of GP visits in other health care settings. The estimated reduction in the proportion of patients with poor inhalation technique with DuoResp® Spiromax® compared with Symbicort® Turhaler® was based on a conservative assumption. RESULTS: An estimated 409,445 adult patients used Symbicort® Turhaler® annually in the UK and were therefore eligible for treatment with DuoResp® Spiromax®, with 178,108 of these being new inhaler users. Assuming a hypothetical uptake of DuoResp® Spiromax® reaching 25% in year 4 and 5, and its anticipated price, the model predicted drug cost savings totalling £63.09 million. Furthermore, 39,266 unscheduled health care events could be avoided due to the predicted improvement in asthma control with DuoResp® Spiromax® compared with Symbicort® Turhaler®, resulting in further savings of £3.50 million. CONCLUSIONS: DuoResp® Spiromax® is likely to offer budgetary savings compared with Symbicort® Turhaler®, with further cost savings potentially resulting from improved inhalation technique.

PRS20 ESTIMATION OF INCREASED COSTS IN SWITCHING FROM Tiotropium TO OTHER LAMA THERAPY DURING MAINTENANCE TREATMENT OF COPD IN THE UK

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OBJECTIVES: Chronic obstructive Pulmonary Disease (COPD) is a prevalent disease with a significant economic burden to the UK National Health Service (NHS). NICE recommends maintenance treatment including inhaled bronchodilator medications such as long-acting muscarinic antagonists (LAMAs); tiotropium is the most widely used LAMA in the UK. The objective of this model was to quantify the budget impact to the NHS of switching patients from tiotropium to another LAMA, compared to remaining on tiotropium. METHODS: Two matched patient groups were considered: patients who switched from tiotropium to another LAMA and patients who remained on tiotropium. The budget impact model was conducted over a 3 month time horizon, with sensitivity analyses conducted over a 12 month time horizon. Costs included were costs of medication, costs of patient identification and new inhaler training, and primary care resource use in the 3 months following inhaler switch, priced according to PSSRU estimates. The number and duration of GP visits was estimated from the CPRD, a representative primary care database. RESULTS: Optimization of COPD therapy in compliance with GOLD guidelines would result in a better treatment for patients and potential savings, in a Portuguese National Health Service perspective.
LABA COMBINATION INHALERS IN THE TREATMENT OF ASTHMA IN SLOVENIA

COST-MINIMIZATION AND BUDGET-ImpACT ANALYSIS Of FIXED-dOse ICS/PRs23

The total budget spends in the private health care system. Given the significant related to pneumonia hospitalization are high and represents a large impact to exacerbations, severe exacerbations, and pneumonia were, for all treatment choices, very severe COPD. Model analysis showed that the expected three-year survival €

BUD/F (€7,340 vs €6,999, p<0.0001). However, during the second and third year the difference in COPD and pneumonia the FAP and PAP groups was 6,511.0084; year 3: €6,647 vs €6,714, p<0.001). PAP recipients had a significantly lower 3-year mortality rate compared with CG (8.2% vs 11.7%, p<0.001; relative risk reduction 30%) was lower in the FAP group (9.4% vs 11.0%, p=0.0048). During post-index period, IPF patients had a higher risk of hospitalization (48.7% vs 20.8%) and all other types of HRU compared with SA and COPD in Germany. A statutory health insurance (SHI) perspective was taken.

The life expectancy predicted by the model was 8.74 years (2014) A323–A686

Results: of patients was followed for 3 years after initiation of PAP therapy. Of these, 1,300 patients in the FAP group and 1,192 patients in the CG had comorbid COPD. This subgroup of patients was followed for 3 years after initiation of FAP therapy. RESULTS: Total COI was higher in the FAP group versus CG in the first year of follow-up (€8,697 vs €6,999, p<0.001). However, during the second and third year the difference in COI between the FAP and PAP groups was 7,715.0084; year 3: €7,847 vs €7,918, p<0.001). PAP recipients had a significantly lower 3-year mortality rate compared with CG (8.2% vs 11.7%, p<0.001; relative risk reduction 30%). CONCLUSIONS: SA patients with COPD treated with PAP showed significantly reduced mortality and morbidity. Total COI was higher in PAP recipients versus CG over the first 3 years of follow-up, but the difference between groups decreased over time. A follow-up period of 3 years may be required to show beneficial economic outcomes in SA patients receiving PAP therapy.

An analysis of US Medicare beneficiaries: burden of direct medical costs in patients with idiopathic pulmonary fibrosis

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With SA patients with COPD treated with PAP showed significant costs in patients with idiopathic pulmonary fibrosis (IPF) are covered by Medicare; yet published data on the economic burden that IPF imposes to this largest US payer are limited. The objective of this study was to compare health care resource utilization (HRU) and costs between Medicare beneficiaries with IPF and matched non-IPF controls. METHODS: Administrative claims from a 5% random sample of Medicare beneficiaries (aged 65+) from years 2000 to 2011 were analyzed. Incident IPF patients were identified based on ICD-9-CM diagnosis codes, with at least one year enrollment before (pre-index) and after (post-index) the first diagnosis (index date). Up to 5 beneficiaries without IPF were matched to each IPF patient, based on age, gender, region, and medical resource costs (excluding outpatient drug costs) during the pre-index and post-index periods were compared between IPF patients and the matched controls and univariate multivariate analyses were performed to compare the differences. RESULTS: Of the total 7,855 IPF patients were matched to 38,856 controls. During pre-index period, IPF patients had 2-3 folds higher risk of COPD, asthma and lung infections, 80% higher risk of hospitalization (28.8% vs 15.8%), and higher total medical costs ($10,124 vs $5,888, p<0.001). During post-index period, IPF patients had a higher risk of hospitalization (48.7% vs 20.8%) and all other types of HRU with the total medical costs $11,955 higher than controls ($20,887 vs $8,992; all p<0.05). Incapent care accounted for 50% of total medical costs of IPF patients in both pre-index and post-index periods. CONCLUSIONS: In the US, IPF patients aged 65 or older had a greater burden of comorbidity and incurred more HRU and medical costs than matched controls. Multidisciplinary team based approach and effective therapies are needed given the high unmet needs.

EXAMINATION OF THE BURDEN OF ILLNESS OF U. S. MEDICARE PATIENTS DIAGNOSED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Xia L1, Kanbury MF2, Du J2, Baser O2

PHARMACOECONOMICS, RISK MANAGEMENT, QUALITY OF LIFE

Veith J, Samet J, 2014 JAMA 311(9):901-908

EXAMINATION OF THE BURDEN OF ILLNESS OF U. S. MEDICARE PATIENTS DIAGNOSED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Xia L1, Kanbury MF2, Du J2, Baser O2

PHARMACOECONOMICS, RISK MANAGEMENT, QUALITY OF LIFE

Veith J, Samet J, 2014 JAMA 311(9):901-908

Objective: to evaluate the economic burden associated with pneumonia hospitalization in the USA. The study population was Medicare beneficiaries aged 65 or older with a diagnosis of pneumonia. All costs were discounted at 3.5%. The study was based on the results of seminal study GOAL (Gaining Optimal Asthma Control) that compared FF/VI with two other FDCs of ICS/LABA were clinically equivalent. We compared FF/VI with currently available FDC options, novel once-daily fixed-dose combination (FDC) of inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) fluticasone furoate/vilanterol (FF/VI) against those of patients was followed for 3 years after initiation of PAP therapy. Of these, 1,300 patients in the FAP group and 1,192 patients in the CG had comorbid COPD. This subgroup of patients was followed for 3 years after initiation of FAP therapy. RESULTS: Total COI was higher in the FAP group versus CG in the first year of follow-up (€8,697 vs €6,999, p<0.001). However, during the second and third year the difference in COI between the FAP and PAP groups was 7,715.0084; year 3: €7,847 vs €7,918, p<0.001). PAP recipients had a significantly lower 3-year mortality rate compared with CG (8.2% vs 11.7%, p<0.001; relative risk reduction 30%). CONCLUSIONS: SA patients with COPD treated with PAP showed significantly reduced mortality and morbidity. Total COI was higher in PAP recipients versus CG over the first 3 years of follow-up, but the difference between groups decreased over time. A follow-up period of 3 years may be required to show beneficial economic outcomes in SA patients receiving PAP therapy.
son cohorts. After applying a 1:1 matching, a total of 123,356 patients were matched from each of the 2 treatment groups. The cost-based episode of COPD in Europe had higher health care utilization, including Medicare carrier (98.1% vs. 70.1%). Durable Medical Equipment (DME, 37.4% vs. 15.8%) and Home Health Agency (HHA, 17.2% vs. 4.6%) claim, outpatient visits (73.9% vs. 41.7%) and inpatient (32.5% vs. 6.8%), skilled nursing facility (SNF, 10.0% vs. 2.9% admissions (1.3% vs. 0.6%) and prescription drug claims (53.4% vs. 49.9%), resulting in higher health care costs for Medicare carrier ($3,391 vs. $1,313), DME ($413 vs. $97), HHA ($923 vs $228), outpatient visits ($7,334 vs $1,894), inpatient ($5,985 vs. $1,065), SNF ($1,562 vs. $368), hospice ($304 vs. $143), pharmacy ($1,180 vs. $692) and total costs ($24,288 vs. $7,399) (p<0.001).

CONCLUSIONS: COPD patients are associated with high economic burden and health care utilization.

PRS28
ESTIMATION OF THE COST OF CHILDHOOD ASTHMA IN TURKEY
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OBJECTIVES: Asthma is the most common chronic disease in childhood, reduces the quality of life of children and their families, and produces high social and health care costs. The aim of this study is to estimate the direct cost of pediatric asthma in Turkey and to examine its variability depending on asthma control level. METHODS: The clinical pathway for childhood asthma was designed by and based on the data from the available Turkish literature. Unavailable data was collected by the expert’s clinical view. To calculate direct costs, the medical management of childhood asthma estimated using ‘cost-of-illness’ methodology for one year per child. All costs were calculated from the health care payer perspective. The costs were covered hospitalizations, physician visits, diagnostic tests, medications, and co morbid diseases. RESULTS: According to the recent studies, the controlled patient was 60%, partial controlled patient was 25%, and uncontrolled patient was 15%. The asthma management based on wellness protocol. The mean annual cost per patient with controlled asthma is 542.9%, partial controlled asthma 714.5% and uncontrolled asthma 734.5%.

CONCLUSIONS: The cost of pediatric asthma in Turkey increased in the past few years. New care pathways should be implemented with different level of spectrum to distributions. To increase the utility and effectiveness of health care system, the findings of this evaluation may guide to construct future policies.

PRS29
COST OF A PULMONARY ARTERIAL HYPERTENSION-RELATED HOSPITALIZATION IN BELGIUM
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Objective: Pulmonary arterial hypertension (PAH) is a rare disease, for which only scarce health care cost data is available in Europe. The progressive nature of the disease often requires hospitalization, the costs of which are currently unknown in Belgium, mainly due to the low number of patients affected. The objective of this study was to estimate the cost and length of stay of PAH-related hospitalization likely related to disease worsening in Belgium.

Methods: A retrospective database analysis was performed using the IMS hospital disease database from 2008 to 2011, in Belgium. The PAH asthma calculation was based on wellness protocol. The mean annual cost per patient with controlled asthma is 542.9%, partial controlled asthma 714.5% and uncontrolled asthma 734.5%.

Conclusions: The cost of PAH-related hospitalization is related to disease severity, except the costs which were related to COPD exacerbation. The costs of COPD exacerbation per-case was calculated and divided into severe-exacerbation (hospitalization and emergency visit) costs and non-severe-exacerbation (related to COPD) costs. The annual maintenance costs per-patient was RR351,599, KRW 401,068, KRW 573,010 and KRW 999,506 for mild, moderate, severe and very-severe according to GOLD criterion, respectively. In case of the COPD exacerbation severe-exacerbation was KRW 163,495 and KRW 276,068.

Conclusions: The severity of disease and exacerbation of COPD have a substantial impact on the medical costs of COPD patients. Improvement of lung function and reduction of occurrence of COPD exacerbation will be beneficial for the reduction of the health care expenditures.

PRS31
THE MEDICAL COSTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN SOUTH KOREA
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OBJECTIVES: The aim of this study is to investigate the medical costs of COPD patients in South Korea.

METHODS: We enrolled 300 COPD patients who had been treated and followed up for more than one year in the three hospitals from 2012 to 2013. The hospital electronic database was used to obtain medical costs and the medical records were reviewed by physicians (respiratory specialists) to assess clinical characteristics. We calculated annual maintenance costs per-patient according to disease severity, except the costs which were related to COPD exacerbation. The costs of COPD exacerbation per-case was calculated and divided into severe-exacerbation (hospitalization and emergency visit) costs and non-severe-exacerbation (related to COPD) costs. The annual maintenance costs per-patient was RR351,599, KRW 401,068, KRW 573,010 and KRW 999,506 for mild, moderate, severe and very-severe according to GOLD criterion, respectively. In case of the COPD exacerbation severe-exacerbation was KRW 163,495 and KRW 276,068.

Conclusions: The severity of disease and exacerbation of COPD have a substantial impact on the medical costs of COPD patients. Improvement of lung function and reduction of occurrence of COPD exacerbation will be beneficial for the reduction of the health care expenditures.

PRS32
THE DIRECT COST OF ASTHMA IN TURKEY
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OBJECTIVES: Asthma is one of the mostly seen chronic illnesses in Turkey, yet there are limited studies on cost of asthma in our country. In addition they were based on a central database and weight of disease. The aim of this study was estimating the nationwide cost of managing asthma and examining its variability depending on asthma control level.

METHODS: The clinical pathway for asthma was determined from the literature. Part of the data was collected from the expert’s clinical view. To calculate the direct costs, the medical management of adult asthma was estimated using ‘cost-of-illness’ methodology for one year per patient. All costs were calculated according to payer perspective. The costs covered were physician visits, hospitalizations, diagnostic tests, medicine and comorbid disease.

RESULTS: According to our studies, the controlled, partially controlled and uncontrolled patients were 22%, 50% and 28% respectively in Turkey. The cost of asthma calculation was based on weighted percentage of control. The annual mean cost per patient was $1047.86. The cost of severe asthma was $1737 ($55), and uncontrolled asthma $2176 ($69), ranging from $1939 ($61) to $2537 ($80) for age groups 50-64 and 75-84 respectively; the cost of episode for low-risk patients was RR1737 ($55), and for moderate-risk RR2378 ($75) for all ages. Average reimbursement rate was RR2,020,925 ($657/mo) for low-risk, RR2,940,947 ($657/mo) for moderate-risk, and RR17,684 ($554/mo) for high-risk patients; with 60%-80% of patients with CAP hospitalized and the estimated number of CAP patients of age 50 and older in Turkey was RR33,448,423 ($3.4 billion); the national estimates of cost of CAP in senior adults was $124 million. Employed patients comprise 12.8% and 18.3% among the inpatient and outpatient cases, respectively. The average LOS and health care cost in Russia, inpatient care constitutes the majority of cost. Cost of treatment was similar across all age and risk groups.

PRS33
ECONOMIC BURDEN IN DIRECT COSTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN RUSSIA
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OBJECTIVES: COPD is one of the leading causes of morbidity and mortality worldwide and has a major burden on Russian’s health care system. It’s lead to frequent use of health care resources. The main aim of this study was to describe the direct cost burden of management of COPD patients with different degree of disease severity.

METHODS: The methodology for cost of illness analysis was based on a previous Russian study (Arkovetsena M. V. et al., 2010). One-year cost studies were identified by searching the Russian data to medical and comorbid disease. The data included 13,266 patients of middle aged sample. The data were collected from 2007 to 2014. The data were used to form 2 variants of COPD costs. In 1st variant were covering 50% (2010/2011) to 34% (2009) of the hospital beds in Russia. In adult patients, who were either hospitalized with a primary diagnosis of primary pulmonary hypertension (PH) (ICD-9-CM code 416.0) or were receiving a 2nd medication indicated for PAH, was extracted. To ensure hospitalization based on wellness protocol. The mean annual cost per patient with controlled asthma is 542.9%, partial controlled asthma 714.5% and uncontrolled asthma 734.5%.

Conclusions: The annual maintenance costs per-patient was $1047.86. The cost of severe asthma was $1737 ($55), and uncontrolled asthma $2176 ($69), ranging from $1939 ($61) to $2537 ($80) for age groups 50-64 and 75-84 respectively; the cost of episode for low-risk patients was RR1737 ($55), and for moderate-risk RR2378 ($75) for all ages. Average reimbursement rate was RR2,020,925 ($657/mo) for low-risk, RR2,940,947 ($657/mo) for moderate-risk, and RR17,684 ($554/mo) for high-risk patients; with 60%-80% of patients with CAP hospitalized and the estimated number of CAP patients of age 50 and older in Turkey was RR33,448,423 ($3.4 billion); the national estimates of cost of CAP in senior adults was $124 million. Employed patients comprise 12.8% and 18.3% among the inpatient and outpatient cases, respectively. The average LOS and health care cost in Russia, inpatient care constitutes the majority of cost. Cost of treatment was similar across all age and risk groups.
structure of direct costs in Russia was as follows – 77% for hospital stays, 21% for patient visits, 2% for ambulance service. COPD exacerbations contributed the major portion of cost and also correlated with disease severity. CONCLUSIONS: COPD associated with significant economic burden on Russian’s health care system. There is a striking direct relationship between the cost of care and severity of the disease with hospitalization leading to disease exacerbation being a major portion of cost.

PR34 THE COSTS OF ILLNESS OF ATOPIC DERMATITIS IN SOUTH KOREA
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OBJECTIVES: Atopic dermatitis is a global public health concern considering its growing prevalence and mounting socioeconomic burden. However, few studies have assessed the economic impact of atopic dermatitis in Korea. To conduct a cost analysis and evaluate the economic impact of atopic dermatitis related annual disease burden, quality of life, and change in medical expenses in regards to change in health related quality of life. METHODS: This prospective cost analysis of atopic dermatitis by reviewing the housekeeping account books of 229 severe atopic dermatitis patients. The actual medical expenses and loss of productivity were calculated. RESULTS: The costs including lab investigations charges, unit costs of treatments, medicines, medical consultations, and loss of productivity were calculated per patient. Data was analysed by Statistical Package for the Social Sciences (SPSS) version 18.0 using various descriptive and inferential statistical tests. RESULTS: A median medical cost of acute exacerbation of atopic dermatitis (AD) of Ministry of Health (MOH) perspective was USD 38.47 per episode. Medication cost comprised the majority (52.38%) of the total medical costs. A median medical cost of acute exacerbation of asthma under Ministry of Health (MOH) perspective was USD 105.00 (RM338.47) per episode. CONCLUSIONS: Asthma exacerbation and loss of time in the hospital were proportional to the direct medical costs. In Malaysia, a substantial proportion of the direct portion of asthma treatment is heavily subsidised for the locals.

PR35 THE COST STUDY OF HEALTH SERVICES IN MONGOLIA
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OBJECTIVES: This study aimed at estimating and identifying different costs and related burden of illness in patients receiving treatment of AECOPD in a tertiary care hospital in Mongolia. METHODS: A prospective follow-up study was performed in Department of Accidental and Emergency Medicine of the hospital. Data were derived on the basis of per exacerbation episode. Relationship between direct medical costs and disease severity was analyzed using various descriptive and inferential statistical tests. RESULTS: The average annual direct medical cost were RM 457.68 (US$ 141.97) and RM 28.25 (US$ 8.76) per exacerbation respectively. Drug cost (41%) was the leading cost driver, followed by unit cost of treatment per bed (35.3%) and lab investigation cost (25.4%). However, food cost (94.4%) represented the largest proportion in out-of-pocket costs. More than 95% of actual direct medical costs were supported by the Government of Mongolia in the patients studied. CONCLUSIONS: Impacts of AECOPD in health care resources are worthy of attention. Cost information from pharmacoeconomic studies is important in decision making for health care professionals and policy makers in order to improve health care outcome and minimize costs.

PR36 A PHARMACOECONOMIC CARE ANALYSIS OF TUBERCULOSIS CONTROL IN PAKISTAN
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OBJECTIVES: To assess the direct and indirect medical costs incurred in the treatment of tuberculosis (TB) in patients attending public hospitals in Pakistan. METHODS: A descriptive cross-sectional study was conducted in patients attending Accident and Emergency and TB wards of the hospitals in Pakistan by convenient-sampling technique. The direct and indirect medical costs were determined by various parameters like consultation fees, cost of medicines, travelling costs and laboratory test expenses etc. All obtained data were analyzed using descriptive and inferential statistics. RESULTS: The mean annual direct medical cost for a TB patient was around Rs. 17317.56 (US$ 176.26) and indirect medical cost was Rs. 12918.50 (US$ 131.48). It was also observed that comparatively higher direct and indirect medical costs per patient (p < 0.001) were associated with large and urban hospitals. Besides, association of indirect medical costs with gender and age were the predominant predictors of the study. CONCLUSIONS: Severity of patients, distance to the hospital and length of stay in the hospital were proportional to the direct and indirect medical costs. In Pakistan, a significant proportion of the direct medical cost for TB treatment is subsidized for the public.

PR37 PHARMACOECONOMIC EVALUATION OF ACUTE EXACERBATION OF ASTHMA IN PATIENTS IN MALAYSIA
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OBJECTIVES: To conduct a study to determine the average cost of therapy for bronchial asthma patients in a tertiary care center. METHODS: A prospective observational study was carried out on 100 asthmatic patients after the ethical clearance was obtained from an Independent Ethical Review (IER) board. The patients selected for the study were in-patients admitted to the Medicine and Pulmonary wards for bronchial asthma related complaints and with and without co-morbidities. The study assessed the average cost of therapy which was obtained from patient records. Statistical analysis was performed using SPSS version 20. RESULTS: The average cost of treatment per patient (N=100) was Rs.53,564.91 (US$ 1590.26). This constituted 61% of the study population. The job profiles of the majority of study population included house wives (53%) and agriculturist (15%). The average cost of therapy among 100 patients was found to range from Rs. 81 to Rs. 598. The impact on the length of stay on cost of therapy per day was classified into <5, 5-10, 11-24 days and cost was found to be Rs. 9.21 ± 5.57, Rs. 12.12 ± 6.95 and Rs.5.60±13.36 respectively. Impact of co-morbidities (35%) and without co-morbidities on cost of therapy per day was found to be Rs.13.03 ± 10.63 and Rs.54 ± 6.77 respectively. CONCLUSIONS: Asthma creates a substantial financial burden on the society and results in compromise on diagnosis and treatment mainly in a developing country like India. There was a substantial increase in the cost of therapy as the duration of hospital stay increased and also in the case of patients with co-morbidities. Pharmacoeconomic analysis is needed to develop strategies to reduce the cost of therapy and thereby achieve greater medical adherence and improved quality of life in asthma patients.

PR38 RESOURCE USE AND HEALTH CARE COSTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN SLOVAKIA
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OBJECTIVES: The objective of this study was to measure the resource utilisation and direct costs of healthcare among upper middle class patients with chronic obstructive pulmonary disease (COPD) in Slovakia and to provide a basis for cost-effectiveness evaluations. METHODS: The cross-sectional survey was performed in order to obtain the information on a 100 patients with COPD and to estimate the direct costs of the disease management. The survey included 4 experts experienced in COPD treatment. The studied population were cohorts of COPD patients evaluated separately according to the stage of the disease (mild, moderate, severe) and very severe COPD. The study was set for one average patient per 3 months of treatment. The cost data were assessed and actualized due the 1st July 2014. All types of health care used in COPD management were evaluated (hospitalization, outpatient visits, diagnostics, laboratory tests and the management of symptoms, use of bronchodilators). Moderate
and severe exacerbations were also evaluated and the costs were set for one single event. RESULTS: The total cost of mild COPD was €26.22, moderate COPD was €30.26, severe COPD €92.04 and for the very severe COPD €267.64 for 1 patient/3 months. Expenses for bronchodilators also vary between different stages of COPD, for mild COPD it represented €17.44, moderate COPD €109.54, severe COPD €219.58 and for very severe COPD €260.15. Costs of treatment of exacerbations were estimated – for moderate exacerbation €67 and for severe exacerbation €1060.27. CONCLUSIONS: In the management of COPD the most expensive are the costs of hospitalization, outpatient care. The cost of medical treatment is a small part of the management of the very severe COPD and severe exacerbation. This survey can be used as the source for cost inputs in pharmacoeconomic evaluations.

PRS42
COST-EFFECTIVENESS OF A COPD DISEASE MANAGEMENT PROGRAM IN PRIMARY CARE: THE RECODE CLUSTER RANDOMIZED TRIAL
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OBJECTIVES: Disease management programs for chronic obstructive pulmonary disease (COPD, CDP-DM) are currently implemented on a broad scale in the Netherlands. However, there is little evidence about their impact on the cost-effectiveness of these interventions. We aimed to conduct a cost-effectiveness analysis of a COPD-DM program in primary care in the Netherlands, called RECODE. In RECODE, a multidisciplinary primary care team aimed to maintain optimal clinical status, to improve patient lifestyle, setting-up virtual care plans, early reorganization and management of exacerbations, and connecting clinical guidelines. In addition, clinical decision making was supported by audit and feedback reports provided by an ICT program and reimbursement of physical activity behavior. RESULTS: A two-year cluster-randomized controlled trial (1086 COPD patients, 40 clusters), the COPD-DM program was compared to usual care. As part of this trial we conducted a cost-effectiveness analysis to relate the effect of the COPD-DM on intermediate and final health outcomes to the costs from a health care and a societal perspective. Detailed self-reported health care utilization data were collected during the trial-period. RESULTS: The 2-year intervention costs of the training for professionals, the ICT, and the audit and feedback reports were estimated to be €524 per patient. Excluding these costs, the intervention group had €584 (95% CI 869 to €1,046) higher health care costs and €645 (95% CI €38 to €1,180) higher costs from the societal perspective compared to the usual care group. Health outcomes were similar in both groups, except for 0.04 (95% CI -0.07 to 0.00) less quality-adjusted life-years in the intervention group. CONCLUSIONS: RECODE was not cost-effective during the 2-year follow-up period. This is most likely due to the fact that the interventions targeted professionals instead of patients and were suboptimally implemented, the relatively mild COPD population, and the national reforms in COPD care that affected the usual care group.

PRS43
COST-EFFECTIVENESS OF BEDAQUILINE FOR THE TREATMENT OF MULTIDRUG-RESISTANT TUBERCULOSIS
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OBJECTIVES: To evaluate the cost-effectiveness of adding bedaquiline to the intensive phase of background regimens (BR) of drugs for multidrug-resistant tuberculosis (MDR-TB) in the United Kingdom (UK). METHODS: A cohort-based Markov model was developed to estimate the incremental cost-effectiveness ratio of bedaquiline plus BR (B+BR) versus BR alone (BR) in the treatment of MDR-TB in the UK, over a 10-year horizon. A National Health Service (NHS) and personal social services perspective was considered. Costs and effectiveness were discounted at a 3.5% per annum rate. Probabilistic and deterministic sensitivity analyses were conducted. RESULTS: The total discounted cost per patient on B+BR was €107,123, compared with €116,616 for BR. The total discounted QALYs per patient on B+BR and BR were 2.81 and 2.74, respectively. The effectiveness of treatment was evaluated in terms of Quality Adjusted Life Years (QALYs) and Disability Adjusted Life Years (DALYs). Data were sourced from a phase II, placebo controlled trial of bedaquiline, NHS reference costs, and the literature. Costs and effectiveness were discounted at a 3.5% per annum rate. Probabilistic and deterministic sensitivity analyses was conducted. RESULTS: The total discounted cost per patient on B+BR was €107,123, compared with €116,616 for BR. The total discounted QALYs per patient on B+BR and BR were 2.81 and 2.74, respectively. The effectiveness of treatment was evaluated in terms of costs savings of €9,493 and an additional 1.04 QALYs over a 10-year period, and is therefore considered to be the dominant (less costly and more effective) strategy over BR. B+BR remained dominant versus BR in the majority of sensitivity analyses. The treatment effectiveness of being 74% probability of being dominant versus BR in the probabilistic sensitivity analyses. CONCLUSIONS: In the UK, bedaquiline is likely to be cost-effective and cost-saving, compared to the current standard of care for MDR-TB under a range of scenarios. Further cost savings were seen in length of hospital stay, which offset bedaquiline drug costs. Bedaquiline remained cost-saving in several sensitivity analyses, highlighting the certainty surrounding the results of the model. These results also indicate that the B+BR regimen may offer substantial benefits in terms of cost savings and improved health compared to an identical vaccination program involving PCV-13. PHiD-CV's potential to better prevent AOM translates into incremental benefits and dominance of PHiD-CV over PCV-13. Sensitivity analyses were performed to evaluate the robustness of the model to variations in the underling input parameters and assumptions. RESULTS: The ITC estimated change from baseline in trough FEV1 of 18.06ml (95% CI -19.11, 55.23, p=0.341) at 12 weeks and 3.97ml (95% CI -18.46, 0.854) at 24 weeks. RESULTS: For PHiD-CV over the price parity, UMEC dominated TIO with incremental QALY of 0.0009, incremental life years of 0.0001 and cost reduction of €4.54. The sensitivity analyses suggested that variation in main parameters will not alter the behavior of the comparison between the two treatments. CONCLUSIONS: At price parity to TIO, UMEC may be considered as a cost-effective treatment alternative for maintenance bronchodilator treatment to relieve symptoms in patients with COPD in the UK.
OBJECTIVES: Asthma is a chronic disorder requires continuous and long-term management. In our patient economic week and produces more burden on short acting β₂-agonists in pressurized metered dose inhalers and dry powdered inhalers are the most commonly prescribed formulations in south Indian clinical settings. The present study aims to investigate and to select appropriate cost effectiveness analysis of pressed metered dose inhalers (MDIs) or dry powdered inhalers (DPIs) for salbutamol. METHODS: It is a prospective comparative study conducted among subjects those who were newly diagnosed with asthma. The patients were divided into two groups based on the type of inhaler used such as MDI or DPI group. All the patients were counseled about the usage of inhalers during their treatment device allotment. Quality of life and FEV 1 were measured at the baseline visit. In addition to that data related to direct cost such as medical, laboratory and re-hospitalization costs were also measured at baseline. Follow up was done for both the groups. Similar to baseline quality visit, FEV1 and direct medical costs were measured during follow up. RESULTS: The present study results shows that there is no significant difference between the groups. Adverse event incidences between the groups were not significant. OBJECTIVES: To evaluate clinical efficacy, safety and cost-effectiveness of treatment with FP/Salmeterol and montelukast sodium in patients with risk factors of poor efficacy (prior administration of antibiotics, comorbidities), comparing generic levofloxacin (Glevo, Glenmark Pharmaceuticals Ltd.) versus original levofloxacin (Tavanic®, Sanofi-Winthrop Ind.) and conventional treatment with first-line antibiotic (lactam antibiotic). METHODS: Out of 1586 patients were randomized into three treatment arms. Mean age was 24±3.15 years. Treatment arm 1 included 61 patient administered GLEVO in the dose of 500 mg/day, whereas in the treatment arm 2 (n= 41) patients were treated with original levofloxacin (Tavanic) in the dose of 500mg/day, and 45 patients in the treatment arm 3 received conventional therapy. Clinical efficacy and safety were evaluated based on clinical, laboratory and radiological data analysis. Cost-effectiveness analysis included calculation of direct medical costs and cost-effectiveness ratios (CER). RESULTS: Clinical efficacy rate in the treatment arm 1 (Glevo) was 98.4%, in the treatment arm 2 (Tavanic)-97.6%, whereas conventional therapy efficacy rate was 84.4%. Average adverse event incidence in the treatment arm 1 was 21.8%, in treatment arms 2 and 3 –14.6% and 35.5% respectively. Treatment duration in the Glevo treatment arm was 2±1.4 days, in the treatment arm 2 –8±1.2, in the conventional therapy arm –7±2.1 days. Time to radiological resolution of pneumonia was comparable. Mean cost of antibiotic administration cycle and the cost-effectiveness ratio in patients administered Glevo was 7.65€ (CERGlevo = 7.8), in the treatment arm 2 –22.4€ (CER1,6=22.9), in the conventional therapy arm–10.8€ (CER1,6=12.8). CONCLUSIONS: Administration of levofloxacin for mild to moderate community-acquired pneumonia in patients with risk factors is superior in clinical efficacy compared to conventional therapy. Administration of Glevo is characterized by favorable cost-effectiveness parameters.

PATIENTS WITH COMMUNITY-ACQUIRED PNEUMONIA TREATMENT

PRS47

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OBJECTIVES: To evaluate clinical efficacy, safety and cost-effectiveness of treatment with FP/Salmeterol and montelukast sodium in patients with risk factors of poor efficacy (prior administration of antibiotics, comorbidities), comparing generic levofloxacin (Glevo, Glenmark Pharmaceuticals Ltd.) versus original levofloxacin (Tavanic®, Sanofi-Winthrop Ind.) and conventional treatment with first-line antibiotic (lactam antibiotic). METHODS: Out of 1586 patients were randomized into three treatment arms. Mean age was 24±3.15 years. Treatment arm 1 included 61 patient administered GLEVO in the dose of 500 mg/day, whereas in the treatment arm 2 (n= 41) patients were treated with original levofloxacin (Tavanic) in the dose of 500mg/day, and 45 patients in the treatment arm 3 received conventional therapy. Clinical efficacy and safety were evaluated based on clinical, laboratory and radiological data analysis. Cost-effectiveness analysis included calculation of direct medical costs and cost-effectiveness ratios (CER). RESULTS: Clinical efficacy rate in the treatment arm 1 (Glevo) was 98.4%, in the treatment arm 2 (Tavanic)-97.6%, whereas conventional therapy efficacy rate was 84.4%. Average adverse event incidence in the treatment arm 1 was 21.8%, in treatment arms 2 and 3 –14.6% and 35.5% respectively. Treatment duration in the Glevo treatment arm was 2±1.4 days, in the treatment arm 2 –8±1.2, in the conventional therapy arm –7±2.1 days. Time to radiological resolution of pneumonia was comparable. Mean cost of antibiotic administration cycle and the cost-effectiveness ratio in patients administered Glevo was 7.65€ (CERGlevo = 7.8), in the treatment arm 2 –22.4€ (CER1,6=22.9), in the conventional therapy arm–10.8€ (CER1,6=12.8). CONCLUSIONS: Administration of levofloxacin for mild to moderate community-acquired pneumonia in patients with risk factors is superior in clinical efficacy compared to conventional therapy. Administration of Glevo is characterized by favorable cost-effectiveness parameters.

HOSPITAL-BASED ASTHMA CLINICS (ACs) ARE HOSPITAL-BASED UNITS RUN BY AN EXPERIENCED TEAM COMPRISING-PHYSICIANS, NURSES, AND ADEQUATE SUPPORT STAFF

PRS51

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OBJECTIVES: Optimal asthma control has been associated with significant reductions in mortality, morbidity, and quality of life gains for the patients. Hospital Asthma Clinics (ACs) are hospital-based units run by an experienced team composed of a pulmologist and a specialized nurse. Their aim is to provide effective treatment and optimal control to asthma patients. However, their impact on disease control and their cost-effectiveness are unknown. The objective of this study is to analyze the disease control and their cost-effectiveness versus traditional management. METHODS: We designed a case–crossover study using the medical records of all patients submitted to one AC in Spain during 2012. We defined a period of 365 days after the index date of AC, and the control period as 365 days before the index date. We calculated changes in relevant disease control indicators and estimated the Incremental Cost Effectiveness Ratio (ICER) for one additional controlled patient. RESULTS: The percentage of controlled patients increased from 41% (n=371) to 72.2% (n=618) in the treatment group. The ICER was 13.72 euros per quality adjusted life year (QALY) gained. CONCLUSIONS: The ACs increases the percentage of patient having asthma controlled in 2012.
alone from 3.6% to 45.8%, and omalizumab from 0% to 6%. Annual hospitalizations and emergency visits decreased by 78% and 75% respectively. The ICER was estimated at €999. Hence, Oralair® may be classified as the dominant treatment for moderate OSAHS patients without high cardiovascular risk. Lifestyle advice and no treatment. CPAP was associated with higher costs and QALYs compared with dental devices, and the other outcomes, SCIT was dominated by UC. A total of 183 adult patients aged 18 to 45 years with persistent moderate to severe OSAHS were randomized to placebo or SCIT using extracts of tree pollen, grass pollen and/or mixed population in previous research. METHODS: The effects of three years of drug treatment on quality-adjusted life years (QALYs) and associated costs were assessed using a Markov model with a nine-year time horizon. Symptom score data were extracted, and the relative efficacy of Omalizumab was assessed through a network meta-analysis (i.e. indirect comparison) of placebo-controlled, clinical trial data in adults and children. Patient symptom scores were translated into the impact on quality of life by means of published sources. Costs associated with drug treatment and other health care resources, including Statutory Health Insurance payments and patient co-payments, were calculated. The incremental costs and QALYs gained and total life-years gained (LYG). The cost-effectiveness of Oralair® has been demonstrated in a controlled trial with two parallel treatment arms was performed, comparing SCIT + usual care (UC) with UC alone, using online resource use and labor productivity questionnaires, and elicitation of EQ-5D and a global subjective symptom (GA). Primary endpoints were the costs per QALY, costs per successfully treated patient and the cost per additional symptom-free day. A Generalized Estimation Equation (GEE) model was used to estimate the incidence cost-effectiveness ratio (ICER) per averted AD case was calculated for PHF-W for the AD prevention in high-risk children. Hence, Oralair® is cost-effective relative to Grazax® in patients with grass pollen-induced AR in Germany. Findings are confirmed by extensive sensitivity analyses.

PRS54
A COST-EFFECTIVENESS ANALYSIS OF TREATMENT FOR MILD TO MODERATE OBSTRUCTIVE SLEEP APNEA-HYPOPNEA SYNDROME (OSAHS) IN FRANCE
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OBJECTIVES: To simulate the lifetime progression of a cohort of mild-to-moderate OSAHS patients. The Excel model was developed to simulate the lifetime progression of a cohort of mild-to-moderate OSAHS patients without high cardiovascular risk. Lifestyle advice is recommended for overweight patients. This study aims to assess the cost-effectiveness of these treatments for mild-to-moderate OSAHS patients. METHODS: This study was commissioned by the French National Authority for Health (HAS) and followed their recommendations. A Markov model was developed to simulate the lifetime progression of a cohort of mild-to-moderate OSAHS patients. Omalizumab was compared with usual care (UC) and -
further. Robustness of results was assessed using sensitivity analyses. The assessed outcomes were the incremental cost per quality-adjusted life-year (QALY) gained and total life-years gained (LYG). RESULTS: This study will inform public decision making about reimbursement of mild-to-moderate OSAHS treatments. CPAP was associated with higher costs and QALYS compared with dental devices, lifestyle advice and no treatment. Several sensitivity analyses were undertaken and it was found that the most sensitive parameters were related to sleepiness and cardiovascular inputs. Further investigation (clinical trial/observational study) of treatment effects on these parameters is needed. CONCLUSIONS: This analysis is the first to assess the cost-effectiveness of treatments in mild-to-moderate OSAHS patients in France. The technical report of this research will be available on the HAS website at the time of the congress (November 2014).

PRS55
COST-EFFECTIVENESS OF SUBCUTANEOUS IMMUNOTHERAPY IN ALLERGIC RHINITIS USING ONE OR MORE ALLERGENS - AN ANALYSIS LONG OVERDUE
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OBJECTIVES: Allergic rhinitis – hay fever and mite hypersensitivity - is a prevalent and increasingly common condition, causing considerable morbidity and eco-

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OBJECTIVES: Severe asthma is a major cause of morbidity and mortality around the world, imposing a heavy societal burden. The aim of this study was to evaluate the economic value of omalizumab in the treatment of adult patients with severe allergic asthma in Greece, from a societal perspective, based on data collected from a clinical trial (INNOVATE) and real-world evidence (RWE) from a prospective observational study conducted in Greece. METHODS: A Markov cohort model was developed in Microsoft Excel to compare the costs and outcomes of omalizumab plus standard treatment (ST), primarily comprised ICS, LABA and SABA versus ST alone. The time horizon was that of a lifetime. Both direct and indirect costs were incorporated. Health outcomes considered were Quality Adjusted Life Years (QALYs). Costs and QALYs were discounted annually at 3.5%.

RESULTS: Costs and QALYs were discounted annually at 3.5%. Unit costs were taken from publically available sources. Productivity losses were calculated based on published data, while utility values were taken from the INNOVATE study. Deterministic and probabilistic sensitivity analyses were undertaken to test the robustness of the model results. The addition of omalizumab to ST was associated with a 12.1% cost per QALY saved and a 32.2% probability of QALYs gained over ST, leading to a reduction of 29,670 AR-symptomatic days annually. Total workplace productivity associated with moving AZ/FP from third-tier to second-tier pricing and reimbursement. METHODS: Population is SAR sufferers taking treatment with AZ/FP. AZ/FP is assumed to gain market share annually with second-tier pricing for four years. The current total number of SAR-related symptomatic days, second, calculate total number of AR-related episodes per year multiplied by number of days per episode, estimate number of years a typical health plan, the estimate of expected number of absenteeism and presenteeism, estimate proportion of patients with poor inhalation technique with DuoResp® Spiromax® compared with Symbicort® Turbuhaler®– a DPI delivering LABA/ICS, Omalizumab appears to be a cost-effective treatment option for adult patients with severe allergic asthma compared with ST in Greece, confirmed by both trial and real-world data.

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COST-EFFECTIVENESS OF INDACATRAL/GLYCOPHYRON (QVA149) AS A MAINTENANCE BRONCHODILATOR TREATMENT IN ADULT PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN SPAIN

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COST-EFFECTIVENESS OF ENDOBRONCHIAL VALVE THERAPY FOR SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A MODEL-PREDICTION BASED ON THE VENT STUDY

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OBJECTIVES: Omalizumab-induced allergic rhinitis (ERB) is an innovative treatment that has been shown to be safe and effective in selected subgroups of patients with severe emphysema. The objective of our study was to assess the cost-effectiveness of valve treatment in the German health care system when compared to medical management, from a sub-analysis of the German Health Care System. The VENT Study (Emphysema Palliation Trial (VENT)) provided information about clinical events, health-related quality of life, and disease staging through 12 months. This information was subsequently used to develop a Markov model to project long-term disease progression, mortality, and health resource utilization. From this combined analysis, we computed the 5-year and 10-year incremental cost-effectiveness ratio (ICER) in euros per quality-adjusted life year (QALY). Costs and effects were discounted at 3% per year. RESULTS: ERB therapy led to clinically meaningful disease restaging at 12 months (37.8% of cohort improved staging, compared to 0% in control). Over 5 years, ERB was projected to increase survival from 66.4% to 70.7%, and to add 0.22 QALYs. Costs were estimated to increase by €10,299, resulting in an ICER of €46,322/QALY. Over 10 years, 0.41 QALYs were gained at additional cost of €10,425, yielding an ICER of €25,142/QALY. CONCLUSIONS: Our model-based analysis suggests that ERB leads to clinically meaningful changes in disease staging and progression when compared to medical management, with resulting gains in unadjusted and quality-adjusted life expectancy. Relative to the acknowledged willingness-to-pay threshold of €50,000/QALY, our results indicate ERB is a cost-effective therapy in the German health care system.

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OBJECTIVES: To assess the cost-effectiveness (CE) of indacaterol/glycopyronium (QVA149) as a maintenance bronchodilator treatment for patients with Chronic Obstructive Pulmonary Disease (COPD) versus salmeterol/fluticasone furoate (SFC; 50µg/500µg).

METHODS: A CE model of micro-simulation over a 3-, 5-, 10-year and lifetime horizon was developed from the perspective of the Spanish National Health System. Patients progress through subsequent COPD stages based on their baseline characteristics and considering the natural decline of Forced Expiratory Volume in 1 second (FEV1) and exacerbation rate. In the model this is counteracted by treatment-associated FEV1 improvements from baseline and exacerbation rate reduction associated to each treatment vs. placebo, which were obtained by direct and indirect comparison of primary data from TORCH (SFC vs. placebo), SHINE (QVA149 vs. placebo) and ILLUMINATE (QVA149 vs SC) clinical trials. Costs were based on their lifetime QALYs gained for the relative treatment and were life-years gained over years (QALYs). Costs estimate (Euros 2014) includes drugs, disease management and mild/severe exacerbation expenditures from Spanish health care cost databases and publications with a discount rate of 3% for costs and effects. RESULTS: QVA149 has shown to be less costly and more effective than the fixed combination with SFC, with an incremental cost-effectiveness ratio (ICER) of €467 lower than with SFC, which resulted from avoiding exacerbation costs and decreasing maintenance cost in relation to slowing COPD progression. Therefore, QVA149 was estimated to be dominant over SFC with respect to both cost and effectiveness. CONCLUSION: QVA149 is associated with an incremental clinical benefit and a cost saving in direct medical costs with respect to SFC, therefore, it represents a cost-effective option for patients with COPD.

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COST-EFFECTIVENESS ANALYSIS OF ALLERGEN IMMUNOTHERAPY IN PATIENTS WITH GRASS POLLEN-INDUCED ALLERGIC RHINITIS IN SPAIN

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OBJECTIVES: To determine the relative impact of treatment with Omalizumab, Grazax®, Panragmin®, Pollinex Quatro®, and symptomatic drug treatment (SDT) on clinical effects and health care costs in patients with grass pollen-induced allergic rhinitis (AR) in Spain. METHODS: The effects of three years of drug treatment on quality-adjusted life years (QALYs) and costs were assessed using a Markov model with a nine-year time horizon. Symptom score data were extracted, and the relative cost-effectiveness on QALYs was assessed through a network meta-analysis (i.e. indirect comparison) of 3-year, placebo-controlled, clinical trial data. Patient symptom scores were translated into the impact on quality of life by means of published sources. Costs associated with drug treatment and other health care resources were calculated. The incremental costs and QALYs gained were generated according to the INNOVATE study. CONCLUSIONS: Our model predicted a dominant relative to Grazax®, while ICERs of €6,931/QALY, €9,703/QALY, and €10,425/QALY were estimated relative to Panragmin®, Pollinex Quatro® and SDT, respectively. Apart from drug costs, the sensitivity analysis suggests that results were mostly driven by drug-specific symptom score values, duration of the pollen season, and inputs for immunotheerapy discontinuation. At a willingness-to-pay threshold of €20,000, the probability of Omalizumab being the most cost-effective treatment option is 65%. CONCLUSIONS: Omalizumab is cost-effective relative to Grazax®, Panragmin®, Pollinex Quatro® and SDT in grass pollen-induced AR in Spain. Findings are confirmed by extensive sensitivity analyses.

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THE POTENTIAL SOCIETAL COST BENEﬁTS OF IMPROVED INHALATION TECHNIQUE WITH DUXOEP® SPIROMAX® (BUDENOSIDE + FORMOTEROL FUMARATE DIHYDRATE) COMPARED WITH SYMCBICORT® TURBUHALER® FOR THE MANAGEMENT OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN SWEDEN

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OBJECTIVES: Duexo® Spiromax® (budesonide + formoterol fumarate dihydrate) is a fixed-dose combination (FDC) of inhaled corticosteroid (ICS) + long-acting beta agonist (LABA) in a novel dry powder inhaler (DPI). An economic model was developed to assess the potential societal cost benefits of switching patients from SFC to DUEXO® Spiromax® compared with Symbicort® Turbuhaler®—a DPI delivering the same FDC—in the management of adult patients with persistent asthma and chronic obstructive pulmonary disease (COPD). The Danish adult patient population was based on statistics from the National Board of Health and Welfare in Sweden. Societal costs (lost productivity) were based on the annual number of work-days lost for asthma and COPD patients in Sweden and the United Kingdom. The average daily cost of time lost in Sweden. Frequency of poor inhalation technique with Symbicort® Turbuhaler® and the subsequent increased risk of unscheduled health care events were taken from a large (n=1,664) cross-sectional, Italian observational study. The estimated reduction in the proportion of patients with poor inhalation technique with Duexo® Spiromax®
compared with Symbicort® Turbuhaler® was based on a conservative assumption.

**RESULTS:** An estimated 167,666 adult patients used Symbicort® Turbuhaler® annually in Sweden and were therefore eligible for treatment with DuoResp® Spiromax®, with 72.9% of these exhibiting poor inhalation technique. Based on the predicted improvement in inhalation technique with DuoResp® Spiromax® compared with Symbicort® Turbuhaler®, and assuming a hypothetical uptake of DuoResp® Spiromax® reaching 25% in years 4 and 5 — estimated societal cost savings through the avoidance of 147,158 lost productive days, totalled SEK285.4 million (€31.2 million). Reduction in DuoResp® Spiromax® was the potential to improve inhalation technique compared with Symbicort® Turbuhaler®, which would likely result in substantial societal cost savings.

**PRS63 IMPACT OF OMAZILUMAB ON ALL-CAUSE AND ASTHMATIC-RELATED HEALTH RESOURCE UTILIZATION IN PATIENTS WITH MODERATE OR SEVERE PERIODICALLY EXACERBATING ASTHMA**

**Objectives:**

- To assess the impact of Omaozilumab (OMA) on health resource utilization (HRU) in patients with moderate or severe asthma.

**Methods:**

- A retrospective, case-control study conducted using the Truven MarketScan database.
- Data collected between 1 January 2007 to 30 September 2012 for patients with asthma who were age 13-16 years old at any time during the analysis period and who continued at least 2 years of continuous enrolment.
- Data stratified by asthma severity based on NHBLI criteria.

**Results:**

- Total of 429 patients (mean age 13.8 years, 48.5% moderate, 51.5% severe) were included in the analysis.
- In the 3 months before baseline, HROs included:
  - Inpatient/day, 42.6% and 36.5% for patients with moderate and severe asthma, respectively.
  - Emergency visits, 27.4% and 26.1%.
  - Outpatient visits, 11.7% and 14.9%.
  - Office visits, 25.2% and 24.2%.
  - Prescription cost, 56.0% and 61.3%.

**Conclusions:** OMA use was associated with significant reductions in all-cause and asthma-related HRU.

**PRS64 DEVICE HANDLING ERRORS AND THE IMPACT ON QUALITY OF LIFE AND HEALTH CARE RESOURCE USE IN ASTHMATIC PATIENTS**

**Objectives:**

- To investigate the relationship of correct inhaler technique with patient satisfaction with drug delivery (p = 0.002), adherence (p = 0.049), and patient HRQoL measured by the SGRQ.

**Methods:**

- Cross-sectional, observational study in 243 patients aged 12-18 years with moderate to severe persistent asthma.
- Questionnaire on HRQoL and device handling errors.

**Results:**

- 92.6% of patients reported correct technique.
- Correct technique was significantly associated with better HRQoL (p = 0.04) and higher satisfaction with drug delivery (p = 0.002).

**Conclusions:**

- Improving asthma control has more recently focused on potentially modifiable clinical and behavioural characteristics including correct inhaler technique, treatment of concomitant allergic rhinitis (AR), adherence and smoking. The Primary Care-Asthma Initiative (PCI) aimed to establish a relationship between measures of asthma control and overall health status to add to the growing body of evidence helping to optimize asthma management interventions.

**PRS65 TERMINAL AVOIDED COSTS: HIGH-DOSE HYPOALLERGENIC DUST: A PREVENTIVE INHALATION IMMUNOTHERAPY VERSUS CONVENTIONAL SYMPTOMATIC TREATMENT**

**Objectives:**

- To evaluate the cost-effectiveness of high-dose hypoallergenic dust extract (HDHE) prophylactic immunotherapy versus conventional symptomatic treatment for patients with seasonal allergic rhinitis.

**Methods:**

- Randomized controlled trial in 648 patients with seasonal allergic rhinitis, randomized to HDHE or standard symptomatic treatment.
- Economic evaluation using a Markov model with a time horizon of 24 years.

**Results:**

- HDHE was associated with lower costs and higher QALYs compared to symptomatic treatment.
- Cost savings were estimated at €31.2 million over 24 years.

**Conclusions:** HDHE prophylactic immunotherapy is cost-effective compared to symptomatic treatment for seasonal allergic rhinitis.

**PRS66 ESTABLISHING THE RELATIONSHIP OF INHALER SATISFACTION, ADHERENCE, SMOKING HISTORY AND ALLERGIC RHINITIS WITH PATIENT OUTCOMES: REAL-WORLD OBSERVATIONS IN US ADULT ASTHMATIC PATIENTS**

**Objectives:**

- To establish the relationship between inhaler satisfaction, adherence, smoking history, and allergic rhinitis with patient outcomes in real-world settings.

**Methods:**

- Retrospective, multicenter study carried out in Spain in 2013.
- 1,476 patients with moderate or severe asthma included.
- Data collected on inhaler satisfaction, adherence, smoking history, and allergic rhinitis.

**Results:**

- Inhaler satisfaction was significantly associated with adherence to treatment (p = 0.0001) and lower rates of smoking (p = 0.0001).
- Smoking history was significantly associated with increased risk of allergic rhinitis (p = 0.0001).

**Conclusions:**

- Improving inhaler satisfaction has the potential to improve adherence, reduce smoking, and manage allergic rhinitis in real-world settings.

**PRS67 TECCEPO II STUDY: HOW TO IMPROVE THE INHALATION TECHNIQUES IN PATIENT WITH COPD. THE INFLUENCE OF PREFERENCES**

**Objectives:**

- To explore patient preferences for inhalation techniques in patients with chronic obstructive pulmonary disease (COPD) and the influence of patient preference on treatment outcomes.

**Methods:**

- Randomized controlled trial in 204 COPD patients.
- Patients randomized to one of two inhalation techniques: dry powder inhaler (DPI) or metered dose inhaler (MDI).

**Results:**

- Patient preferences significantly influenced the choice of inhalation technique.
- DPI was associated with higher patient satisfaction and better treatment adherence.

**Conclusions:**

- Inhaled corticosteroids and long-acting β2-agonists (LABAs) for COPD should be tailored to patient preference to optimize treatment outcomes.
oids (76.7%), inhaled-anticholinergic (70.7%), mucolitices (19.4%), xanthine (7.3%); oral-corticosteroids (1.3%). BDI: grade 2 primary outcome. RCT cohorts: there was no difference between control and intervention A and there were statistically significant differences between intervention B versus control (p<0.001), NNT=3.22 (IC95%, 2.27-5.88) and versus intervention A, NNT=4.16 (IC95%, 2.63-10). In the PPS cohort, NNT=4.01 (IC95%, 2.00-8.02). Results of a previous international trial described the frequency of dyspneia for all devices. The patients’ preferences enhance the efficacy of intervention.

**PRS68**

**INHALATION TECHNIQUE EVOLUTION AFTER TRAINING IN COPD. THE ROLE OF THE DEVICE**

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**OBJECTIVES:** To test the efficacy of two educational interventions to improve the inhalation techniques per device in patients with COPD and the influence of patient preference. **METHODS:** Design: Multicenter patients’ preference trial or comprehensive cohort design SRTCTN15162646. Patients: 465 COPD patients (to detect a difference between groups of 25%, 80% statistical power, 95% confidence level, 40% expected losses), with inhaled treatment, written consent. Non-probabilistic consecutively sampled. Allocation: Patients without strong preferences for a treatment are randomised. RCT group (block randomization), and those with strong preferences are assigned to their preferred device. **RESULTS:** The mean improvement in the patients’ QoL was 14.4% for the correct inhalation technique. **CONCLUSIONS:** A leaflet with correct inhalation technique.

**PRS69**

**IDENTIFICATION OF DRY POWDER INHALER ATTRIBUTES, AND THEIR RELATIVE IMPORTANCE TO ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS: TO INFORM A DISCRETE CHOICE EXPERIMENT**

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**Objective:** To identify characteristics of dry powder inhalers (DPIs) considered important by asthma and chronic obstructive pulmonary disease (COPD) patients, in order to determine the attributes and attribute-levels for a discrete choice experiment. **METHODS:** Qualitative data was collected from a literature review performed to determine which inhaler attributes impact inhaler satisfaction and adherence among asthma and COPD patients using DPIs. Focus groups with asthma and COPD patients were conducted. **RESULTS:** Most important attributes and attribute-levels for a discrete choice experiment were: overall ease-of-use, low inspiratory flow requirements, presence of a dosing marker, and the mean % predicted DLCO was 35±16. Patients were treated with oral steroids (22.1%, as monotherapy in 7.1%); N-acetylcysteine (34.8%), pirfenidone (47.2%), and long-term O2 therapy (34.4%). The physician rated the disease in 35.6% as stable, 42.4% as slowly progressing and in 11.9% as rapidly one. In four patients described their current state of health as at least good, and every fifth as poor. The mean EQ-5D TTO score was 0.80±0.2 45% of the patients showed depressed symptoms based on the WHO-5. The mean SGRQ sum score was 47.5±10 describing difficulties with breathing in the previous 3 months. Higher EQ-5D TTO scores were significantly associated with a lower number of comorbid diseases (r<0.31), higher 6-minute walk distance (r<0.20), higher FVC % predicted (r<0.07), less depression (r<0.66) and more use of rescue medication. **CONCLUSIONS:** The French idiopathic pulmonary fibrosis registry had a more severe disease, a higher symptom burden and more compromised quality of life compared to recent randomised controlled trials.

**PRS71**

**TRANSLATION AND LINGUISTIC VALIDATION OF TWO COPD SYMPTOM DIARIES (NISCI and EMSCI) FOR USE IN 14 COUNTRIES**


**OBJECTIVES:** The Nighttime Symptoms of COPD Instrument (NISCI) and Early Morning Symptoms of COPD Instrument (EMSCI) were developed to support treatment benefit endpoints in global clinical trials. Translations that were conceptually equivalent to the English source version and easily understood by the target country population were required. The purpose of this study was to translate and assess conceptual equivalence of the NISCI and EMSCI for use in 14 countries: Austria, Bulgaria, Canada, Czech Republic, France, Germany, Hungary, Italy, Lithuania, The Netherlands, Poland, South Africa, Spain, and United Kingdom. **METHODS:** The NISCI and EMSCI were translated following ISPOR guidelines for linguistic validation of PRO measures (Wild et al., 2005) using the universal approach discussed in the recent e-PRO task force report (Wild et al., 2009). The universal English, Spanish and French versions were previously translated (Erennec et al., 2012). For the remaining languages, two forward translations by native translators, reconciliation of the forwards, one back-translation by an English-speaking fluent in the target language, and reciprocal translation by a native English speaker were conducted for both measures. Harmonization was performed to ensure conceptual equivalence across languages. Interviews were conducted with five native-speaking COPD patients from each country to explore harmonization. Instruments were analyzed to assess linguistic and cultural validity in each language and confirm conceptual equivalence. **RESULTS:** Mean age of the sample (N=80) was 60 years (range 41-83) and 54% were male. The translations were well understood and considered relevant, with no necessary only minor modifications. The French translation was compared to the universal French (chest congestion), Hungarian (wheezing, chest congestion), Italian (chest congestion, moderately), and Lithuanian (interviews, wheezing, shortness of breath, experienced) following the patient interviews. **CONCLUSIONS:** All translated versions of the NISCI and EMSCI in this study were found to be conceptually equivalent and acceptable for use in the 14 evaluated countries.

**PRS72**

**TESTING E-PRO DEVICE USABILITY DURING THE TRANSLATION PROCESS: A CASE STUDY OF THE EXACT IN 7 COUNTRIES**

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**OBJECTIVES:** Usability testing of electronic Patient-Reported Outcomes (ePRO) instruments is typically conducted during instrument development, in the language/country of origin. It has been suggested that usability testing also be performed during the translation process. It is unclear whether this additional step is necessary. In this study, usability testing was conducted as part of the linguistic validation process in English (UK), German (Europe), French (France), Russian (Russia), and Spanish (Universal, tested in Chile, Spain, and US) for the Exacerbations of Chronic obstructive pulmonary disease Tool (EXACT), an e-PRO developed and tested in English (UK). The purpose of this process followed ISPOR guidelines (Wild et al., 2005). Cognitive interviews were conducted with 2-3 native-speaking COPD respondents per language/country combination in 2008. Subjects completed the EXACT in paper–pen screenshot format and were interviewed after the translation process. Subsequently they were instructed to use a PDA (Tungsten E2; CRF, Inc.) to complete the first 5 EXACT items and were interviewed regarding device usability. Interviewers rated subjects’ ability to use the device. **RESULTS:** Subjects (N=20) were 65-94 years, 60% male, and 60% with secondary education or less. Most (n=18) had not used a PDA previously; all (n=10) reported
it was easy to use, the screens were easy to read, and that they could sign on and move through the questions with no difficulty. Subjects from the Spanish-speaking countries had the lowest reported difficulty turning the device on, with higher levels of difficulty observed by the interviewers in China, who reported “somewhat” for two of the three respondents. Interviewers observed that the majority (n = 15) could “easily” or “very easily” use the device. In general, the device was a consistent ease-of-use findings in these diverse, device naive subjects across 7 countries and the emphasis on subject training in clinical trials, it was determined that usability testing with future 2.0 version was unnecessary.

**PR573**

**A COMPARISON OF THE RELIABILITY AND VALIDITY OF THE FOUR-ITEM AND SIX-ITEM NSIC SYMPTOM SUMMARY SCORES**

**Objectives:** The Nighttime Symptoms of COPD instrument (NSiSC), developed through qualitative research with patients, includes six symptom items: coughing, wheezing, shortness of breath, difficulty bringing up phlegm, chest congestion, and chest pain. A symptom severity score is computed based on these items. In situations where patient burden is a major consideration, a smaller set of items may be preferable. Clinicians identified coughing, wheezing, shortness of breath, and difficulty bringing up phlegm as the most relevant for COPD patients. Exploratory psychometric analyses were conducted for the symptom summary score based on these four items compared with all six items. **Methods:** Psychometric properties of the four-item versus six-item symptom summary scores were compared relative to the symptom summary score derived from a random sample of clinical trial data. **Results:** Four-item symptom summary scores were found to have a similar psychometric properties to the six-item symptom summary score. **Conclusions:** The four-item versus six-item symptom summary scores could “easily” or “very easily” use the device.

**PR587**

**HEALTH RELATED QUALITY OF LIFE AND HEALTH CARE UTILIZATION IN PRIMARY CARE PATIENTS WITH MODERATE/PERSISTENT SEVERE ASTHMA**

**Objectives:** The aim of this study is to evaluate the health related quality of life (HRQoL) and health care utilization in primary care (PC) patients with asthma and compare HRQoL with the general population. **Methods:** In the study, we compared HRQoL and health care utilization from a cohort of 65 patients over 6 months. The mean EQ-5D analogue scale score of the studied population was found to be 0.83 (SD 0.15). The Chi square test showed the association between smoking with family history of smoking, alcohol consumption and social consumption (p < 0.001 and 0.05 respectively). Mann Whitney U test showed as significant difference in the VAS scores among smokers and non-smokers (p < 0.05).

**Conclusions:** Health Related Quality of Life is severely compromised by smoking, hence there is an urgent need to create awareness among young students.

**PR588**

**HEALTH-RELATED QUALITY OF LIFE AND HEALTH RESOURCES CONSUMPTION IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS**

**Objectives:** Idiopathic pulmonary fibrosis (IPF) is a progressive disease characterized by declining lung function, leading to debilitating limitations on activity which affects the patient’s quality of life (QoL). However, HRQoL data in IPF population are limited. The primary objective was to evaluate HRQoL in IPF using measures from the Patient Reported Outcomes Measurement Information System (PROMIS). The secondary objective was to examine the association between key symptoms and HRQoL. **Methods:** IPF patients were recruited from University of Malaga, Malaga, Spain, 2Respiratory group of SEMERGEN, Córdoba, Spain. **Results:** The 25% survey participants showed worse PROMIS-29 scores than the general population in all measured domains (mean value: anxiety=63.9, depression=61.9, fatigue=60.1; pain=62.6; sleep disturbance=55.8; physical function=56.2; social role=42.2). Dyspnea severity was associated with worse mean PROMIS-29 scores (p < 0.05). PROMIS-Dyspnea (mean=58.7) and Functional Limitations Due to Dyspnea (mean=58.4) were worse than the COPD reference population. Cough severity was associated with worse HRQoL measured by ATIQ-IF. Reliability of PROMIS-29 scores exceeded 0.65 and were moderately correlated with measures of similar constructs. A limitation of the study is that data drawn from a sample from advocacy organizations might not be generalizable to the entire IPF population. **Conclusions:** Patients with IPF report substantial deficits in HRQoL, particularly with respect to physical function, anxiety, pain, depression and fatigue. Patients suffering from dyspnea and cough had poorer HRQoL. These deficits should be monitored in clinical practice and evaluated in investigational trials aiming to improve the HRQoL of IPF patients.

**PR574**

**HEALTH-RELATED QUALITY OF LIFE (HRQL) IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS**

**Objectives:** Idiopathic pulmonary fibrosis (IPF) is a progressive disease characterized by declining lung function, leading to debilitating limitations on activity which affects the patient’s quality of life (QoL). However, HRQoL data in IPF population are limited. The primary objective was to evaluate HRQoL in IPF using measures from the Patient Reported Outcomes Measurement Information System (PROMIS). The secondary objective was to examine the association between key symptoms and HRQoL. **Methods:** IPF patients were recruited from University of Malaga, Malaga, Spain, 2Respiratory group of SEMERGEN, Córdoba, Spain. **Results:** The 25% survey participants showed worse PROMIS-29 scores than the general population in all measured domains (mean value: anxiety=63.9, depression=61.9, fatigue=60.1; pain=62.6; sleep disturbance=55.8; physical function=56.2; social role=42.2). Dyspnea severity was associated with worse mean PROMIS-29 scores (p < 0.05). PROMIS-Dyspnea (mean=58.7) and Functional Limitations Due to Dyspnea (mean=58.4) were worse than the COPD reference population. Cough severity was associated with worse HRQoL measured by ATIQ-IF. Reliability of PROMIS-29 scores exceeded 0.65 and were moderately correlated with measures of similar constructs. A limitation of the study is that data drawn from a sample from advocacy organizations might not be generalizable to the entire IPF population. **Conclusions:** Patients with IPF report substantial deficits in HRQoL, particularly with respect to physical function, anxiety, pain, depression and fatigue. Patients suffering from dyspnea and cough had poorer HRQoL. These deficits should be monitored in clinical practice and evaluated in investigational trials aiming to improve the HRQoL of IPF patients.

**PR576**

**HEALTH RELATED QUALITY OF LIFE AMONG YOUNG SMOKERS**

**Objectives:** As young students are more prone to smoking and associated dangers, the study also evaluated utility of various socio-demographic and clinical factors that potentially related with the mentioned respiratory diseases prevalence, as sex, smoking habits were analyzed. Four groups were compared: 1) asthma patients, 2) COPD patients, 3) patients with other chronic conditions, and 4) global Spanish population. **Results:** Data from 21,007 adults was recorded. Prevalence of asthma was slightly above COPD (6.5% vs 4.7%), and 47.2% were suffering from chronic obstructive pulmonary disease. Asthma patients used more bronchodilators (β2 vs β1 as an average, respectively). Concerning EQ-5D results, the dimensions mainly affected either in COPD or asthma were, respectively, pain/discomfort (53.7% / 37.4%) and mobility (42% / 37.4%), usual activities (34% / 21.8%), and depression/anxiety (32.4% / 25.4%). Based on the EQ-5D questionnaire, the QALYs calculation was 0.75% for COPD and 0.90 for asthma patients, the latter results were similar to the other chronic conditions and to the global population. Health resources in COPD patients were significantly higher than in the other three groups analyzed. Health related quality of life (HRQoL) is also associated with a higher health resources consumption, which implies a relevant impact on the Spanish National Health System.
are directly and indirectly linked with HRQoL of TB patients. **METHODS:** A prospective study was conducted among 400 TB outpatients who were admitted as a case report in a tuberculosis hospital in one of the provinces of Western Pakistan, the Punjab. Data was collected by using WHOQL-BREF questionnaire (Greek version, pretested for reliability and validity) by means of face-to-face interviews and where possible by gender-focused group sessions. In addition, facilitators used few open-ended questions in order to get patients' demographic and socioeconomic data. Participants were also asked to share their personal experiences of being diagnosed and treated with TB and what impact it had on their quality of life. All observed changes and data were collated and analyzed descriptively and statistically.

**RESULTS:** The overall Cronbach's alpha coefficient of the revalidated WHOQL-BREF questionnaire was 0.785. The confirmatory factor analysis also provided an acceptable fit to a four-factor model in the studied sample. The scores for negative feelings, blue mood, depression, and personal relationships and sex life were significantly different in the psychological health and social relations domains. Age, gender, and physical exercise were also significantly associated with the WHO-QoL. This study showed that although participants had significant changes in the health status of their patients and were a significant problem. The main users of the NCS medication between 6 months (range <24 hours-2 years) for the SS for was a return to their original NCS medication (n=11). Although most found getting their SS straightforward, this required at least two HCIs for half the sample, and it took up to three months to achieve. Most expected symptoms to improve following the SS but nine patients still had sub-optimal ACT scores. Lasting impacts included damaged relationships with HCPs, stronger views about NCS and concern about NCS medicines. **CONCLUSIONS:** The RQLQ is an effective tool for measuring changes that can have lasting impacts. It is important to note that NCS can incur costs associated with rejection of medicines and additional consultations, thus negating any attempt at cost saving.

**RESPIRATORY-RELATED DISORDERS – Health Care Use & Policy Studies**

**PRSS2**

**EVALUATION OF SELECTED KENDRGS IN GREEK PUBLIC HOSPITALS: THE LIMITS WHICH THEY REFLECT ACTUAL EXPENDITURE AND AVERAGE LENGTH OF STAY**


**OBJECTIVES:** To test the limits which the Quality Life (QoL) and cost per KENDRG were derived from Gazette 946/27/03/2012. Continuous variables did not follow normal distribution, so non-parametric methods (Spearman's correlation coefficient, Kruskal-Wallis test and Mann-Whitney test) were used. A two sided p-value ≤0.05 was considered statistically significant. **RESULTS:** Failure to inform and involve patients in medication changes can have lasting impacts. It is important to note that NCS can incur costs associated with rejection of medicines and additional consultations, thus negating any attempt at cost saving.

**Conclusions:**

**PRSS3**

**PATTERNS OF ASTHMA TREATMENT UTILIZATION IN NEWLY DIAGNOSED ELDERLY PATIENTS INCONSISTENT WITH ASTHMA MANAGEMENT GUIDELINES**

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**OBJECTIVES:** Asthma is under-diagnosed and under-treated in elderly, and utilization of asthma medications in this population is not well characterized. This study describes utilization patterns of asthma medications in newly diagnosed ≥50 patients. **METHODS:** Medicare enrollees are followed for 12 months after first asthma diagnosis between Q1 2004–Q3 2012 (ICD-9-CM code: 493). Treatment pattern analysis was applied to initiators of asthma medications. Patients with ≥1 prescription of second-line therapy following exposure to first-line therapy are considered therapy switchers or augmenters. Patients with history of chronic obstructive pulmonary disease are excluded (ICD-9-CM codes: 490, 491, 492, 494, 495 & 496). **RESULTS:** Among 126,277 patients with asthma, 62% received asthma therapy within 12 months of asthma diagnosis (70% women, median age 70 years). 319 (1.3%) continued therapy with one drug class (first-line therapy), 13,940 (58%) increased treatment to two drug classes. 37,440 (15%) received one drug class (second-line therapy), and 6,293 (2.6%) added second-line therapy (augmented). About 34% of patients initiated therapy with inhaled short-acting beta-agonists (SABA), majority of them either discontinued SABA or added a controller medication. 19% of patients discontinued SABA and 12% switched to another asthma controller. Among con-

**Conclusions:** The introduction of KENDRGs was a useful first step to modernize the hospital reimbursement system. However, further revisions are required in order for KENDRGs to become more effective.
inflammatory formulations were discontinued during 12 months after asthma diagnosis. CONCLUSIONS: Asthma treatment utilization patterns reflect poor asthma control among newly diagnosed elderly patients, and initiation of anti-inflammatory treatment after asthma diagnosis appears to be inconsistent with asthma management guidelines.

**PRS84**

**DOCTORS’ FAILURE IN OBSERVANCE OF THE COPD MANAGEMENT GUIDELINES: CASE OF THE CZECH REPUBLIC**

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OBJECTIVES: The primary objective of this study was to examine the accuracy of the GOLD 2011 strategy implementation among the Czech respiratory specialists, esp. with respect to the patients’ classification. The secondary objective was to explore the effect that classification has on inappropiate use of inhaler-therapy (ICS).

METHODS: Multicentre cross-sectional study was conducted among COPD specialists, consisting of general questionnaire and patient-specific forms. A subjective classification into the GOLD 2011 groups as practiced by the health care professionals was examined and then compared with the objective classification achieved by rigorous software-computed classification. Adequacy of the ICS prescription was evaluated with regard to the subjective classification.

RESULTS: GOLD 2011 were claimed to be the leading guidelines for 143 out of 144 specialists involved, often accompanied by CPPS guidelines (83.3%) and the ACP/ACCP/ATS/ERS standards (50.7%). Based on 1355 patient forms, a discrepancy between the subjective and objective classification was found in 12.8% of cases. The most common reason for inaccuracies was the omission of the data on the under-estimation in 23.9% of cases and over-estimation in 8.9% of the examined patients’ records. Specialists seeing more than 120 patients per month were most likely to misclassify their condition, i.e. in 36.7% of all seen patients. In general, whilst examining the subjectively-driven ICS prescription, it was found that 19.5% of patients received ICS incorrectly, while in 12.2% of cases the ICS was erroneously omitted. Furthermore, with consideration to the objectively computed classification, it was discovered that 15.4% received ICS unnecessarily, whereas in 15.8% of cases the ICS was not prescribed though, in fact, it would be adequate seeing the patient’s condition. Patients failed in correct prescription more frequently than men, predominantly by describing ICS.

CONCLUSIONS: Despite high awareness of the GOLD 2011 guidelines, its implementation is insufficient. Czech specialists tend to either under-classify or overuse the ICS.

**PRS85**

**SOCIAL MEDIA MEETS POPULATION HEALTH: A SENTIMENT AND DEMOGRAPHIC ANALYSIS OF TOBACCO AND E-CIGARETTE USE ACROSS THE TWITTERSPHERE**

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OBJECTIVES: Twitter, a popular social media outlet, has become a useful tool for the study of social behavior through user interactions called tweets. The location, time, and content of tweets provide an invaluable social and demographic information for an applied comparison of social behaviors across the world. Our goal is to determine the density and sentiment surrounding tobacco and e-cigarette related keywords and use this information for an applied comparison of social behaviors across the world. Our objective was to explore what effect a misclassification has on inadequate use of inhaler-therapy (ICS).

METHODS: Multi-centre cross-sectional study was conducted among COPD specialists, consisting of general questionnaire and patient-specific forms. A subjective classification into the GOLD 2011 groups as practiced by the health care professionals was examined and then compared with the objective classification achieved by rigorous software-computed classification. Adequacy of the ICS prescription was evaluated with regard to the subjective classification.

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CONCLUSIONS: Despite high awareness of the GOLD 2011 guidelines, its implementation is insufficient. Czech specialists tend to either under-classify or overuse the ICS.

**PRS87**

**MONTE-CARLO SIMULATION TO ESTIMATE THE HEALTH CARE COSTS AVOIDED WITH FLUTICASONE FUROATE/VILANTEROL DUE TO EXACERBATION RATE REDUCTION IN SPANISH COPD PATIENTS**


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OBJECTIVES: Exacerbations are considered one of the main drivers of costs of Chronic Obstructive Pulmonary Disease (COPD). In moderate to severe COPD patients with a history of exacerbations, the addition of an inhaled corticosteroid (ICS) to a long-acting agonist (LABA) has been associated with a decreased rate of exacerbations, but high cost. This study aims to evaluate the health care costs that the addition of the ICS Fluticasone Furoate (FF) to the LABA vilanterol (VI) could avoid versus LABA monotherapy in Spanish patients due to the reduction of exacerbations. METHODS: The number of moderate to severe COPD patients >40 years old with a history of exacerbation potentially treated with FF+VI was estimated from Spanish prevalence data. 1-year Monte Carlo simulation (random simulations where the parameters used in the simulations were the yearly rate of moderate-severe exacerbations with FF+VI and VI obtained from pooled-analysis of two head-to-head clinical trials (NCT01017752 and NCT01017752) and the number of moderate and severe exacerbations and the health care costs avoided with FF+VI versus VI from the National Health System (NHS) perspective. Monte Carlo simulation was chosen as it allows simulating the effect of changes in different parameters from clinical or real-life distributions. Parameters used in the simulations were the yearly rate of moderate-severe exacerbations with FF+VI and VI obtained from pooled-analysis of two head-to-head clinical trials (NCT01017752 and NCT01017752) and the number of moderate and severe exacerbations. RESULTS: Adherence was defined a using minimal 80% of the in guidelines recommended adherence for each group. Pharmacotherapy with application of preparations-analogs to levofloxacin, is costly, as 32.7% of preparations of this group are preparations of low availability in the Spanish NHS. Based on 1355 patient forms, a discrepancy between the subjective and objective classification into the GOLD 2011 groups as practiced by the health care professionals was examined and then compared with the objective classification achieved by rigorous software-computed classification. Adequacy of the ICS prescription was evaluated with regard to the subjective classification.

RESULTS: GOLD 2011 were claimed to be the leading guidelines for 143 out of 144 specialists involved, often accompanied by CPPS guidelines (83.3%) and the ACP/ACCP/ATS/ERS standards (50.7%). Based on 1355 patient forms, a discrepancy between the subjective and objective classification was found in 12.8% of cases. The most common reason for inaccuracies was the omission of the data on the under-estimation in 23.9% of cases and over-estimation in 8.9% of the examined patients’ records. Specialists seeing more than 120 patients per month were most likely to misclassify their condition, i.e. in 36.7% of all seen patients. In general, whilst examining the subjectively-driven ICS prescription, it was found that 19.5% of patients received ICS incorrectly, while in 12.2% of cases the ICS was erroneously omitted. Furthermore, with consideration to the objectively computed classification, it was discovered that 15.4% received ICS unnecessarily, whereas in 15.8% of cases the ICS was not prescribed though, in fact, it would be adequate seeing the patient’s condition. Patients failed in correct prescription more frequently than men, predominantly by describing ICS.

CONCLUSIONS: Despite high awareness of the GOLD 2011 guidelines, its implementation is insufficient. Czech specialists tend to either under-classify or overuse the ICS.

**PRS88**

**DETERMINATION OF AVAILABILITY OF ANTIMICROBIAL PREPARATIONS FOR TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN UKRAINE**

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OBJECTIVES: Data of British specialists show, that 5-11 out of 1000 adults have community-acquired pneumonia (CAP) every year, which is 5-12% of all cases of lower respiratory tract infections. The rate of CAP in elderly over three in the structure of total respiratory organs disease rate in Ukraine within years 2007-2011. METHODS: The data of use of antimicrobial preparations (AP): cefepime (cefepraxin), penicillins (amoxicillin and enzyme inhibitor), macrolides (azithromycin) and fluoroquinolones (ciprofloxacin, levofloxacin) for CAP treatment in Kharkiv hospital were used. Analysis of affordability as of index of payment capacity (Ca. s) of trade names (TNS) provided in pharmaceutical market of Ukraine on indicated INN has been carried to determine the availability of such preparations for wider population of Ukraine. RESULTS: Results of the AP affordability analysis made in five groups of INN, showed, that the ratio of therapy of high, middle and low availability for each AP group is different, but in all pharmaceutical groups except for ceftaxamine group, highly affordable therapy prevail. Percentage of highly affordable preparations in the studied groups of INN is: azithromycin (92.2%) > ciprofloxacin (74.3%) > amoxicillin and enzyme inhibitor (67.5%) > cefazolin (49.02%) > levofloxacin (46.94%). As of preparations of middle availability, costing 5% - 15% of average monthly salary, ceftriaxone preparations are most (49.02%), azithromycin preparations are least (6.49%). There are no low availability preparations in ciprofloxacin fluoroquinolone group. Cephalexins and macrolides group preparations have one AP of low availability. Pharmacotherapy with application of preparations-analogous to levofloxacin, is costly, as 32.7% of preparations of this group are preparations of low availability in the Spanish NHS. BASELINE: The treatment costs are higher during reimbursement. Increasing the awareness of health care providers on adherence issues is warranted.

**PRS89**

**HOW MUCH THE APPROPRIATE TOBACCO PRICE WOULD BE? A DISCRETE CHOICE EXPERIMENT OF GENERAL PUBLIC IN JAPAN**

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OBJECTIVES: Though tobacco price increases are effective in reducing tobacco consumption and prevalence of smoking, tobacco tax in Japan is still lower than those in other developed countries. General public, particularly non-smokers, may think that

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RESULTS: We found that the smoking fraction was lower in the current smokers compared to the former smokers and the never smokers. The average smoking fraction was 42.5% in current smokers, 56.8% in former smokers, and 60.3% in never smokers. The smoking fraction was significantly different between the three groups (p < 0.001). The average smoking duration was 15.6 years in current smokers, 19.8 years in former smokers, and 23.1 years in never smokers. The smoking duration was also significantly different between the three groups (p < 0.001). The average number of cigarettes smoked per day was 15.3 in current smokers, 10.9 in former smokers, and 9.1 in never smokers. The number of cigarettes smoked per day was significantly different between the three groups (p < 0.001).

CONCLUSIONS: The smoking fraction, smoking duration, and number of cigarettes smoked per day were significantly different between the three groups. The current smokers had a lower smoking fraction and a shorter smoking duration compared to the former smokers and the never smokers. The current smokers also had a lower number of cigarettes smoked per day compared to the former smokers and the never smokers. These findings suggest that the current smokers were more likely to quit smoking compared to the former smokers and the never smokers. Therefore, the current smokers may be a target group for smoking cessation interventions. Additionally, the current smokers may be at a higher risk for nicotine addiction compared to the former smokers and the never smokers. Therefore, the current smokers may require more intensive smoking cessation interventions.

PS35

PS35 DEDUCTIBLE COST-EFFECTIVENESS OF OZALIZUMAB IN CHRONIC IDIOPATHIC URticaria: EXPERIENCE FROM A TURKISH HEALTH CARE PERSPECTIVE

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1University of Ankara, Ankara, Turkey, 2Gazi University, Ankara, Turkey, 3Siyami Ersek Thoracic and Cardiovascular Surgery Hospital, Ankara, Turkey, 4Malazgirt Hospital, Sivas, Turkey

OBJECTIVES: The aim of this study was to evaluate the cost-effectiveness of ozalizumab treatment from a Turkish health care payer perspective.

METHODS: A Retrospective cohort study was conducted on 50 patients with chronic idiopathic urticaria who received ozalizumab treatment. The effectiveness of the treatment was measured using the UAS7 score at baseline, 12 weeks, and 24 weeks. The costs were calculated based on the Turkish Health Care System tariffs. The incremental cost-effectiveness ratio (ICER) was calculated to compare the cost-effectiveness of ozalizumab treatment with the standard care.

RESULTS: The mean cost per patient was 59,625 Turkish Liras at baseline, 133,403 Turkish Liras at 12 weeks, and 153,600 Turkish Liras at 24 weeks. The mean UAS7 score was 16.2 at baseline, 6.3 at 12 weeks, and 5.1 at 24 weeks. The ICER was 8,547 Turkish Liras per UAS7 score improvement. The results showed that ozalizumab treatment was cost-effective compared to the standard care.

CONCLUSIONS: Ozalizumab treatment was cost-effective compared to the standard care in the treatment of chronic idiopathic urticaria from a Turkish health care payer perspective. Further studies are needed to confirm these findings.

PS36

PS36 COST-EFFECTIVENESS OF OMALIZUMAB IN CHRONIC IDIOPATHIC URTICARIA: A NETWORK META-ANALYSIS

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1Medical University of Innsbruck, Innsbruck, Austria, 2University of Bielefeld, Bielefeld, Germany, 3Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: To evaluate the cost-effectiveness of omalizumab in chronic idiopathic urticaria from a Swiss health care payer perspective.

METHODS: A network meta-analysis was conducted using the SciELO database. The cost-effectiveness was assessed using the incremental cost-effectiveness ratio (ICER). The results were compared with the standard care.

RESULTS: The mean cost per patient was 5,432 Swiss Francs at baseline, 9,148 Swiss Francs at 12 weeks, and 12,136 Swiss Francs at 24 weeks. The mean UAS7 score was 15.7 at baseline, 6.2 at 12 weeks, and 5.1 at 24 weeks. The ICER was 2,715 Swiss Francs per UAS7 score improvement. The results showed that omalizumab treatment was cost-effective compared to the standard care.

CONCLUSIONS: Omalizumab treatment was cost-effective compared to the standard care in the treatment of chronic idiopathic urticaria from a Swiss health care payer perspective.

S10

S10 COST-EFFECTIVENESS OF OMALIZUMAB IN CHRONIC IDIOPATHIC URTICARIA: A NETWORK META-ANALYSIS

Dreisdeil M., Otto C., Furrer C., Held P., Kopp C., Spinas C.

1Medical University of Innsbruck, Innsbruck, Austria, 2University of Bielefeld, Bielefeld, Germany, 3Novartis Pharma AG, Basel, Switzerland

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CONCLUSIONS: Omalizumab treatment was cost-effective compared to the standard care in the treatment of chronic idiopathic urticaria from a Swiss health care payer perspective.
TREATMENT Of VENOUS LEG ULCERS IN OUTPATIENT CARE SETTINGS

The majority of patients was male (50.5%), Caucasian (74.1%), and

A605

PHARMACEUTICALS OF CELLULAR/TISSUE DERIVED PRODUCTS FOR THE TREATMENT OF VULNERABLE ULcers (VULNERABLE ULcers) or VULNERABLE TISSUES

OBJECTIVES: To evaluate the safety and efficacy of the study product in the treatment of VLU.

METHODS: Open-label, single-arm, multicenter clinical trial in 102 outpatient wound centers. Patients ≥ 18 years of age with VLU were enrolled regardless of disease activity

CONCLUSIONS: The incidence of both primary and secondary endpoints were lower than those not in full health or better vision function at baseline. In addition, the value of health

SENSORY SYSTEMS DISORDERS – Cost Studies

PSS10

A US HOSPITAL ECONOMIC IMPACT MODEL FOR ORITAVANCIN IN ABSSSI PATIENTS WITH RISK OF MRSA INFECTIONS

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1ICON plc, Cambridge, MA, USA, 2The Medicines Company, Parsippany, NJ, USA

OBJECTIVES: To estimate the acute bacterial skin and skin structure infections (ABSSSI) treatment cost for about 10% of hospital admisions in the US. Analysys of hosptial claims indicate that 74% of ABSSSI admissions involve empiric treatment with methicillin-resistant Staphylococcus aureus (MRSA) active antibiotics. Hospitalization costs could be reduced if moderate-severe ABSSSI patients were treated to a greater extent in the observational unit followed by discharge to outpatient parenteral antibiotic therapy (OPAT). Oritavancin is a novel single-dose regimen, intravenous lipoglycopeptide antibiotic for ABSSSI caused by gram-positive bacteria, including MRSA. The aim of this study was to gain experience in the clinical use of oritavancin for ABSSSI patients at risk of MRSA from a US hospital perspective.

METHODS: A decision analytic model based on current clinical practice was developed to estimate the economic value of reducing hospital resource use by using oritavancin. Utilization of antibiotics was informed by analysis of the Premier hospital database. Demographic and clinical data were derived from a targeted literature review, observation, laboratory, administration costs were from Medicare National Lists. The aim of this study was to gain experience in the clinical use of oritavancin for ABSSSI patients at risk of MRSA from a US hospital perspective.

CONCLUSIONS: Using oritavancin in moderate-severe ABSSSI patients, including those at risk of MRSA, is estimated to deliver an estimated cost reduction of $2,752/patient by shifting patient care to the OPAT setting, and decreasing resource utilization.

PSS11

ECONOMIC IMPACT OF VISUAL IMPAIRMENT: A PILOT STUDY IN SINGAPORE

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1National University of Singapore, Singapore, 2Saw Swee Hock School of Public Health, National University of Singapore, Singapore, 3University of Melbourne, Melbourne, Australia, 4Singapore National Eye Centre, Singapore

OBJECTIVES: To examine the economic impact and independent determinants of visual impairment (VI) in Singapore. METHODS: 100 patients with VI associated with the most common eye diseases were recruited from the Singapore National Eye Centre. VI was classified as mild and moderate/severe VI based on the presenting visual acuity (VA) in the better-seeing eye. Medical costs (MC) and loss of productivity (LP) in the patients and their families were estimated based on the center's billing data and self-reported data, respectively. LP was calculated for working patients based on absenteeism due to VI. Linear regression models were used to assess the associations between VI (EQ-5D), and visual acuity (VF-14) with EQ-5D and VF-14.

RESULTS: The median (range) age of participants was 73.0 years old (47.0-92.0). The proportion of male was 48.0% and the median (range) presenting visual acuity was 0.00 (0.00-0.20). The proportion of participants with one or more co-conditions was 61.0% (2.8%). A 0.13-$S53.59K and $50 ($S0-$57.62K) per person, respectively. The yearly MC for those with mild VI ($S35.00K) was significantly lower than those with moderate/severe VI ($S5.21K) (<P<0.0001). The yearly MC in patients reporting full health or better vision was lower than that in patients in full health or better vision (MC=$S53.59K for full health and better vision vs MC=$S5.21K for full health or better vision). This difference was not in full health or better vision (Mc for patients in full health=$S2.96K; MC for patients not in full health=$S55.19K; P<0.0001). After adjusting for socio-demographic characteristics, the association between MC and VI, EQ-5D and VF-14 remained the same. LP had a similar association with EQ-5D and VF-14 with or without adjustment, however, LP
decreased with VI severity (the adjusted difference in LP between participants with mild/moderate/severe VI = $50.22, P = 0.0486). **CONCLUSIONS:** Visual impairment poses substantial economic burden on individuals and families in Singapore. The economic burden of VI is mainly medical costs. Self-reported health problems seem to be better predictors of costs of VI than clinical measures.

**PSS13 COSTS OF BURN CARE: A SYSTEMATIC REVIEW**
Hop M1, Polinder S2, Middelkoop E3, van Baar T4
1Association of Dutch Burn Centres, Rotterdam, The Netherlands, 2Erasmus MC, Rotterdam, The Netherlands, 3Association of Dutch Burn Centres, Beverwijk, The Netherlands

**OBJECTIVES:** Burn care is traditionally considered expensive care. However, detailed information about the costs of burn care is scarce, despite the need for better information and the enhanced focus on health care cost control. In this study, economic literature on burn care was systematically reviewed to examine the problem of burn care costs and to determine the resources and costs related to the diagnosis and treatment of patients with CIU, and to estimate the annual economic burden to the Social Security Institution (SGK). **METHODS:** Delphi technique was used to determine the amount of costs for different stages of CIU defined as mild or moderate to severe based on physicians clinical assessment. The Delphi method solicits the opinion of an expert panel through a carefully designed questionnaire which in this case included questions on: epidemiology, diagnosis, treatment of symptoms and angioedema, adverse events, follow-up visits, hospital and emergency service admissions. The responses were analysed and discussed in a face to face meeting followed by consensus building steps. Unit costs of resources used in outpatient clinics were obtained from SGK’s Reimbursement Guideline-List of Procedure Fees Per Service. **RESULTS:** Hospitalizations, emergency admissions, outpatient visits and treatments, are the key components of the burden of CIU. The annual economic burden calculated to be 275.36 Turkish Liras (TL) for mild CIU, 1,322.61 TL for moderate CIU and 2,478.75 TL for severe CIU. The total annual cost of CIU to SGK is estimated to be 262 million TL. This is the first study that aims to estimate the resource utilisation and cost burden of CIU in Turkey by using the Delphi technique. Cost effective treatment of CIU is an unmet need given the heavy burden to SGK identified by the Delphi Panel.

**PSS17 THE DIRECT AND INDIRECT COSTS OF WET AGE-RELATED MACULAR DEGENERATION (WAMD). A SYSTEMATIC LITERATURE REVIEW IN GREECE**
Geltina M1, Karagiannis D2, Pantelopoulou G2, Hatziouli M3, Kousoulakou H4
1University of Peloponnese, Corinth, Greece, 2Eye Hospital of Athens, Athens, Greece, 3Novartis Hellas, Athens, Greece, 4Novartis Hellas, Athens, Greece

**OBJECTIVES:** Treatment delays in patients with WAMD and DME are very important since they are associated with disease progression. This is the first study in Greece to highlight patient’s access delays’ treatment and to estimate the burden of delays in the expert panel with WAMD and DME. **METHODS:** The Delphi technique was used to determine the amount of costs for different stages of CIU defined as mild or moderate to severe based on physicians clinical assessment. The Delphi method solicits the opinion of an expert panel through a carefully designed questionnaire which in this case included questions on: epidemiology, diagnosis, treatment of symptoms and angioedema, adverse events, follow-up visits, hospital and emergency service admissions. The responses were analysed and discussed in a face to face meeting followed by consensus building steps. Unit costs of resources used in outpatient clinics were obtained from SGK’s Reimbursement Guideline-List of Procedure Fees Per Service. **RESULTS:** Hospitalizations, emergency admissions, outpatient visits and treatments, are the key components of the burden of CIU. The annual economic burden calculated to be 275.36 Turkish Liras (TL) for mild CIU, 1,322.61 TL for moderate CIU and 2,478.75 TL for severe CIU. The total annual cost of CIU to SGK is estimated to be 262 million TL. This is the first study that aims to estimate the resource utilisation and cost burden of CIU in Turkey by using the Delphi technique. Cost effective treatment of CIU is an unmet need given the heavy burden to SGK identified by the Delphi Panel.

**PSS11 THE ECONOMIC BURDEN OF EYE DISEASE IN DIABETIC PATIENTS: LITERATURE REVIEW**
Riera M1, Ducrós M1, Paz S2, Cornella M1, Lázar L2
1Novartis Farmaçonica S.A., Barcelona, Spain, 2Outcomes 10, Castellón, Spain, 3Outcomes 10, Castellón, Spain

**OBJECTIVES:** To appraise the literature referred to direct and indirect costs of pso-

tinopathy, macular edema, blindness and low vision. Posterior filters included

**RESULTS:**

**PSS15 ECONOMIC BURDEN OF BURN INJURIES IN THE NETHERLANDS**
Hop M1, Wijnen BF2, Nieuwenhuis MJ3, Dokter J4, Middelkoop E5, Polinder S6, van Baar TM7
1Association of Dutch Burn Centres, Rotterdam, The Netherlands, 2Maastricht University, Maastricht, The Netherlands, 3Association of Dutch Burn Centres, Groningen, The Netherlands, 4Association of Dutch Burn Centres, Beverwijk, The Netherlands, 5Erasmus MC, Rotterdam, The Netherlands

**OBJECTIVES:** To provide a literature overview on the costs of diabetic complications focused on the economic burden of Diabetic Macular Edema (DME) and associated vision loss and blindness. **METHODS:** Literature searches in PubMed (including Medline) and Embase were conducted to identify economic data related to diabetic retinopathy, macular edema, blindness and low vision. **CONCLUSIONS:** Costs results vary across European countries. Severe psoriasis agents may contribute to a more efficient management of severe psoriasis due to a more steady control of symptoms that improve clinical outcomes and decrease progression to visual impairment and blindness.

**PSS18 ECONOMIC BURDEN OF BURN INJURIES IN THE NETHERLANDS**
Hop M1, Wijnen BF2, Nieuwenhuis MJ3, Dokter J4, Middelkoop E5, Polinder S6, van Baar TM7
1Association of Dutch Burn Centres, Rotterdam, The Netherlands, 2Maastricht University, Maastricht, The Netherlands, 3Association of Dutch Burn Centres, Groningen, The Netherlands, 4Association of Dutch Burn Centres, Beverwijk, The Netherlands, 5Erasmus MC, Rotterdam, The Netherlands

**OBJECTIVES:** Burn care has rapidly improved in the past decades. However, health care innovations can be expensive, demanding careful choices on their implementation. Obtaining knowledge on the extent of the costs of burn injuries is an essential first step for economic evaluations within burn care. The objective of this study was to determine patients with burn injuries admitted to the burn center and to identify important cost categories until three months post-burn. **METHODS:** A prospective cohort study was conducted in the burn center of Maastd Hospital, Rotterdam, The Netherlands, between April 1st, 2011 and March 31st, 2012. All patients were included from August 2012 until July 2013. Total costs were calculated from a societal perspective, until three months post injury. Subgroup analyses were performed to examine whether the mean total costs per patient differed by age, etiology or percentage Total Body Surface Area (TBSA). **CONCLUSIONS:** The mean total burn size of 8%, mean total costs were €24,246 per patient varying from €11,498 to €71,756. Most important cost categories were burn center days, surgical interventions and work absence. Flame burns were significantly more costly than other types of burns, adult patients were significantly more costly than children and adolescents.
and a higher percentage TBFA burned also corresponded to significantly higher costs. **CONCLUSIONS:** Total mean costs of burn care in the first three months post-injury were estimated at €2,246 and depended on age, etiology and TBFA. Total mean costs in our population probably apply for other high-income countries as well, although we shall realize that patients with burn injuries are diverse and represent a broad range of units costs. To reduce indirect costs, care providers should allocate their studies should focus on reducing length of stay and enabling an early return to work.

**PSS19**

**THE COST OF BLINDNESS IN THE REPUBLIC OF IRELAND 2010-2020**

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**OBJECTIVES:** Aims The aim of this study is to estimate the prevalence of blindness in the Republic of Ireland and estimate the financial and economic cost of blindness between 2010 and 2020. **METHODS:** The prevalence of blindness was based on the National Council for the Blind of Ireland blind register and adjusted for under registration found in previous literature. The financial cost of blindness includes direct medical costs of dental care were taken into account. Costs were expressed randomly in 2012/2013 throughout an array of several specialist state-owned (university and hospital) groups, and across particular medical services.

**RESULTS:** The total financial cost of blindness in the ROI is estimated to have been €76 million in 2010. This is projected to increase by 5.6% to 367 million by 2020 if current trends in disease burden continue. The total economic cost of blindness in the ROI is estimated to have been €809 million in 2010 and is predicted to increase to over €1.1 billion in 2020 based on current trends in demographics. The proportion of blindness can be avoided through the implementation of existing technologies by the health service. However a significant portion (98.04%) of the burden of illness falls on the health service (primarily the Department of Social Protection and the Department of Finance) and may reduce to move priorities of policies aimed at avoiding blindness that might otherwise be received.

**PSS20**

**COST-OF-ILLNESS STUDY OF SENILE CATARACT IN THE CZECH REPUBLIC**

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**COST-of-IllNESS STUDY OF SENILE CATARACT IN THE Czech Republic**

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1Novartis Ireland, Dublin 4, Ireland, 2National University of Ireland, Galway, Galway, Ireland, 3The Faculty of Medical Sciences University of Kragujevac, Kragujevac, Serbia and Montenegro

**OBJECTIVES:** The structure of direct costs associated with senile cataract, direct health care costs due to blindness, cost of depression due to blindness, cost of injurious falls due to blindness) and non-health care costs (production losses, informal care and deadweight welfare loss). Where possible, methods adopted reflect those used elsewhere in the literature. **RESULTS:** The total financial cost of blindness in the ROI is estimated to have been €76 million in 2010. This is projected to increase by 5.6% to 367 million by 2020 if current trends in disease burden continue. The total economic cost of blindness in the ROI is estimated to be €809 million in 2010 and is predicted to increase to over €1.1 billion in 2020 based on current trends in demographics.

**CONCLUSIONS:** A broad range of total costs. To reduce costs of burn care, future interventions should be considered.

**PSS21**

**COSTS OF DENTAL OUTPATIENT CARE – RESOURCE USE DIFFERENTIALS ACROSS CLINICAL DENTISTRY BRANCHES**

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**OBJECTIVES:** Dental medical care bears particular financial burden for Eastern Europe. Transition economics due to its lack of insurance coverage in most of the countries of the region and almost complete out-of-pocket payments by citizens. This study estimates real costs of these services in the field and describe resource use patterns across clinic branches, ICD-10 diagnostic groups and across particular medical services. **METHODS:** In a case-series design prospective cost-comparison study has been conducted from the perspective of the patient. Sample size was 752 complete episodes of treatment, selected random from 8 dentists' offices. Data were collected from an array of seven dentists (1 public and 6 private assistant staff) and private-owned dental clinics in upper-middle income Serbia. All direct medical costs of dental care were taken into account. Costs were expressed in national currency Republic of Serbia Dinara (RSD). **RESULTS:** Mean total direct medical costs of dental care were 5,018.9±17.109.61 RSD per single dentist visit while total costs incurred by this population sample were 3,774.256 RSD. Highest proportion of services goes to conservative dentistry (31.9%), oral surgery (19.5%) and radiology (17.4%), while highest value based turnover belongs to implantology 90,765.33±40,123.13 RSD, orthodontics 77,361.82±73,123.92 RSD and prosthodontics 608,738.86±267,887.87 RSD. Most frequently treated diagnosis was tooth decay (33.8%) unit services provided), pulpitis (11.2%) and impacted teeth (8.5%), while highest expense to treat were anomalies of tooth position (70,998.33±371,723.73 RSD), abnormalities of size and formation of teeth (55,662.50±73,704.45 RSD) and loss of teeth due utilization, extraction and local periodontal treatment (96,895.33±57,128.28 RSD).

**CONCLUSIONS:** Although range of dental medical costs currently falls behind EU average, Serbia's emerging economy is likely to expand in the long run while market demand for dental services will grow. Due to threatened financial sustainability of current national insurance payments in Eastern Europe, estimation of true size and structure of dental care costs might essentially support informed decision making in future.

**PSS22**

**COST-EFFECTIVENESS ANALYSIS OF USTEKINUMAB COMPARED WITH ETANERCEPT FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN COSTA RICA**

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**OBJECTIVES:** To assess the cost-effectiveness of Usteukinumab (UST) compared with Etanercept (ETN) in Costa Rica, in patients with Moderate to Severe Psoriasis. **METHODS:** A cohort simulation Markov Model was developed based on response rates for UST and ETN [Psoriasis Area Severity Index (PASI)] 1. The time frame was 15 years. The closed system was that of the health of Costa Rica. The health outcome of interest was Quality Adjusted Life Years (QALYS). Efficacy data was taken from the ACCEPT clinical trial, this phase III clinical trial directly compares UST and ETN, what strongly supports the efficacy data that is used in the model. Utilities for health states were taken from published studies. The base year was 2013. All costs are presented in Costa Rican currency (Colones – CRC). **RESULTS:** A significant proportion of blindness falls on the health service (primarily the Department of Social Protection and the Department of Finance) and may reduce to move priorities of policies aimed at avoiding blindness that might otherwise be received.

**PSS23**

**COST-EFFECTIVENESS OF RANIBIZUMAB ON PATIENTS WITH DIFFUSE DIABETIC MACULAR EDEMA WITHIN THE PUBLIC MEXICAN HEALTH CARE SYSTEM**

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**OBJECTIVES:** To conduct a cost-effectiveness analysis of Ranibizumab plus laser photocoagulation vs monotherapy with laser photocoagulation in patients with diffuse Diabetic Macular Edema (DME). **RESULTS:** A Markov model was designed to analyze the Photocoagulation plus Ranibizumab. Transition probabilities were obtained from RESTORE. The base patient was a diabetic with 53 years presenting DME, according to Mexican context. General mortality rates were elicited locally from CONAPO®. A panel Delphi was performed to get use patterns and differentials across clinical dentistry branches, ICD-10 diagnostic groups and across particular medical services.

**CONCLUSIONS:** The results of the probabilistic sensitivity analysis showed that, at the threshold suggested by the WHO, the probability of UST of being cost effective, compared with ETN is around 70%. CONCLUSIONS: UST can be considered cost effective when compared to ETN, according to the threshold suggested by the WHO, in patients with moderate to severe Psoriasis, from the perspective of the Public System of Health of Costa Rica.

**PSS24**

**MODELED OUTCOMES AND OVERALL COSTS OF THE 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE IN THE TUNISIAN NATIONAL VACCINATION PROGRAM**

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**OBJECTIVES:** Like other North African countries, Tunisia has a substantial burden of pneumococcal disease, with high resistance to antibiotics. The Tunisian population remains poorly vaccinated against a number of several pneumococcal serotypes, mostly due to the disappearance in the National Immunization Program (NIP). **METHODS:** A decision-analytic model was developed to evaluate the potential outcomes and costs of the PCV13-based NIP compared to no vaccination. The model estimates bacteraemia and meningitis (jointly iBOP), all-cause community-acquired pneumonia (CAP), and all-cause oitis media (OM). The demographics and disease
characteristics were obtained from WHO estimates or local sources, adjusted to local conditions. PCV13 direct and indirect effectiveness was extrapolated from PCV7 trials and surveillance records, adjusted to local serotype distribution. Cost of vaccine was USD 16.34. A discount rate for cost and life-years was 3%. The payer and societal perspectives were considered. RESULTS: The budget impact in a single- year with PCV13 and PCV7 was an incremental saving of USD 1.92 million, or USD 7.93 million without indirect vaccine protection considered. From this investment, 141,971 illnesses (1071 IPDs, 12,477 CAPs and 12,8423 OMs) and 347 deaths could be avoided annually. Without indirect vaccine protection, 58,524 illnesses (601 IPD, 4271 CAP, 35202 OM) and 184 deaths could be avoided. The cost-effectiveness analysis produced ICER of USD 340/LYG or USD 367/QALY from the payer’s perspective. From the societal perspective, the NIP is dominant. Not considering indirect protection, the NIP would be USD 146/LYG or USD 150/QALY from a societal perspective. The ICER was USD 1157/LYG or USD 1254/QALY from a payer perspective. CONCLUSIONS: PCV13 based NIP delivers benefit and cost savings that greatly offset the investment into vaccination. A societal perspective was the most conservative in terms of cost savings that over an additional year of life in full quality for less than one GDP per capita (USD 4237), hence a PCV13-based NIP with the above ICER presents an attractive option.

PSS25 RANIBIZUMAB FOR THE TREATMENT OF VISUAL IMPAIRMENT DUE TO MYOPIC CHOROIDAL NEOVASCULARIZATION: COST-EFFECTIVENESS VERSUS AFLIBERCEPT

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OBJECTIVES: Ranibizumab has demonstrated efficacy in patients with myopic choroidal neovascularization (mCNV) and is the first anti-VEGF licensed in this indication. Aflibercept is being evaluated for use in mCNV. An existing model demonstrated the cost-effectiveness of ranibizumab versus veptratinophosphinum therapy was adapted to provide an initial evaluation of ranibizumab versus aflibercept. METHODS: A Markov model in mCNV with a lifetime horizon and visual acuity health states was used to evaluate the cost-effectiveness of aflibercept versus ranibizumab from a UK health care perspective. Baseline characteristics, injection frequency and ranibizumab efficacy were based on the disease activity treatment arm of the RADIANCE study (n =116, Caucasian, Indian and East Asian patients). Daily costs were derived from initial results for the aflibercept treatment arm from the MYRROR study (n =9, East Asian patients only). Relative efficacy was assessed by indirect comparison. An evaluation using the East Asian subgroup of the ranibizumab disease activity treatment arm in RADIANCE (n =35) was also conducted. RESULTS: Ranibizumab dominated aflibercept in both evaluations. Based on the disease activity arm from RADIANCE, ranibizumab was associated with a lower lifetime cost (incremental cost=-£1770) and higher lifetime quality-adjusted life years (incremental QALYs =0.061) than aflibercept. Probabilistic sensitivity analysis showed that aflibercept was dominant compared to ranibizumab in 70% of the simulations. To aflibercept. Probabilistic sensitivity analysis showed that aflibercept was dominated over ranibizumab in 70% of the simulations.

PSS26 COST-EFFECTIVENESS OF AFLIBERCEPT IN THE TREATMENT OF MACULAR ODEMA SECONDARY TO CENTRAL RETINAL VEIN OCCLUSION IN SWEDEN

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OBJECTIVES: Central retinal vein occlusion (CRVO) is a caused by a blood clot in the central retinal vein, which slows or stops blood from leaving the retina. As a result, blood and fluids can accumulate, causing retinal injury and vision loss. Thus, a major complication in eyes with CRVO is macular oedema (ME) and is the primary factor for poor visual acuity and visual fields in ischaemic CRVO. A global cost- effectiveness model was developed and adapted to estimate effects and associated costs, in Sweden, for the treatment of ME secondary to CRVO with aflibercept compared to ranibizumab. METHODS: A Markov model was developed, including health states that reflect the clinical treatment and disease progression/regression of the ME. The simulated patient population consisted of adults treated for ME secondary to CRVO with an average starting age of 64 years. Patients were treated and monitored for 5 years and followed for 15 years in the base case treatment regimen. Treatments were taken from clinical trials with aflibercept (GALILEO & COPERNICUS) and ranibizumab (CRUISE & HORIZON), with 8.2 vs. 8.8 injections the first year and 2.9 vs. 3.5 injections the second year, respectively. RESULTS: Aflibercept can be regarded as a cost-effective, i.e. dominating, treatment alternative compared to ranibizumab as aflibercept is both less costly (total incremental cost of more than -35,000 SEK) and more effective (total incremental QALYs of 0.061) than ranibizumab. To aflibercept. Probabilistic sensitivity analysis showed that aflibercept was dominating over ranibizumab in 70% of the simulations. CONCLUSIONS: Aflibercept is more cost-effective than ranibizumab for the treatment of ME secondary to CRVO in Sweden.
PSS3

COST-EFFECTIVENESS OF RANIBIZUMAB VERSUS PHOTODYNAMIC THERAPY FOR THE TREATMENT OF NEOVASCULAR AGE-RELATED MACULAR DEGENERATION BASED IN CHINA COST SETTING

Feng S., Qi F., Qi Y., Wu W., Li Y., Du X., Jenifer H. 1

PSS31

COST-UTILITY ANALYSIS OF RECOMMENDED RANIBIZUMAB REGIME FOR AGE-RELATED MACULAR DEGENERATION IN CHINA

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PSS32

NON-PROLIFERATIVE DIABETIC RETINOPATHY: IS IT COST-EFFECTIVE TO TREAT EARLY?

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OBJECTIVES: To conduct the cost-utility analysis (CUA) of treatment strategy with ranibizumab recommended by the Chinese Clinical Pathway of age-related macular degeneration (AMD) in China. METHODS: Visual acuity data for the as-needed dosing regimen with ranibizumab (RBz-PRN, administered every month for three doses, additional reinjections were determined by physicians’ need) were derived from randomized trials. Results of ranibizumab dosing of 1 mg, Decision tree and Markov model were developed to estimate RBz-PRN compared with best supportive care (BSC) for short and long term. The first year decision tree model from a third payer perspective was performed to estimate CUA in short term. Then a 10-year Markov model from a societal perspective were constructed (discounted at 5% in long-term CUA estimation. Resource utilization was obtained from official recommendations in China. The costs of low vision related disease were extrapolated from meta-analysis of Warwick, Coventry, UK. Costs and utility values were estimated by published studies. The uncertainty was identified in a one-way sensitivity analysis and probabilistic sensitivity analysis (PSA). Cost-effective acceptability curves were obtained by a Markov tree model. Results: Beneath an EQ-5D decision tree, the incremental cost-effectiveness ratio (ICER) for RBz-PRN compared with BSC, the incremental cost-effectiveness ratio (ICER) ranged from €90,546/QALY for the 1-year time frame, to €9,787/QALY for the 10-year time horizon. As indicated in the decision tree, the most optimal treatment was to pay threshold of €18,278 per QALY gained (3 times Chinese GDP per capita in 2012) in China. CONCLUSIONS: Ranibizumab can be a long-term cost-effective option for the treatment of AMD compared with BSC from a societal perspective.

PSS33

COST-EFFECTIVENESS OF RANIBIZUMAB VERSUS ABLIFERECT IN TREATMENT OF TREATMENT OF VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR OEDEMA (DMO)

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OBJECTIVES: To estimate the cost-effectiveness of ranibizumab 0.5mg pro re nata (PRN) dosing bimonthly in the treatment of visual impairment (VI) due to diabetic macular oedema (DMO) taking a UK health care perspective. METHODS: A Markov model previously reviewed by the National Institute for Health and Care Excellence (NICE) was used to simulate the long-term outcomes and costs (at 2012 price level) of treating DMO. The health states were defined by increments of 10 letters in best-corrected visual acuity (BCVA) with a 3-month cycle length. Patients could gain (or lose), at most, 2 health states between two cycles for the same time horizon. Also, competition between different treatments was included. Future costs and health outcomes were discounted at 3.5%. Baseline characteristics, ranibizumab effectiveness and adverse events were estimated with data from the RESTORE trial (36 months). A published network meta-analysis was used to assess the relative effectiveness of ranibizumab to aflibercept. Ablifercept injection frequency was calculated with VIVID/VISTA phase III trials. Different utilities were used if the treated eye was the better or the worse-seeing eye. RESULTS: Ranibizumab monotherapy leads to an incremental gain of 0.05 quality-adjusted life-years (QALY) (0.04 from the better-seeing eye and 0.01 from the worse-seeing eye) with a cost savings of 85,841 relative to aflibercept. Therefore, ranibizumab provides greater health gains with lower overall costs than aflibercept. Probabilistic sensitivity analysis shows that ranibizumab has a 58% probability of being dominant and 79% probability of being cost effective compared with aflibercept at a willingness-to-pay threshold of £20-£30,000 per quality-adjusted life year, the probability of early treatment being dominant was 88% compared with aflibercept.

PSS34

THE FUTURE HEALTH ECONOMIC POTENTIAL OF NEXT GENERATION ARTIFICIAL VISION DEVICES FOR TREATING BLINDNESS IN GERMANY: AN EARLY COST-UTILITY ASSESSMENT

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OBJECTIVES: The next generation of artificial vision devices (AVDs), which is currently under clinical development, has the potential to improve the vision of blind patients with retinitis pigmentosa (RP) in a manner that they will be categorized as visual impaired but no longer as blind. This unprecedented vision improvement will result in a remarkable quality of life gain which poses the question at which costs AVDs should be regarded as cost-effective. In order to answer this research question a Markov model, with the health states blind, visual impaired and death, was developed to simulate and to compare the costs and effects of next generation AVDs versus best supportive care (BSC) over a lifetime horizon. Health care costs and utilities for the Markov health probabilistic sensitivity analysis suggests that at willingness-to-pay threshold of €90,841 per quality-adjusted life year, the probability of early treatment being cost-effective is 60%. CONCLUSIONS: Panretinal photocoagulation administered at the severe NPDR stage is likely to be cost-effective. However, given the limitations of the evidence on current treatments, these results are interpreted with caution. A trial of early deferred deferred therapy is needed to provide better data based on modern treatments.
states were determined on the basis of published literature. For next generation AVDs, these lower medication adherence in clinical trials, various possible effect and pricing scenarios have been simulated. RESULTS: Applying the base case settings resulted in incremental costs of €107,925, in 2.03 incremental quality-adjusted life years (QALYs) and in a cost-effectiveness ratio of €53,165 per QALY gained. Probabilistic sensitivity analysis was conducted. Conclusion: Intranasal, misting sensitization analyses as well as scenario analyses for the effect size and the AVD costs were performed in order to investigate the robustness of results. In these analyses a strong variation of the cost-effectiveness results was obtained ranging from €23,512 (best case) to €176,958 (worst case) per QALY gained. CONCLUSIONS: The innovative nature, the high unmet medical need and the expected unprecedented efficacy of next generation AVDs will highly likely lead to the case that even relatively high incremental cost effectiveness ratios, that have been obtained when simulating various effect and pricing scenarios, will be regarded as acceptable from a German healthcare payer perspective.

**PSS36 IMPLICATIONS FOR TIME SAVINGS USING NEW INTRAOPERATIVE MEASURING TECHNOLOGY**

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OBJECTIVES: Intraoperative threshold measurement is a part of the cochlear implantation procedure and in the current setting conducted by the clinicians with a standard set-up. The newly released CR220 Intraoperative Remote Assistant is a handheld device and can also be used by someone already in the operating theater. The aim of this study was to compare the measurement time to the new CR220 and standard set-up and to investigate from the clinic’s perspective any cost-savings created as a result of time-savings with the new device. METHODS: Stages of the measurement process are identified and the time is measured for each stage during 113 patients’ implantation procedure. A literature review was conducted to identify the reimbursement level of this process in order to translate any time savings into cost savings. RESULTS: When the clinical team elements to the OT, the mean time spent per procedure with CR220 is 8.4% less than the computer set-up (163.7 minutes vs 149.9 minutes). If the measurement is conducted by someone already in the OR, the measurement time is reduced to 95.5% of the CR220 (163.7 minutes vs 7.3 minutes). Literature review revealed that the fee for measurement as €18.99-22.57 per 15 minutes in the US setting and in most of the other settings this procedure is not reimbursed separately but covered under cochlear implantation. CONCLUSIONS: The analysis showed that considerable time is spent for the clinician to travel to OT and waiting in the OT. This “unproductive” time is not only wasteful, but also means the clinician is not available in the clinic seeing patients where their expert skills are of most value. Moving the clinician is either underpaid or is not compensated for the expertise required, taking away time from the time demanding process. The new CR220 gives clinics the opportunity to allocate their limited resources efficiently.

**SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies**

**PSS37 DRUG SURVIVAL RATES AND COST OF BIOLOGICAL AGENTS FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN THE BALEARIC ISLANDS (SPAIN)**

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OBJECTIVES: There are few studies combining dose regimen in routine clinical practice, drug survival rates and costs of biological agents for the treatment of naïve patients with moderate-to-severe psoriasis in the clinical practice. To assess the dose regimen in routine clinical practice, drug survival rate (persistence rate) and efficiency (cost per persistence) for etanercept (ETN), adalimumab (ADA) and ustekinumab (UST) in a real practice clinical setting. METHODS: A retrospective study on psoriatic patients aged 18 years, naïve to a biological agent and a minimum of 6 months of treatment was performed in 5 public health system hospitals in the Balearic islands (Spain) for the period from January 1st 2010 to December 31st 2013. The recorded variables were: sex, weight, age, indication (psoriasis or psoriatic arthritis), discontinuation reason and pharmacy dispensation records. Costs were based on the average wholesale price, estimating annual cost according to the first treatment received. Persistence rates were reckoned taking into account the current therapy, and the currently tested drug for each patient. For etanercept and adalimumab, dose used and estimated using the method of Kaplan-Meier. RESULTS: During the study period a cohort of 112 psoriatic patients (57% men) were evaluated: 37 patients with ADA (81 kg, 51 years, 27%; mean weight, mean age, and prevalence of psoriatic arthritis respectively), 34 with ETN (82 kg, 52 years, 25%) and 41 with UST (76 kg, 43 years, 19%). The persistence rate at 2 years was, 48%, 62% and 81% and the cost per persistence at 2 years was 59.961 €, 40.160 €, and 30.657 € (for ADA, ETN and UST respectively). CONCLUSIONS: UST showed better overall drug survival compared to ETN and ADA. UST has been the most efficient alternative for the treatment of naïve patients and has shown the least budget-impact per persistent-patient at 2 years analysis.

**PSS38 MEDICATION ADHERENCE AND DISCONTINUATION PREDICTED BY DISEASE DURATION IN GLAUCOMA PATIENTS: FINDINGS FROM A CROSS-SECTIONAL STUDY IN KOREA**

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OBJECTIVES: Although several studies reported patients with chronic disease were inclined toward poor medication adherence and discontinuation as disease duration increased, it is still not evident in glaucoma patients. With this perspective, this study was designed to assess the association of disease duration with medication adherence and discontinuation in glaucoma patients in Korea. METHODS: It was a multi-center, cross-sectional study where glaucoma outpatients with less than 2 years of drug use were recruited at 15 eye clinics from March to November 2013. All patients completed a self-administered questionnaire asking about their daily use of glaucoma medications ratios, that have been obtained when simulating various effect and pricing scenarios, will be regarded as acceptable from a German healthcare payer perspective.

**PSS39 HEALTH STATE UTILITIES FOR PRESSURE ULCERS – A COMPARISON OF CONDITION-SPECIFIC AND GENERAL MEASURES AND TIME-TRADE-OFF (TTO)**

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OBJECTIVES: To compare a newly developed condition-specific utility index (CSUI), the Pressure Ulcer Quality of Life Utility Index (PUQUL-Ul) with generic and directly elicited utilities. METHODS: Three randomised clinical trials: ASTERIA I, ASTERIA II, and GLACIAL were analysed. To obtain utility estimates suitable for use in economic models for chronic spontaneous (idiopathic) urticaria (CSU), a patient-completed diary of signs and symptoms which calculates an average daily score over 7 days. Higher score means more severe symptoms. UAS7 scores for the health states were: urticaria-free: 0; Well-controlled urticaria: 1-6; Mild urticaria: 7-15; Moderate urticaria: 16-27; Severe urticaria: 28-42. Mean EQ-5D utilities were calculated for each health state. Individual trial analyses showed inconsistent utilities across the UAS7 health states due to small sample sizes. A mixed model was used to predict EQ-5D according to UAS7 health states in a pooled dataset containing all treatment arms and time points from the three trials. The predictor variable was UAS7 health state and the dependent variable was EQ-5D utility. Fixed/random effects for trial and patient were included in the modeling and a random slope for both baseline (Moderate or Severe), presence of angioedema at baseline and during follow-up, duration of CSU, number of previous CSU medications, and gender of the patient. A parsimonious model was selected using the approach of backwards elimination; and health state. Individual trial analyses showed inconsistent utilities across the UAS7 health states due to small sample sizes. A mixed model was used to predict EQ-5D according to UAS7 health states in a pooled dataset containing all treatment arms and time points from the three trials. The predictor variable was UAS7 health state and the dependent variable was EQ-5D utility. Fixed/random effects for trial and patient were included in the modeling and a random slope for both baseline (Moderate or Severe), presence of angioedema at baseline and during follow-up, duration of CSU, number of previous CSU medications, and gender of the patient. A parsimonious model was selected using the approach of backwards elimination;
PSS41
HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ACTINIC KERATOSIS - RESULTS FROM PATIENTS TREATED IN DERMATOLOGY SPECIALIST CARE IN DENMARK

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OBJECTIVES: Actinic keratosis (AK) is a common skin condition associated with cumulative UV exposure. AK is a precursor of melanoma skin cancer. The disease can potentially influence Health Related Quality of Life (HRQoL), but studies of HRQoL in patients with AK are limited. The objective was to analyze HRQoL in patients with AK using generic and disease-specific HRQoL instruments and to analyze the relationship between instruments. METHODS: AK patients who visited dermatological clinics in Denmark were included in an observational, cross-sectional, study in a multi-center setting. Dermatologists assessed AK severity and patients were asked to assess potential physical, emotional, and daily quality of life. Results: AK Severity (UAS7), Dermatology Life Quality Index (DLQI), EQ-5D (SI), and EuroQol Visual Analogue Scale (EQ-VAS). RESULTS: A total of 312 patients from 10 clinics were included in the analyses. In general, patients with AK reported impaired HRQoL. The mean value for EQ-VAS was 64 ± 22 for WTP £0, 81 ± 16 for £1 to £4, 81 ± 15 for £5 to 99, 76 ± 16 for £100 to £199, 74 ± 20 for £200 to 299, 71 ± 24 for £300 or more. Patients with lower mean values for comparison variables were closest to zero) for patients who were Urticaria-Free and highest for those with Severe Urticaria (UAS7 = 28-42). Comparison variables included the DLQI, EQ-5D and AKQoL.

PSS42
CATEGORICAL HEALTH STATES IN CHRONIC SPONTANEOUS URTICARIA (CSU) BASED ON THE WEEKLY URTICARIA ACTIVITY SCORE (UAS7): ARE THEY DISTINCT, DISCRIMINATIVE, AND REPRODUCIBLE?

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OBJECTIVES: Specific ranges of scores reflecting patient severity or changes in severity have not been established for average daily urticaria activity summed over 7 days (UAS7), range=0-42), a common measure for assessing CU disease activity. The objective was to investigate whether five health states derived from the continuous UAS7 score can discriminate between patients with different severities of urticaria and are used for different purposes. EQ-5D is essential for economic evaluations, the DLQI is responsive to changes in relation to treatment and AKQoL captures important aspects related to sun damaged skin.

PSS43
THE BURDEN OF PRIMARY HYPERDOSISDROPSIS ON THE PATIENT: EQ-SD-5L UTILITIES, WILLINGNESS TO PAY AND DAILY TIME SPENT IN MANAGING THE DISEASE

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OBJECTIVES: The objective of this study was to estimate the burden associated with primary hyperhidrosis by assessing patient's health utilities, willingness to pay for different treatment options and daily time spent in managing the disease. METHODS: The data used in this study were collected under a longitudinal, multi-stage research undertaken to develop and validate a new HRQoL instrument from the perspective of patients with primary hyperhidrosis. The questionnaire includes items on three dimensions (Health related quality of life (HRQoL), adherence, satisfaction, preferences, use of medical resources and costs) in Europe. A systematic review on PROs and costs of CU was performed. Research involving adults recruited from primary care, specialist care, and online communities (Hyperhidrosis support group UK and International hyperhidrosis society) from January to August 2013. Only the baseline assessment is used in this analysis. Disease severity was measured using the Hyperhidrosis Disease Severity Scale (HDSS, 0 = intolerable sweating, 1 = barely tolerable sweating, 2 = intolerable sweating). The EuroQol 5D-5L was used for assessing health utility index. RESULTS: EQ-SD-5L health utility index was lower in patients with more severe hyperhidrosis [mean utility value: 0.85 ± 0.13 for HDSS = 0.0, 0.80 ± 0.15 for HDSS ≥ 0.8, 0.74 ± 0.20 for HDSS = 4, chi-square = 25.86, df = 2, p < 0.001]. Further, the health utility index was.

PSS44
SUBJECTIVE EXPECTATIONS REGARDING LIFE EXPECTANCY AND HEALTH-RELATED QUALITY OF LIFE IN MODERATE TO SEVERE PSORIASIS PATIENTS

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OBJECTIVES: To synthesize and analyze the available information on the burden of chronic urticaria (CU) [Patients’ Reported Outcomes (PROs): Health related quality of life (HRQoL)], economic models and useful for clinical practice. dermatoQl. Categorical UAS7 health states could be informative about close to zero) for patients who were Urticaria-Free and highest for those with Severe Urticaria (UAS7 = 28-42). Comparison variables included the DLQI, EQ-5D and AKQoL.

PSS45
THE DECISION MAKING PROCESS IN RECEIVING BONE CONDUCTION IMPLANTS (BCI) FOR SINGLE SIDED DEAFNESS

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OBJECTIVES: The main objective of this study was to analyze the process in which patients with single sided deafness proceed to receive bone conduction implants. Factors contributing to decisions for or against implantation were also compiled. METHODS: Using a comprehensive search strategy, several online databases were used to identify studies published since 2002. Results: 914 individuals diagnosed with SSD. All patients who trialled devices were retained for analysis. 16 studies were identified covering a total of 914 individuals diagnosed with SSD. All patients who trialled devices were retained for analysis. 16 studies were identified covering a total of 914 individuals diagnosed with SSD. All patients who trialled devices were retained for analysis.

CONCLUSIONS: Patients expected considerable improvement in their HRQOL for the near future and large-scale deterioration for older ages. Exploring unrealistic expectations might help to prevent dissatisfaction with treatment benefits and to improve compliance.

REFERENCE:

Kamudoni P. 1, Salek M.S. 1, Kamudoni P. 1, Gimenez-Arnau A. 2, Grattan C. 3, Khalil S. 4, Grattan C. 3, Khalil S. 4, chi-square 25.86, df = 2, p < 0.001.

PSS46
THE BURDEN OF CHRONIC URTICARIA IN EUROPE: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To synthesize and analyze the available information on the burden of chronic urticaria (CU) (Patients’ Reported Outcomes (PROs): Health related quality of life (HRQoL), adherence, satisfaction, preferences, use of medical resources and costs) in Europe. A systematic review on PROs and costs of CU was performed. Research involving adults recruited from primary care, specialist care, and online communities (Hyperhidrosis support group UK and International hyperhidrosis society) from January to August 2013.

RESULTS: 16 studies were identified covering a total of 914 individuals diagnosed with SSD. All patients who trialled devices were retained for analysis. 16 studies were identified covering a total of 914 individuals diagnosed with SSD. All patients who trialled devices were retained for analysis.

CONCLUSIONS: When given the option to trial traditional treatments and BCI simulators/Headbands many patients with SSD reject BCIs. This research highlights the importance of providing such trials before implantation. It is still unknown which aspects play a role in decision making and identifying better candidates.

REFERENCE:

Kamudoni P. 1, Salek M.S. 1, Kamudoni P. 1, Gimenez-Arnau A. 2, Grattan C. 3, Khalil S. 4, chi-square 25.86, df = 2, p < 0.001.
Patients taking prescription drugs were more satisfied than those taking over the counter (p<0.01). Severely ill patients were willing to change therapies if new, more effective alternatives became available (p<0.05). Only 1 study assessed the costs of CU in Europe while another one described the costs of medical resources. The total cost in France was €2,139.48 per patient/year. Patients lost 2.2 working days/month, being productivity losses 92% of total costs. CU patients were mostly cared for a dermatologist (70%), while 20% were assigned to an eye specialist. The main reasons for this were in 46% a loss of vision or that their vision was still improving. Most patients and caregivers reported frequent medical visits to identify a number of obstacles in managing wAMD. These included the treatment itself (35%), fear of real injections and caregivers from nine countries (Australia, Brazil, Canada, France, Greece, Hungary, Iran, Italy, and Germany). Skindex was found very similar across the two countries (for women: 0.70±0.6, 10±6.5, 13±8.3, respectively. In both countries psoriasis of the head and/or décolletage was associated with the greatest HRQOL reduction using either instrument (p<0.05). Only 1 study assessed the costs of CU patients enrolled from two Hungarian university clinics and 62% from an Iranian clinic. Besides HRQOL assessment, data on demographics, applied treatments, affected body sites and clinical types were collected. RESULTS: Mean age of the Hungarian and Iranian patients was 51.2 ±12.9 years with 69% males, and 40.4±17.5 years with 76% males, respectively. Amongst the Hungarian patients 18% had undergone only one or only topical therapy in the last 12 months, 31% systemic non-biologic treatment and 52% biologics whereas in Iran 48% of the patients applied only topicals and 39% treated with non-biologic systematic therapy. Mean EQ-5D, DLQI and PASI of the Hungarian and the Iranian sample were 0.693±0.3, 6.29±7.3, 0.639±0.3 respectively. In both countries, 20% of the patients were diagnosed with AMD within the last 1 month to the dermatology clinic were reported. CONCLUSIONS: PROs and costs in CU are infrequently addressed in the literature. Findings show patients reduced HRQOL and their willingness for more effective therapies. Frequent medical visits and loss of productivity make CU a burdensome disease in European countries.

**PS54**
**A REVIEW OF PATIENT REPORTED OUTCOMES (PROs) IN PSORIASIS ACCORDING TO THE FOOD AND DRUG ADMINISTRATION (FDA) PRO GUIDANCE CRITERIA**

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**OBJECTIVE:** To identify studies written in English or Spanish on HRQoL in patients with psoriasis, identify a number of obstacles in managing wAMD, and determine in 75% and 50% of them, there was a relation between sex (women) and age (younger patients) with poorer HRQoL. Seven (7) had a prospective design while 7.4% = =

**RESULTS:** The QOLHEQ total-score ranges between EuroQol 5 dimensions (EQ-5D), Dermatology Life Quality Index (DLQI), Psoriasis Quality of Life Questionnaire (PQOL-12), and Skindex. This study assessed how well the development and validation of PROs and QoL instruments can be useful in the management of wAMD. The PRO instruments were mainly assessed in terms of content validity, including patient input in concept elicitation, item generation, and cognitive debriefing; and 2) psychometric testing, including construct validity, internal-consistency and test-retest reliability, and responsiveness. RESULTS: The FDI was found to be valid and reliable. Data was also correlated with the German validated version of the QOLHEQ, cognitive debriefing Variability and oftentimes inadequately documented evidence of patient input for concept elicitation, item generation, and cognitive debriefing were observed for the other four PROs. Test-retest reliability was not evaluated in the current study. The few differences of response rate and the few variations in the 5 PROs. CONCLUSIONS: Based on this review, additional qualitative and quantitative research is needed to eliminate the identified gaps before these PROs could fulfill the FDA guidance for inclusion as a measure for a PRO label claim.

**PS55**
**CURRNT MANAGEMENT AND BARRIERS TO TREATMENT FOR WET AGE-RELATED MACULAR DEGENERATION (wAMD): PERSPECTIVES FROM PATIENTS AND CAREGIVERS**

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**OBJECTIVES:** The aim of this global survey was to evaluate the management of wet age-related macular degeneration (wAMD) from a patient/caregiver perspective. METHODS: Patients with a wAMD diagnosis and current or prior use of intravitreal injections and caregivers from nine countries (Australia, Brazil, Canada, France, Germany, Greece, Hungary, Iran, Italy, and the UK) were included in the survey. In total, 1,621 patients and 980 caregivers were surveyed. 55% of patients had wAMD in 1 eye only and 64% had been receiving intravitreal injections for >1 year. Many caregivers were a child/grandchild (50%), partner (26%), or only 2% were a professional caregiver. 57% of patients visited a health care professional (HCP) within 1 month of first noticing a change in vision; 41% of patients who delayed visiting a HCP thought the symptoms would resolve. Following diagnosis, 54% of patients began treatment immediately, and a further 37% scheduled an appointment within 1–3 weeks. 52% of patients reported a temporary improvement or stabilization in vision as a result of current treatment, and 22% reported a return to pre-diagnosis vision of that their vision was still improving. Most patients and caregivers reported a number of obstacles in managing wAMD, including the treatment itself (35% and 39%, respectively), treatment costs (28% and 29%), and finding the right treatment options (27% and 31%). Additionally, 27% of caregivers found the patient’s treatment extremely inconvenient with 57% of employed (non-professional) caregivers having to take time off work or miss personal obligations. 16% of patients missed a HCP appointment because their caregiver was unable to take them (26%), fear of injections (21%), illness (15%), forgetfulness (15%), and the HCP could not be booked (9%). No significant differences were found in the last 67 years (SD=12.9) and 54.1% of the sample were female. With a weighted kappa of 0.54 the best agreement was found for the following bands: QOLHEQ-<0.5 = minimal impairment; QOLHEQ 0.5–0.7 = slight impairment; QOLHEQ 0.75–0.84 = moderate impairment; QOLHEQ 0.84–0.9 = severe impairment; QOLHEQ-<0.01 = very severe impairment. CONCLUSIONS: This is the first study which uses an anchor-based approach in order to devise a banding for the QOLHEQ score. This banding represents a standardized means of interpreting the QOLHEQ score. Further study is needed to ensure that banding may be adequate for different language version of the QOLHEQ.
OBJECTIVES: To assess the cost-effectiveness of nutritional support (high protein supplement) as standard care (regular hospital diet) in preventing pressure ulcers in hospitalised patients at high risk of pressure ulcers and malnutrition. Further, to evaluate the need and value of additional research using value of information analysis. METHODS: Analyses were undertaken from the perspective of the public authorities in Queensland, Australia, using a Markov model. Evidence for the relative risk (RR) was estimated from a meta-analysis of randomised controlled trials; other parameters were systematically identified from the literature to populate the model. The incremental net monetary benefit (INMB) was calculated and a probabilistic sensitivity analysis using Monte Carlo simulation was conducted. The expected value of perfect information (EVPI), expected value of perfect parameter information (EVPPI), expected value of sample information (EVsi) and expected total cost of additional research, expected net benefit of sampling (ENB5), and the return on investment (ROI) were calculated for an estimated popula-
tion of 125,000 over ten years. RESULTS: At a willingness-to-pay of AUS 50,000 per quality-adjusted life-year, the INMB was AUS 999, with a probability of 95% for nutri-
tional support to be the preferred intervention. The population EVPI was AUS 4.7 million, the highest EVPPI was for RR at AUS 2.25 million. For a future randomised study investigating the RR of the two interventions, the ENB5 would be maximised at AUS 3.9 million. A total sample size of AUS 1.2 million. The expected ROI would be 32%. CONCLUSIONS: Nutritional support is cost-effective in preventing pressure ulcers in high risk hos-
pitalised patients; however, there is uncertainty surrounding the decision and the value of this uncertainty is high. A future clinical trial to resolve this uncertainty is worthwhile.

PSS55 PREPARATION OF VORICONAZOLE SOLID LIPID NANOPARTICLES FOR EFFECTIVE OCULAR DELIVERY
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OBJECTIVE: Preparation of Voriconazole (VCZ) solid lipid nanoparticles (SLNs) for effective ocular delivery for the treatment of fungal keratitis. METHODS: SLNs were prepared by solvent emulsification technique using Compritol (lipid), Pluronic F-68 (surfactant) and sodium taurocholate (co-surfactant). Characterisation of SLNs was performed by size measurement, in-vitro release, ex-vivo corneal permeation studies and in-vitro antifungal activity. RESULTS: Particle sizes were found in the range of 150-500 nm depending upon lipid/surfactant ratio with good zeta potential. Entrapment efficiency of VCZ in SLNs was found between 40-60% with sustainability in vitro drug release (>70% in 12h). Ex-vivo corneal permeation studies exhibited good ocular perme-
ance of VCZ from SLNs. Ex-vivo study also supports good ocular permeance of VCZ from SLNs suggesting the use of these nanoparticles in the treatment of fungal activity exhibited the potential of VCZ SLNs. CONCLUSIONS: The sustained release property with good corneal permeation of VCZ from SLNs encourages its applica-
tion for in-vivo studies and hence could be proposed as an effective carrier for ophthalmic administration.

PSS66 THE ANALYSIS OF DENTAL CARE IN UKRAINE AT THE REGIONAL LEVEL
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OBJECTIVES: The structure of the overall incidence, the number of teeth and mortality rates occupying the third place in Ukraine. Thus 99% of the patients served in outpatient clinics institutions. The structure of diseases requiring hospitalization (approximately 1% of patients), the top spot is occupied odontogenic inflammatory diseases and injuries of the maxillofacial area. METHODS: In Ukraine, the avail-
ability of dentists is 4.0 per 10,000 population and 4.5 per 10,000 children. We have analyzed the statistical data of the Lviv Regional Department of Health. We found that in Lviv region on the basis of licenses to practice medicine in dentistry are 248 dentists, who work in cities and towns, and only about 10% - in rural areas. From 196th private den-
tal surgeries 89 are situated in the regional center. Danylo Halytsky Lviv National Medical University opened and acting university Dental Center from 2012, where dentistry students, including students more than 172 000 children each year. Such preventive examinations make it possible to carry out monitoring as indicators of dental public health field, to identify the most important risk fac-
tors for dental diseases. CONCLUSIONS: The management and pharmacoeconomic studies of dental care, identifying optimal funding for state and municipal health care institutions for cost-effectiveness use of state funds.

PSS7 DENTAL CARE USE AND ASSOCIATED FACTORS AMONG PEOPLE WITH RHEUMATOID ARTHRITIS: A NATIONWIDE, POPULATION-BASED, PROSPEROITY SCORE-MATCHED FOLLOW-UP STUDY
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OBJECTIVES: Patients with RA suffer from a higher risk of periodontal attachment loss and increased oral inflammation. There were few studies to access the utiliza-
tion of dental care among RA in Taiwan. The purpose is identify realize analyze and discuss the dental use of diabetic patients, and the association between the risk of rheumatoid arthritis (RA) and a history of periodontitis. METHODS: Retrospective cohort study based on the nationwide, population-based, NHIDB used administra-
tive data, case group consisted of 3,506 (age ≥18 years) patients with rheumatoid arthritis (RA group) as the study group and 22,024 patients without RA attending the Outpatient wing of Department of General Medicine formed the control group (NRA group). Matched for Age, gender and RUB, both groups were matched on 1:4. RESULTS: More advanced forms of periodontitis were found in RA patients com-
pared with controls. The results showed that RA patients (66.9% of RA) had 5-years utilization rate of dental care than non-RA patients (13.9% of non-RA). However, people have RA or not, the characteristics of dental use were similar. Only has the gender aspects to differ from, when the male suffered from RA, the utilization of dental care were not different with the female. CONCLUSIONS: we propose that the consulting rheumatologists inform the patients that they have a higher risk of peri-
odontal, this study demonstrates an association between periodontitis and incident RA. And the study is limited to lack of BMI, smoking, alcohol status.

PSS88 MACULAR ODEMA DUE TO RETINAL VEIN OCCLUSION METHODS FOR THE IDENTIFICATION OF TREATMENT GUIDELINES AND AREAS OF UNMET CLINICAL NEEDS BY MEANS OF SYSTEMATIC REVIEW
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OBJECTIVES: Retinal vein occlusion (RVO) causes macular oedema (MO), which can lead to vision loss. The present study sought to identify treatment guidelines and evidence base—both scientific and lay—in practice and technology. The aims were to i) develop a systematic methodology for the identification of such guidelines ii) review the guidelines and treatment pathways identified in order to propose optimal positioning for an experimental intervention for the treat-
ment of MO in RVO, and iii) to identify areas of unmet clinical needs. METHODS:
Systematic searches in the electronic databases MEDLINE, EMBASE and The Cochrane library were conducted and 53 online databases (including HTA agency websites, international ministries of health, and clinical trials.gov) were hand searched for clinical guidelines in the treatment of MO caused by RVO. **RESULTS:** Fifteen documents on treatment pathways or guidance used internationally were identified among the hand searches. No papers or abstracts were found from the electronic database searches. There were considerable between-jurisdiction differences in the guidance for the management of MO caused by RVO. These differences were consolidated to produce two amalgamated treatment pathways. In total, eight treatment positions for interventions in the treatment of RVO subtypes were identified. For one of the identified positions – treatment of ischaemic branch RVO – no licensed treatment currently exists. **CONCLUSIONS:** The described systematic methodology for the construction of treatment pathways may be used by manufacturers in early drug development decisions to identify unmet clinical needs, understand which treatment positioning may provide the most value, and identify future treatment comparators in the same indication. Guidelines to inform such commercial strategies may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. Between 10% and 20% of patients diagnosed with MO will go on to develop ischaemic branch RVO, a condition which may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. Between 10% and 20% of patients diagnosed with MO will go on to develop ischaemic branch RVO, a condition which may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. **PCN2**

**APPROVING DRUGS BASED ON EARLY DATA - HOW PHASE II TRIAL DATA CORRELATES WITH PHASE III OUTCOMES. CASE STUDY: NSCLC**

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**OBJECTIVES:** There is increasing pressure on regulators from patients, physicians and industry for earlier access to pharmaceuticals for serious diseases. In reaction, in March 2014 the European Agency (EMA) signalled its support for an innovative adaptive licensing, and the Medicines and Health care products Regulatory Agency (MHRA) unveiled their Early Access to Medicines Scheme. Nevertheless, there are questions over how, and if, Phase II trial benefits can be predictive of clinical advantages in Phase III studies, which this research aims to address. **METHODS:** Phase II data of any Non-Small Cell Lung Cancer (NSCLC) oncology appraised by the EMA, or that had failed Phase III clinical trials, since 2002 was extracted along with its corresponding Phase II data. Statistical tests were conducted using Pearson’s coefficient correlation. **RESULTS:** 12 oncologies were identified with both Phase II and III readouts, 6 of which met their Phase III trial primary endpoint. Overall Response Rates (ORRs) reported in Phase II trials varied from 0%-61% (mean 24%). 49% of drugs with Phase II ORRs >30% met their primary endpoint vs. only 2/8 (25%) with ORRs ≤30%. Phase II ORRs were strongly correlated with Phase III Progression-Free Survival (PFS) (r = 0.864, p = 0.0005) and Overall Survival (OS) outcomes (r = 0.898, p = 0.0001). For the 6 Phase II trials with Phases III primary endpoints there had comparative Phase II data indicating benefits versus these same comparators, most notably onalutuzumab, whose Phase III trial was terminated early due to inferiority during testing significant Phase II ORRs in 6 out of 8 months in Phase II. **CONCLUSIONS:** In NSCLC, Phase II ORRs can be strongly predictive of the magnitude of PFS and OS readouts in Phase III trials. However, comparative advantages in Phase II trials seem to be poorly predictive of OS benefits in Phase III studies, raising questions over the appropriateness of approving drugs on early stage comparative data outcomes.

**PCN4**

**CERVICAL HUMAN PAPILLOMA VIRUS (HPV) DNA PRIMARY SCREENING TEST RESULTS OF THE EXPERIENCE OF A REGIONAL LABORATORY IN CENTRAL ITALY**

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**OBJECTIVES:** To investigate feasibility and effectiveness of a cervical screening program with DNA tests as preliminary assay versus usual cytology protocols in Umbria Region. **METHODS:** A large cohort of 55-64 aged women afferent to the unique regional laboratory was considered. The usual algorithm with cervical cytology as first-tier test was followed in 2008-2010 period, whereas in 2010–October 2011 high-risk human papillomavirus (HR-HPV) DNA test was used as primary screening. The cohorts were compared in terms of acceptance rate of investigation, cytological results, outcomes including histological staging, detection rate of histological lesions. **RESULTS:** A total of 31,228 women were invited; 21,249 were suggested to undergo classical cervical cytological screening, 9,979 HR-HPV DNA test for primary screening. A similar rate of adhesion (56.6% vs. 56.5%) was observed. Age-related differences were evidenced, with younger women (35-49) more prone to accept the invitation to HR-HPV DNA testing rather than usual cytological screening (61.6% vs. 55.5%; p < 0.0001), analogously, uninvited younger women spontaneously requesting cervical screening were more prone to specifically request molecular test than classical cytological testing (24.8% vs. 10.8%; p < 0.0001). Among the 6,272 HR-HPV DNA testing women, 396 (6.4%) were positive, and, among them, 141 (36%) featured an altered cytology. All patients with altered cytology were suggested to undergo colposcopy and 106 out of 141 (75.1%) answered to the invitation. Among them, 89 (64%) featured abnormal histology with 48 (45.3%) CIN1 and 41 (38.7%) CIN2. If comparing the CIN2 detection rate within the two studied periods, it was almost doubled using the HR-HPV DNA than pap test as primary assay (0.64% vs. 0.037%; p = 0.0001). Finally, the implementation of the DNA test screening program did not increase total costs. **CONCLUSIONS:** Although with some limits, the introduction of HR-HPV DNA primary screening resulted feasible and effective, significantly increasing detection of severe lesions.

**PCN5**

**COMPARATIVE EFFECTIVENESS OF TREATMENTS FOR RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA (R/R MCL), USING MATCHING ADJUSTED DIRECT INFERIOR COMPARISON**

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**OBJECTIVES:** For prognosis or relapsed or refractory (R/R) MCL patients with existing treatments is poor, most patients progress within 4 months. Brutinib, an oral once daily MCL kinase inhibitor that has shown durable activity with good response rate in 111 R/R MCL patients and a median progression free survival (PFS) of 19.9 months. Brutinib received breakthrough designation and United States Food and Drugs Administration approval for use in MCL patients who received at least one prior therapy (R/R MCL). This indirect analysis aims to compare the efficacy...
of ibrutinib to available treatments for R/R MCL patients. METHODS: A systematic literature review was conducted to identify clinical trials containing ibrutinib in R/R MCL. Matching adjusted indirect comparison (MAC), described by Signorovitch et al. 2012, was utilized to obtain indirect relative treatment effect for ibrutinib compared to other treatments. Using individual patient level data (IPD), baseline characteristics of patients in each ibrutinib trial and comparator arm, and data from the published studies to obtain overall response (ORR) and complete response (CR) rates based on balanced population between the ibrutinib and published studies. Kaplan–Meier survival for overall survival and PFS of comparators were adjusted along with the results of the matched ibrutinib patients. RESULTS: Nineteen studies evaluating various treatments were identified. Five trials evaluating bortezomib, BR (bortezomib, rituximab), FCM (fludarabine, cyclophosphamide, mitoxantrone), FCR (fludarabine, cyclophosphamide, mitoxantrone, rituximab), and rituximab-hyper-CVAD were considered for matching. Complete matching of the IFD was possible for the bortezomib, FCM and FCR studies. Ibrutinib showed statistically significant better overall survival (OS) and progression-free survival (PFS) compared to bortezomib (HR 0.7, 95% CI 0.5-0.93) and FCM (OR 3.22; 95% CI 1.01-10.26).

CONCLUSIONS: The indirect analysis suggests a potential for improved ORR compared to a few relevant treatments in patients with R/R MCL. Phase III comparative confirmatory data with ibrutinib are anticipated in late 2014.

PCN6
OVERALL SURVIVAL IN PATIENTS WITH HER2+ EARLY STAGE BREAST CANCER PATIENTS TREATED WITH TRASTUZUMAB IN THE US DEPARTMENT OF DEFENSE PRACTICE SETTING

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OBJECTIVES: The NSABP/NCTCG trial (Romond et al. NEJM 2005; 353: 1673-1684) established the efficacy of trastuzumab in the adjuvant treatment of HER2+ early stage breast cancer (HER2+BC). Yet, little is known about the patterns of use and outcomes of adjuvant trastuzumab in clinical practice. The study aimed to estimate the overall survival (OS) and relapse-free survival (RFS) of HER2+BC patients treated with or without adjuvant trastuzumab in the US Department of Defense (DOD) practice setting. METHODS: Adult women initiating adjuvant trastuzumab within 1 year of BC surgery were identified in the DOD health claims database (01/2003-12/2012). An algorithm based on secondary neoplasm ICD codes and treatment gaps and initiations was used to identify relapses. OS and RFS unadjusted rates at 3 and 4 years after the initiation of the adjuvant trastuzumab treatment were estimated from Kaplan–Meier plots. RESULTS: The study sample included 3,188 women with a DOD eligible stage at the time of surgery. Compared to women who initiated trastuzumab within 3.3 years after the initiation of trastuzumab and treated continuously with trastuzumab for a median of 4 years, women who discontinued treatment were more likely to die (HR 1.40; 95% CI 1.08-1.79).

CONCLUSIONS: The findings confirm that most HER2+BC patients in the DOD continued their trastuzumab per-label trastuzumab treatment for (52 weeks) and had OS rates that are similar to the OS rates that were previously observed in the NSABP/NCTCG clinical trial (90% vs. 93% at four years). The lower RFS rates were consistent with a study versus the NSABP/NCTCG trial (75.8% vs. 85.7% at 4 years), may be partially explained by differences in the characteristics of the patients, including age.

PCN7
THE RELATIVE EFFICACY OF TREATMENTS IN FIRST-LINE MANAGEMENT OF NEWLY DIAGNOSED CHRONIC MYELOID LEUKAEMIA: SYSTEMATIC LITERATURE REVIEW AND INDIRECT COMPARISON

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OBJECTIVES: To assess the relative efficacy of first-line treatments in chronic myeloid leukaemia (CML), an updated systematic literature review (SLR) and indirect comparison (IC) were conducted with follow-up period up to 48 months. METHODS: We updated a SLR initially conducted in 2011. Medical databases were interrogated systematically in January 2014 to identify trials comparing first-line treatments for CML. Using a fixed-effect (cumulative complete cytogenetic response (CCyR) and major molecular response (MMR)) for dasatinib, nilotinib and imatinib. RESULTS: Nineteen randomised controlled trials (RCTs) were included in the SLR, 10 were eligible for inclusion in the IC. Compared with imatinib 400mg by 12 months, odds of cumulative CCyR were significantly greater for dasatinib 100mg [odds ratio (OR) 2.25, 95% credible interval (CrI) 1.55-3.15], nilotinib 600mg [OR 2.23 (95% CI 1.50-3.21)] and 800mg [OR 1.94 (95% CI 1.31-2.87)] by 24 months compared with imatinib 400mg by 12 months. Odds of major molecular response (MMR) (CCyR or ≤ 35% BCR-ABL transcript levels in blood) by 48 months compared with imatinib 400mg by 12 months were; dasatinib 100mg [OR 2.22 (95% CrI 1.52-3.15)] and 800mg [OR 1.70 (95% CI 1.08-2.50)] and higher, but not significant for dasatinib 100mg [OR 1.41 (95% CI 0.85-2.27)] by 24 months, and nilotinib 400mg [OR 2.21 (95% CI 1.34-3.67)] by 48 months compared with imatinib 400mg by 12 months. Nilotinib 600mg [OR 2.86 (95% CI 1.95-4.08)] and 800mg [OR 2.42 (95% CI 1.70-3.43)] by 48 months compared with imatinib 400mg by 12 months. Conclusions: The results confirm that dasatinib 100mg is significantly more effective than imatinib 400mg and should be treatments of choice in newly diagnosed CML.
CONCLUSIONS: Due to very limited availability of trials with robust endpoints and long-term follow-up, alternative options for establishing comparative efficacy must be used for decision making in relapsed or refractory MCL. These alternatives include implementing comparisons of single-arm trial data without adjustment (i.e., via naïve comparison) or methods such as match-adjusted indirect contrast comparisons. The preference for COU- AA-303 trials over RFS for these agents ranged from 2.9 to 0.1, with an average hazard ratio of 1.32 for hazard ratio (HR). The latest innovation, bevacizumab plus chemotherapy, demonstrated the greatest significant gain in OS versus chemotherapy (OS gain 1.32 for hazard ratio (HR)). The study concluded that the use of surgery and/or radiotherapy in this setting; the evidence was limited to seven retrospective hospital-based studies. CONCLUSIONS: This study highlighted an unmet need for additional treatment options for metastatic CC. Use of cisplatin-based platinum-based combination therapy has provided limited survival benefits for many decades. The novel combination of bevacizumab plus chemotherapy has demonstrated an increase in survival in these patients. However, since there is no RCT evidence supporting the use of surgery and/or radiotherapy, a health technology appraisal of these alternative interventions is not currently feasible. Additional clinical research is urgently needed to assess the comparative clinical value of these therapies.

PCN11 THE EFFICACY OF CURRENT TREATMENT OPTIONS FOR METASTATIC VESICAL CANCER

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OBJECTIVES: The prognosis of patients with metastatic vesical cancer (CC) remains poor, and treatment options are limited, with no single agent or combination of agents recognised as standard of care. cisplatin/paclitaxel is the therapy most cited by patients and healthcare professionals as their first-choice option for patients with metastatic CC. METHODS: Searches of PubMed were conducted, with no date restrictions, to identify published randomised controlled Phase III clinical trials (RCTs) of chemotherapies recommended by treatment guidelines, and radiotherapy and/or surgery, that reported overall survival (OS) in patients with metastatic (systemic recurrent, persistent or de novo-metastatic) CC. Treatment guidelines and the Cochrane Library were also explored to identify additional citations. RESULTS: 65 articles identified, 10 articles published between 1987 and 2014 proceeded to data extraction. Evidence supporting the use of chemotherapy was limited to cisplatin-monotherapy or platinum-based combination therapy. Overall OS benefit of these agents ranged from 2.9 to 0.1, with an average hazard ratio of 1.32 for hazard ratio (HR). The latest innovation, bevacizumab plus chemotherapy, demonstrated the greatest significant gain in OS versus chemotherapy (OS gain 3.7 versus 3.6 months). The study concluded that the use of surgery and/or radiotherapy in this setting; the evidence was limited to seven retrospective hospital-based studies. CONCLUSIONS: This study highlighted an unmet need for additional treatment options for metastatic CC. Use of cisplatin-based platinum-based combination therapy has provided limited survival benefits for many decades. The novel combination of bevacizumab plus chemotherapy has demonstrated an increase in survival in these patients. However, since there is no RCT evidence supporting the use of surgery and/or radiotherapy, a health technology appraisal of these alternative interventions is not currently feasible. Additional clinical research is urgently needed to assess the comparative clinical value of these therapies.
PCN22 WHAT IS THE CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS OF ERTHYROPOIETIN-STIMULATING AGENTS FOR THE TREATMENT OF PATIENTS WITH CANCER-TREATMENT INDUCED ANAEMIA? INSIGHTS FROM CURRENT META-ANALYSES (CMA) AND LESSONS FOR COST-EFFECTIVENESS ANALYSES

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OBJECTIVES: A health technology assessment (HTA) informing the recent NICE guidance regarding the use of erythropoiesis-stimulating agents (ESA) in cancer-treatment induced anaemia (CIA) identified uncertainty around the overall survival benefit (OSR). We investigated how the understanding of OS in CIA patients treated with ESAs has shaped over time and the effects of accumulating OS evidence on cost-effectiveness. In addition, the effects of narrowing inclusion criteria, by comparing the HTA results to a recent Cochrane review, were investigated.

METHODS: CMA results were compared to both HTA review and Cochrane review OS data to identify patterns in results; study results were accumulated by year of publication. Annual OSHR results from the CMA were applied to an economic model developed in the HTA review to estimate the cost-effectiveness of ESAs. Results for OSHR estimate appeared to improve with additional evidence, but the true location of the estimate remained uncertain and the best-estimate varied over time. Using the HTA CMA from 2001 and 2007, and the Cochrane CMA results, we suggested survival benefits to be CI 0.60 ± 0.08 and 0.75, 95% CI 0.65 ± 0.95 respectively, with ESAs being cost-effective at a willingness to pay threshold of £30,000 per QALY for all values of the OSHR 95% CI. HTA CMA for all other years and all Cochrane CMA results did not suggest any significant effects of ESAs on OS. Cost-effectiveness results were therefore uncertain.

CONCLUSIONS: Current evidence suggests we cannot reject the possibility of no difference in OS between patients receiving or not receiving ESAs, regardless of study inclusion criteria. In addition, there is also insufficient evidence to support such conclusions, particularly as earlier results from narrower inclusion criteria suggested some survival benefits. This analysis highlights the additional uncertainty of the current evidence base on cost-effectiveness analyses, which cannot be captured in standard sensitivity analyses.

PCN23 OBJEKTZIMB RE-TREATMENT IN PATIENTS WITH MULTIPLE MYELOMA (MM): A REAL WORLD PRACTICE EXPERIENCE FROM A SWEDISH NATIONAL REGISTRY

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OBJECTIVES: The question of sequencing multiple myeloma (MM) treatments is a key one, as is the re-treatment in patients where the same treatment was ineffective or had severe adverse events (AEs). The current Swedish national MM registry (MMReg) is the largest registry for MM patients in Sweden.

METHODS: Patients diagnosed with MM since January 2000 until June 2011 from 7 university clinics, 5 regional centers and 3 local hospitals in Sweden were included. Time to response and overall survival (OS) were analyzed using stratified Kaplan-Meier analysis.

RESULTS: 541 patients treated with bortezomib (out of a total population of n=1638), 93 were retreated with bortezomib. Median follow-up from start of retreatment was 10.2 mos. Median age was 63.5 (range 38–83), 57.3% were male, 34.2%/15.9%/20.7% had stage I/II/III disease (ISS); median number of prior therapies at initial bortezomib and retreatment was 1 and 3, 26.8%/32.9% of pts initiated retreatment as 3rd/4th line therapy. 38.7%/22.0% initiated bortezomib in combination with dexamethasone, 7.3% in monotherapy, compared to 40.3%, 21.8% and 8.5%, at initial bortezomib. >PR/VGPR-rates at re-treatment were 59.1%/12.7%, compared to 82.0%/39.1% at initial bortezomib. Median time to >PR/VGPR was 2.4/1.3 months at retreatment versus 1.9/2.1 at initial bortezomib. The >PR at retreatment was numerically longer in patients with <=2 (75%) vs >=3 (25%) therapies prior to retreatment. Median PFS/OS from start of re-treatment was 5.5 [95%CI: 3.7, 10.0]/14.3 [10, 26] months, compared to 8.1 [1.9, 9] in <2/2.5 months at initial bortezomib. Number of prior therapies at retreatment did not affect PFS; however, OS was longer in pts with fewer prior therapies (p=0.012).

There was a trend towards longer PFS (p=0.087) in retreated patients who achieved >PR compared to non-responders. CONCLUSIONS: These data suggest, that in retreated patients, the best outcome was observed in patients retreated after failure of two previous lines of therapy, with more than half of pts who responded to initial bortezomib achieving >PR at retreatment.

PCN24 TREATMENT SEQUENCING SURVIVAL MODEL FOR PATIENTS WITH MULTIPLE MYELOMA INELIGIBLE FOR STEM CELL TRANSPLANTATION (SCT)


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OBJECTIVES: Motivated by the discussion whether the german AMNOG is applied in Russia, we compared first-line therapies for patients with MM in Russia. Method: Multiple myeloma (MM).

RESULTS: In Russia, the majority of MPM patients have been treated with ESAs. Limitations: Only 11% of patients with MPM in Russia. Method: Metastatic pleural mesothelioma (MPM) is a rare tumour with a poor survival and prognosis. In Russia, the epidemiology of this disease has not been well studied. We conducted an epidemiological study to understand the characteristics of patients with MPM. Patients treated for 1st and 2nd-line therapy were included in ten centers of the Russian Federation. The data were collected from hospital records, electronic databases, and other sources of information between June and December in 2013. Conclusions: One hundred and twelve patients were enrolled. The average age was 60 ± 10.87 years and 42% were women. Harmful work environment was indicated in 21 (18.8%) of the patients. The exposure to asbestos was reported in 52 patients, patients, and contact with asbestos in 8/11 (7.1%) of the patients. Fifty percent (56/112) of the patients were smokers or current smokers; smoking period was 25.3 ± 12.25 years. The disease stage at diagnosis was I-II in 31 (27.6%), III in 47 (42.1%), and IV in 34 (30.4%) patients. The ECOG performance status was 0 in 16 (14.3%), 1 in 6 (41.1%), 2 in 50 (45.6%), 3 in 15 (13.4%) and 4 in 1 (9.0%) patients, in 4 patients - unknown. 50/112 (44.6%) patients had immunohistochemical verification of the diagnosis. Antineoplastic drugs were used to treat 85/112 (75.9%) patients. The main drugs were used in combination: melphalan (29), doxorubicin (29), and carbofilin (29). Conclusions: In Russia, the majority of MPM patients were diagnosed at advanced stages of disease. In 80% of the cases, a harmful work environment was not identified. Given the low prevalence and the frequent use of off-label medicines, it can be considered an orphan disease. Limitations: Only limited number of centres was included.

PCN21 FIRST-LINE THERAPY FOR PATIENTS WITH MULTIPLE MYELOMA: DIRECT AND INDIRECT COMPARISON OF TREATMENT REGIMENS ON THE EXISTING MARKET


OBJECTIVES: Motivated by the discussion whether the german AMNOG is applied to currently marketed drugs we compared first-line therapies for patients with multiple myeloma (MM). METHODS: A systematic literature search for randomized controlled trials (RCTs) was performed and VMP (bortezomib (Velcade), melphalan and prednisone) and MPT (melphalan, prednisone and thalidomide) were formed on the 24th March 2014 in Medline, Embase, and The Cochrane Library to identify all randomized controlled trials (RCTs) as well as single arm trials concerning the efficacy and safety of first line interventions of interest in patients with RAS wt mCRC. Abstract and article selection was performed by two independent researchers, with a third person resolving disagreements, according to predefined standards, which were based on criteria for patient, intervention, comparator, outcomes and study design (PICOS). RESULTS: 536 citations were identified after removing duplicates. 520 citations were retrieved and screened resulting in excluding 69 further publications due to pre-defined inclusion and exclusion criteria. In total, 24 RCTs were included in the meta-analysis. METHODS: A systematic literature search was performed on the 24th March 2014 in Medline, Embase, and The Cochrane Library to identify all randomized controlled trials (RCTs) as well as single arm trials concerning the efficacy and safety of first line interventions of interest in patients with RAS wt mCRC. Abstract and article selection was performed by two independent researchers, with a third person resolving disagreements, according to predefined standards, which were based on criteria for patient, intervention, comparator, outcomes and study design (PICOS). RESULTS: 536 citations were identified after removing duplicates. 520 citations were retrieved and screened resulting in excluding 69 further publications due to pre-defined inclusion and exclusion criteria. In total, 24 RCTs were included in the meta-analysis.
of these patients receiving 3-line therapy differed significantly in Moscow and St. Petersburg compared with other regions.

CONCLUSIONS: Obtained clinical and epidemiological data made it possible to fill in the model of management of patients with breast cancer in particular regions of Russia.

PC27
PROJECTING HEALTH GAINS: THE POPULATION IMPACT OF NEW TREATMENTS TO METASTATIC BREAST CANCER
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OBJECTIVES: Breast cancer is a leading cause of oncological death among Portuguese women but the standardized mortality rates is well documented and due to an increasing frequency of early diagnosis (more than 85% of the women aged 45–69 years, underwent a screening mammography according to the most recent Portugal Health survey) access to more efficient treatments, including adjuvant and neoadjuvant chemotherapy. However, certain tumor characteristics, such as Human epidermal growth factor receptor 2 (HER2)-positive breast cancer, are associated with poor prognosis for patients with both early and metastatic breast cancer, significantly prolonged progression-free survival. The study is based on an integrated dataset and the outcomes are presented by region and setting. The study was supported by the National Cancer Institute (NCI) and the European Society for Medical Oncology (ESMO) in order to promote evidence-based decision making.

METHODS: The study was based on an integrated dataset and the outcomes are presented by region and setting. The study was supported by the National Cancer Institute (NCI) and the European Society for Medical Oncology (ESMO) in order to promote evidence-based decision making.

RESULTS: Approximately 66% of the patients treated with a HER2-positive breast cancer (BC) were younger than 65 years, and 85% were younger than 75 years. The incidence of HER2-positive BC was similar across the different regions and countries. The patients with HER2-positive BC were more likely to be diagnosed at an early stage of the disease, with a median age of 60 years. The patients with HER2-negative BC were more likely to be diagnosed at an advanced stage of the disease, with a median age of 70 years. The patients with HER2-positive BC were more likely to receive chemotherapy, with a median number of 4 cycles. The patients with HER2-negative BC were more likely to receive hormonal therapy, with a median number of 6 months. The patients with HER2-positive BC were more likely to receive targeted therapy, with a median number of 3 months. The patients with HER2-negative BC were more likely to receive surgery, with a median number of 2 procedures.

CONCLUSIONS: The study provides evidence that patients with HER2-positive breast cancer are more likely to be diagnosed at an early stage of the disease and to receive chemotherapy, while patients with HER2-negative breast cancer are more likely to be diagnosed at an advanced stage of the disease and to receive hormonal therapy. The study also highlights the importance of targeted therapy and surgery in the management of breast cancer.

PC28
LONG-TERM TRENDS IN BREAST CANCER EPIDEMIOLOGY IN THE SLOVAK REPUBLIC
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OBJECTIVES: The study was based on an integrated dataset and the outcomes are presented by region and setting. The study was supported by the National Cancer Institute (NCI) and the European Society for Medical Oncology (ESMO) in order to promote evidence-based decision making.

METHODS: The study was based on an integrated dataset and the outcomes are presented by region and setting. The study was supported by the National Cancer Institute (NCI) and the European Society for Medical Oncology (ESMO) in order to promote evidence-based decision making.

RESULTS: The patients with HER2-positive BC were more likely to receive chemotherapy, with a median number of 4 cycles. The patients with HER2-negative BC were more likely to receive hormonal therapy, with a median number of 6 months. The patients with HER2-positive BC were more likely to receive targeted therapy, with a median number of 3 months. The patients with HER2-negative BC were more likely to receive surgery, with a median number of 2 procedures.

CONCLUSIONS: The study provides evidence that patients with HER2-positive breast cancer are more likely to be diagnosed at an early stage of the disease and to receive chemotherapy, while patients with HER2-negative breast cancer are more likely to be diagnosed at an advanced stage of the disease and to receive hormonal therapy. The study also highlights the importance of targeted therapy and surgery in the management of breast cancer.
using electronic hospital records. Survival was assessed using the Kaplan-Meier estimator. Recurrence patterns were investigated by type of first recurrence and time-to-recurrence. A multivariate cox regression was used to analyze whether time-to-recurrence was associated with gender, age and tumor thickness. Emigrated cancer registries, published scientific studies and proprietary physician surveys were used to assess and report the incidence of mCRPC patients. Among patients diagnosed mCRPC over the past year. Of these patients, 35% (26,400 patients) went on to receive supportive therapy and second generation Hormone Therapies (ADT). ADT manipulations were performed to forecast the AM population using historical rate data (1991-2012) and other population parameters including incidence rate annual percent change, stage at diagnosis, rates of disease progression and survival obtained through a comprehensive literature review and search of cancer registries. The time-to-recurrence was not statistically significantly associated with gender (HR = 0.81; p = 0.29), age (HR = 1.01; p = 0.38) and tumor thickness (HR = 1.23; p = 0.70). CONCLUSIONS: The results of long-term surveillance of stage IV patients among the cancer population (14.6%, n = 10,621). Consistently, this rate was even higher in patients diagnosed with pancreatic (28.7%, n = 362), liver (27.0%, n = 256) and endometrial cancer (21.7%, n = 161). CONCLUSIONS: This retrospective analysis showed that T2DM may increase the risk of diabetes among people with the diabetes and non-diabetic popula-

PCN30

EPILEPIDOMY OF PATIENTS WITH METASTATIC CAstrate RESISTANT PROSTATE CANCER IN EUROPE AND AUSTRALIA

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OBJECTIVES: The objective of this study was to evaluate both the incidence of metastatic Castrate Resistant Prostate Cancer (mCRPC) and the number of mCRPC patients who receive specific mCRPC treatments (mCRPC/TT): chemotherapy, endocrine, targeted therapy or endocrine and targeted therapy (ADT and ADT manipulations were not included).

METHODS: This study was conducted in 8 European countries and Australia. The incidence of mCRPC patients was assessed using several sources: national cancer registries, published scientific studies and proprietary physician surveys comprising 292 oncologists, 76 onco-radiotherapists and 357 urologists reported information about 417,71 prostate cancer patients. Of these, 2,400 had metastatic castrate resistant disease. Patient characteristics and treatments received were assessed and reported separated by country. RESULTS: Across all 9 countries, 76,200 new patients were diagnosed mCRPC over the past year. Of these patients, 35% (26,400 patients) went on to receive supportive therapy without recurrence. The time-to-recurrence was 2.5 years (minimum: 0.01 years; maximum: 9.8 years). The time-to-recurrence was not statistically significantly associated with gender (HR = 0.81; p = 0.29), age (HR = 1.01; p = 0.38) and tumor thickness (HR = 1.23; p = 0.70). CONCLUSIONS: The results of long-term surveillance of stage IV patients among the cancer population (14.6%, n = 10,621). Consistently, this rate was even higher in patients diagnosed with pancreatic (28.7%, n = 362), liver (27.0%, n = 256) and endometrial cancer (21.7%, n = 161). CONCLUSIONS: This retrospective analysis showed that T2DM may increase the risk of diabetes among people with the diabetes and non-diabetic popula-

PCN31

COMPARISON OF EPIDEMIOLOGY AND DRUG TREATMENT IN HER2 NEGATIVE METASTATIC BREAST CANCER (MBC) IN EU5

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OBJECTIVES: Explore differences/similarities in epidemiology and drug treatment of metastatic breast cancer (MBC) in EU5. METHODS: All data was derived from the Kantar database consisting of 17 cancer registries, published scientific studies and proprietary physician surveys comprising 85 doctors seeing 9,255 patients per month. Age and gender specific incidence rates, annual stage specific progression rates and annual stage specific survival rates are used to calculate total number of surviving patients at a specific stage up to 10 years after diagnosis. RESULTS: Prevalence of BC ranged between 41.73 per 100K population across EU-5. Among BC patients, prevalence of MBC was similar: 8% (UK, Italy) to 10% (Germany, France, Spain). Overall 62% of MBC patients were diagnosed with HER2-negative disease (56% Germany-70% France) Among these patients 35-40% had active disease and were treated with chemotherapy. Patients with triple negative disease had had fewer lines of treatment than did not triple negative. Patients who are HER2-negative generally receive between two and three lines of chemo therapy on average. Second line chemotherapy regimens varied. Capecitabine was the most common (mono or combination) in all countries (40%-66%); docetaxel from 36% (UK) to 40% (Germany). 3rd and 4th most common therapies were vinorelbine (23%-26%) and paclitaxel (20%-23%) in Germany, Italy and Spain vs. docetaxel (18%-34%) and paclitaxel (11%-19%) in UK and France. In third line, the most commonly used agents were capecitabine (16%-44%) and vinorelbine (18%-26%). Eribulin was used in second line (3%-6%) and third line (11%-19%) in all countries except for Spain. CONCLUSIONS: Capecitabine is the most utilized chemotherapeutic agent in the second and third lines chemotherapy in Western Europe. The overall incidence of various other regimens, primarily monotherapies, may also be used in later lines, including vinorelbine, gemcitabine, eribulin, and docetaxel.

PCN32

ASSOCIATION OF DIABETES AND CANCER DIAGNOSIS IN PRIMARY CARE PRACTICES IN FRANCE

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OBJECTIVES: Several studies suggest that diabetes carries an increased risk for a number of different cancer types. The aim of this study was to investigate the incidence of 14 different cancer types in the diabetic and non-diabetic popula-

PCN33

PATIENT COUNT PROJECTIONS FOR ADVANCED MELANOMA BY LINE OF THERAPY AND OTHER CLINICAL CHARACTERISTICS IN EU COUNTRIES: RESULTS FROM THE UK, GERMANY, FRANCE, ITALY AND SPAIN (EU-5)

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OBJECTIVES: To provide an updated estimate of the number of advanced melanoma patients in 8 European countries. METHODS: T2DM may increase the risk of diabetes among people with the diabetes and non-diabetic popula-

PCN34

A VALIDATED PREDICTION MODEL AND NOMOGRAM FOR RISK OF RECURRENCE IN EARLY BREAST CANCER PATIENTS

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OBJECTIVES: The objective of this study is to develop and validate a conditional logistic regression model for the prediction of locoregional recurrence (LRB) of breast cancer. To make a translation to clinical practice a web based nomogram was made. METHODS: Women first diagnosed with early breast cancer (without distant metastases) were investigated in the Netherlands Cancer Registry (NCR) between 2003-2006 for women diagnosed to stage IB and II, and an untreated group of the same age. Patients from 2018 are included in the nomogram. The nomogram was assessed, as well as the discrimination by means of the area under the ROC curve and calibration by the Hosmer-Lemeshow goodness-of-fit test in discriminative power. RESULTS: Prognostic factors for LR recurrence were tumor size, multifocality, and nodal involvement of the primary tumour, type of surgery, and whether patients were treated with radio-, chemoradio or hormone therapy. The modelling group showed a higher proportion of diabetic patients among the AM population using historical rate data (1991-2012) and other population parameters including incidence rate annual percent change, stage at diagnosis, rates of disease progression and survival obtained through a comprehensive literature review and search of cancer registries. The time-to-recurrence was not statistically significantly associated with gender (HR = 0.81; p = 0.29), age (HR = 1.01; p = 0.38) and tumor thickness (HR = 1.23; p = 0.70). CONCLUSIONS: The results of long-term surveillance of stage IV patients among the cancer population (14.6%, n = 10,621). Consistently, this rate was even higher in patients diagnosed with pancreatic (28.7%, n = 362), liver (27.0%, n = 256) and endometrial cancer (21.7%, n = 161). CONCLUSIONS: This retrospective analysis showed that T2DM may increase the risk of diabetes among people with the diabetes and non-diabetic popula-

A619

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SURVIVAL AFTER LOCOREGIONAL RECURRENCE OR SECOND PRIMARY BREAST CANCER: IMPACT OF THE DISEASE-FREE INTERVAL

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OBJECTIVES: The association between the disease-free interval (DFI) and survival after a locoregional recurrence (LRR) or second primary (SP) breast cancer remains uncertain. The objective of this study is to clarify this association to obtain more information on expected prognosis.

Methods: Women first diagnosed with early breast cancer between 2003-2006 were selected from the Netherlands Cancer Registry. LRRs and SP tumours within five years of first diagnosis were examined. The follow-up period was further broken down into more equal intervals. Prognostic significance of the DFI on survival after a LRR or SP tumour was determined using Kaplan-Meier estimates and multivariable Cox regression analysis. Follow-up was complete until January 1, 2013.

Results: A total of 36,255 women was included in the analysis, of which 1,646 (4.5%) patients: 55% developed a LRR and 45% SP breast cancer. Longer DFI was strongly and independently related to an improved survival after a LRR (longer versus short HR 0.63, 95% CI 0.56-0.71, median survival +8.4 months vs. +4.3 months). Other factors related to improved survival after LRR were younger age (<70 years) and surgical removal of the recurrence. No significant association was found between DFI and survival after SP tumours.

Conclusions: This is the first study to explore the association between the disease-free interval (DFI) and survival after LRR or SP breast cancer. The results of this study clarify the association between the DFI and survival after LRR in a large, homogeneous, non-selected breast cancer population.

LONG TERM SURVIVAL OF PATIENTS WITH VARIOUS LUNG CANCER HISTOLOGY IN SEER BETWEEN 2004-2011

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OBJECTIVES: Overall survival (OS) data from clinical trials in oncology are often incomplete, thus modelling over the lifetime horizon requires long term extrapolation and it is a critical input to cost-effectiveness studies. Data from the Surveillance, Epidemiology, and End Results (SEER) program may provide validation on the long term OS: the objective was to examine the parametric functions that best fit data in lung cancer (LC) of various histologies in SEER.

METHODS: SEER data (2004-2011) were analyzed for patients diagnosed with stage IV small cell, large cell, squamous cell, adenocarcinoma, and metastatic breast cancer. The DFI before a LRR is an independent prognostic factor for survival, with a longer DFI predicting better prognosis.

CONCLUSIONS: Long term survival of patients with various lung cancer histology was evaluated with SEER data and the Kaplan-Meier estimator. Life expectancy results were compared to the restricted mean life expectancy of patients in low volume hospitals had a HR of 1.08 (95%CI 1.00-1.16) influenced death, all to a larger extent than surgical volume. OS was extrapolated to estimate survival outcomes. Clinical inputs for comparator arms were informed by published literature.

ORAL ABSTRACTS: VALUE IN HEALTH 17 (2014) A323–A686

SImULATION mOdEL Of IBRUTINIB fOR CHRONIC LymPHOCyTIC LEUkEmIA (MCL)

Peng S, Sörensen S, Pan F, Dorman E, Sun S, Van Sanden S, Sengupta N, Gaudzi M

1Evira, Bethesda, MD, USA, 2Janssen, Pharmaceutical Companies of Johnson and Johnson, 3Janssen Pharmaceuticals, Inc, 4MIRA Institute for Biomedical Technology & Technical Medicine and University of Twente, The Netherlands

OBJECTIVES: For patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL), prognosis is poor, with a median survival of one to two years, and treatment options are limited. A620

CONCLUSIONS: In the Netherlands, surgical hospital volume influences 10-year overpowers or may marginally, and far less than patients and tumour characteristics.

SImULATION mOdEL Of IBRUTINIB IN TREATmENT Of RELAPSEd OR REFRACTORY MANTLE CELL LYMPHOMA (MCL)

Peng S, Sörensen S, Pan F, Dorman E, Sun S, Van Sanden S, Sengupta N, Gaudzi M

1Evira, Bethesda, MD, USA, 2Janssen, Pharmaceutical Companies of Johnson and Johnson, 3Janssen Pharmaceuticals, Inc, Neuus, Germany

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PCN38 SIMULATION MODEL OF IBRUTINIB IN TREATMENT OF RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA (MCL)

Peng S, Sörensen S, Pan F, Dorman E, Sun S, Van Sanden S, Sengupta N, Gaudzi M

1Evira, Bethesda, MD, USA, 2Janssen, Pharmaceutical Companies of Johnson and Johnson, 3Janssen Pharmaceuticals, Inc, Neuus, Germany

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1Evira, Bethesda, MD, USA, 2Janssen, Pharmaceutical Companies of Johnson and Johnson, 3Janssen Pharmaceuticals, Inc, Neuus, Germany

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CONCLUSIONS: In the Netherlands, surgical hospital volume influences 10-year overpowers or may marginally, and far less than patients and tumour characteristics.
CANCER – Cost Studies

PCN41

BUDGET IMPACT ANALYSIS OF AFLIBERCEPT IN THE TREATMENT OF METASTATIC COLORRECTAL CANCER (mCRC) IN POLAND

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OBJECTIVES: To estimate the budget impact resulting from the introduction of aflibercept for the treatment of metastatic colorectal cancer (mCRC) within the SHI program in Poland. METHODS: Analysis was performed in 3-year time horizon (2014-2016) from the public payer (NHF) perspective. Target population is defined as adult patients with mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen (including patients with distant relapse within 6 months of completion of oxalipatin-based adjuvant therapy). Eligible patient population was estimated by compilation of following data: epidemiological studies, local market study, IMS data, survey among Polish oncologists. Market shares of different regimens (aflibercept 4 mg/kg + FOLFOX4, bevacizumab 10 mg/kg + FOLFOX4 – FOLFIRO) were projected on the NHF data and experts’ opinion. Cost following categories were included: drug acquisition and administration (anti VEGF, chemotherapy drugs, antibiotics, and adverse events (grade 3-4)). RESULTS: With the introduction of aflibercept, estimated annual number of patients starting aflibercept treatment will be 90, 209 and 224 in year 2014, 2015 and 2016, respectively. Total annual expenditures in year 2014, 2015 and 2016 were calculated to be 109.3, 40.3 and 41.2 million PLN in scenario without aflibercept, compared to 37.4, 3.49 and 35.0 million PLN, respectively, with the introduction of aflibercept. In case of aflibercept introduction, reimbursement, the NHF would save 1.9 million PLN in year 2014, 5.3 million PLN in year 2015 and 24.4 million PLN in year 2016. CONCLUSIONS: The introduction of aflibercept would result in savings for the NHF in Poland, mainly as a consequence of reduced pharmacological costs compared to bevacizumab.

PCN42

ESTIMATING THE ECONOMIC IMPACT OF SORAFENIB IN TREATMENT OF LOCALALLY RECURRENT METASTATIC, PROGRESSIVE, DIFFERENTIATED THYROID CARCINOMA (DTC) THAT IS REFRACTORY TO RADIOACTIVE IODINE (RAI) TREATMENT

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OBJECTIVES: Sorafenib, a multikinase inhibitor, received Food and Drug Administration (FDA) approval in 2013 for treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory (RAI-r) differentiated thyroid carcinoma (DTC). A budget impact model (BIM) was developed from a United States (US) payer perspective to estimate the costs of adding sorafenib to the set of available treatments in a hypothetical health plan in the RAI-r DTC population. METHODS: An Excel-based BIM evaluated costs of RAI-r DTC with other FDA-approved and condemned-recommended treatments using baseline and projected market shares. Clinical inputs included the prevalence of RAI-r, average monthly dosage, and average duration of sorafenib and other FDA-approved and condemned-recommended treatments. Economic inputs for each treatment included the wholesale acquisition cost (WAC) per dose and hospital administration costs per month. A net per-month cost to the payer for sorafenib was $6,872. Laboratory testing costs were derived from product-specific package administration costs per month. A net per-month cost to the payer for sorafenib resulted in better health outcomes, increamentally increasing LYS by 0.79. Ibrutinib was also associated with increased ofatumumab, which lead to 0.47 incremental QALYs. In a 10 year time horizon by 0.63 and progression-free LY by 0.87 over a 5-year time horizon compared to ofatumumab alone. In the model, ibrutinib was more cost-effective than sorafenib to the set of available treatments in a hypothetical health plan in the RAI-r DTC population.

PCN43

ESTIMATING OUTPATIENT PHARMACEUTICAL EXPENSE COST IN TREATMENT OF AML IN GERMANY

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OBJECTIVES: To allow budget-holders to project the impact of new drugs in Germany, we forecasted future outpatient pharmaceutical expenditure for cancer treatment from the perspective of the statutory health insurance (SHI) for 2016. METHODS: Based on data of the Techniker Krankenkasse (TK), a large German sickness fund with more than 8.2 million insured, we forecasted pharmaceutical expenditure for 12 cancer indications in 2016 (according to ICD-10: C16, C18-21, C22, C26.9/C49.9, C34, C43, C50, C56, C61, C73, C90, C91.1). To extrapolate results to whole Germany, we adjusted for differences in demographics of insured between TK and SHI using publicly available data, i.e. KM6 statistics. We also incorporated trends in membership to SHI. To assess the impact of new drugs, we obtained expert opinions from clinicians in 37 hospitals on 0.47 incremental LYs and 0.47 incremental QALYs of drug launched in the German market, (b) the expected prices of new drugs and (c) the extent to that new drugs will replace existing pharmaceuticals. For calculations, we assumed that newly launched drugs will reach on average a diffusion of 25% of their market potential until 2016. RESULTS: According to our model, SHI outpatient pharmaceutical expenditure for these 12 cancer indications was million €2,780 in 2012, i.e. 9.5% of total outpatient pharmaceutical expenditure. In 2016, we expect annual pharmaceutical expenditure for these indications to increase by 17.2% to million €2,256. Of the 25 new drugs identified to be launched until 2016, 10 will at least partly replace existing pharmaceutical treatments. Thus, million €526 of our budget estimate will be due to new drugs, 2,650 million will be due to pharmaceuticals that were already launched in 2014. Thus, 392 million will be due to generic drugs. CONCLUSIONS: The expected increase in costs for cancer drugs are a financial challenge for German SHI. Whether benefit of new drugs and expected costs can be considered fair value needs to be investigated elsewhere.

PCN44

BUDGET IMPACT ANALYSIS OF EVEROLIMUS FOR THE TREATMENT OF HORMONE RECEPTOR POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR-2 NEGATIVE (HER2-) ADVANCED BREAST CANCER IN KAZAKHSTAN

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OBJECTIVES: To determine the budget impact of everolimus (in combination with letrozole/anastrozole) as a second line treatment for ER+ HER2-advanced breast cancer and metastatic breast cancer in postmenopausal women in Kazakhstan. METHODS: A cumulative cohort model was developed to estimate the five-year costs associated with introducing everolimus to the Kazakh health care system, with two scenarios: patients “with everolimus” and “without everolimus”. Treatment-specific PFS and OS data were extrapolated from trial data using a Weibull function. It was assumed that data from the BOLERO-2 trial (everolimus+exemestane vs exemestane alone) were representative of everolimus+letrozole/anastrozole or letrozole/anastrozole alone, chemotherapy and tamoxifen. RESULTS: The within-trial data from BOLERO-2 reported 17 month OS of 74.7% and 67.6% for everolimus+exemestane and exemestane alone, respectively. The five year results was reported in BOLERO-2 Trials were 77% and 70.70 for everolimus+exemestane and exemestane alone, respectively. The five year results demonstrate that the introduction of everolimus leads to a 12% increase in drug costs, a 2% reduction in pre-progression health state costs, a 1% increase in post-progression health state costs and 2% reduction in hospital costs. The net result is a 2% increase in total costs, from T16.97 billion to T17.389 billion over a period of five years. CONCLUSIONS: The analysis estimated that, if everolimus were to be introduced to the Kazakh health care market for the treatment of ER+ HER2-advanced breast cancer, there would be a small impact upon overall health care expenditure. An increase in drug acquisition costs was largely offset by a reduction in other health care costs due to improved disease management.

PCN45

BUDGET IMPACT ANALYSIS OF CYCV219 GENOTYPING TO TARGET VORICONAZOLE PROPHYLAXIS DURING INDUCTION-CONSOLIDATION THERAPY IN ACUTE MYELOID LEUKEMIA (AML) IN THE UNITED STATES

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OBJECTIVES: To assess the impact of genotyping acute myeloid leukemia (AML) patients for CYCL219*17 gene variant status prior to induction-consolidation therapy from the perspective of a United States (U. S.) payer. METHODS: Developed to aid U. S. payers regarding the budgetary impact of DNA genotyping, this model examines the predicted economic outcomes of a hypothetical cohort of 100 neuropenic AML patients under two alternatives: (1) standard voriconazole prophylaxis and (2) targeted voriconazole prophylaxis. Published literature from CYCL219*17 gene variant status among the general population may have at least one “17” allele. The presence of the CYCL219*17 allele results in more rapid metabolism and clearance of voriconazole, which is known to lead to undertreatment of the target gene group men. The incidence of invasive fungal infection is 15% without effective prophylaxis and is reduced to 6.6% upon adequate prophylaxis. Targeted prophylaxis based on genotyping prescribes an alternative drug or higher voriconazole dose in patients with a “17” allele. Further research and development is needed in this literature and 2014 CMS Laboratory Fee Schedule. RESULTS: The average total cost of care for AML patients receiving standard versus targeted voriconazole prophylaxis was $46,795 and $46,385 per patient, respectively. In addition to the $410 saved per patient, the number of invasive fungal infections was reduced from 6.6 to 4.3
by targeting prophylaxis based on patient genotype. The deterministic sensitivity analysis showed that the savings is more dependent on the incidence of invasive fungal infection, cost of treating an invasive fungal infection, and frequency of “+” infection in the population. CONCLUSIONS: Genotyping AML patients for CYP2C19*17 prior to induction-consolidation is expected to be cost-neutral or potentially cost-saving by reducing the incidence of invasive fungal infections and administering prophylactic azoles. These results may mitigate potential budgetary concerns, thereby reducing barriers to a test that can be clinically beneficial to AML patients.

PCN46 BUDGET IMPACT ANALYSIS OF THE INTRODUCTION OF NEW THERAPEUTIC AGENTS FOR THE TREATMENT OF METASTATIC CASTRATION RESISTANT PROSTATIC CANCER (mCRPC) PATIENTS AFTER DOXETAXEL FAILURE IN THE BRAZILIAN PRIVATE HEALTH SYSTEM
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OBJECTIVES: In the latest years several drugs demonstrated to increase survival in mCRPC patients post chemotherapy failure. However, issues related to the treatment sequencing of these drugs. The aim of this study is to estimate the budget impact of the introduction of enzalutamide in the Brazilian setting from public health care institution perspective.

PCN47 BUDGET IMPACT MODEL OF CEPLENE® AS MAINTENANCE THERAPY IN ADULT PATIENTS WITH ACUTE MYELOID LEUKEMIA IN FIRST REMISSION
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OBJECTIVES: To assess the economic impact of Ceplene® with low-dose Interleukin-2 (IL-2) for the treatment of adult patients with Acute Myeloid Leukemia (AML) in first complete remission (CR1) which previously received chemotherapy in Spain.

PCN50 BUDGET IMPACT ANALYSIS OF RITUXIMAB FOR CHRONIC LYMPHOCYTIC LEUKEMIA: THE CASE OF BRAZILIAN PUBLIC HEALTH
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BACKGROUND: Chronic Lymphocytic Leukemia (CLL) is a malignant disease incurable by the lymphoid system, that affects predominantly elderly, especially in Western countries. Your treatment when necessary is based on the administration of chemotherapy with association of Fludarabine plus cyclophosphamide (FC), the most widely used schema. Recently the addition of rituximab, a monoclonal antibody has been associated with this scheme, known as FCR. OBJECTIVES: To elabo- rate a budget impact analysis (BIA) of rituximab for chronic lymphocytic leukemia for help the decision making. METHODS: A BIA of association of Fludarabine plus cyclophosphamide in SUS compared to rituximab with this scheme was performed. The analysis’ time horizon was 5 years, using a CLL prevalence of 4.4% and 25% of CLL refractory between them (1.6%), considering an annual growth rate of 0.814% and a market share of 25% and 75% according the classification of diagnosis and stage of Rai & Keating. The mean total rituximab dose considered was 375/mg/ month, an average personal weight and size of 70kg and 1.70m, which means €81.75 mp per cycle. All cost purchase prices and remission rate of rituximab (22%) are already covered.

PCN51 BUDGET IMPACT ANALYSIS OF EVEROLIMUS PLUS EXEMESTANE VERSUS GEMCITABINE PLUS PLATINAXEL AND CAPECITABINE PLUS DOXETAXEL IN METASTATIC BREAST CANCER PATIENTS IN EGYPT
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1Ministry of Health, Faculty of Pharmacy Helwan University, Cairo, Egypt, 2Central Administration for Pharmaceutical Affairs, Cairo, Egypt, 3Ministry of Health, Cairo, Egypt
OBJECTIVES: To estimate the budget impact of everolimus-exemestane versus the most commonly used regimens in the Egyptian practice, gemcitabine-platinaelix and capecitabine-doxetaxel for a health care plan that introduces everolimus for post-menopausal hormone receptor positive, human epidermal growth fac- tor (HER2) negative metastatic breast cancer (HR-HER2) patients. RESULTS: The estimated annual health care costs were estimated based on the annual per patient cost, the ability of overall survival without or with a relapse, and death without relapse, as estimated for both treatment options and no treatment depending on the prob- ability of overall survival without or with a relapse, and death without relapse as well as the duration until relapse or death without relapse during this period. Total annual health care costs were estimated based on the number of patients per cost, the target population, and the market shares associated with each option, before and after the introduction of Ceplene®/IL-2. RESULTS: Patients eligible for Ceplene®/ IL-2 were estimated to increase up to 1,509 in 2016. The overall budget impact with the introduction of Ceplene®/IL-2 was estimated to decrease with €674,149 and €728,945 in 2014 and 2016, and an increase of €202,322 in 2015. Overall budget impact savings over the period 2014-2016 are estimated at €1,130,894. CONCLUSIONS: The introduction of Ceplene®/IL-2 as maintenance therapy suppresses savings in the budget impact for the treatment of AML patients in CR-1 in Spain. Ceplene®/IL-2 is expected to fulfil a direct medical need for patients not eligible or having an unfavourable profile for an unrelated allo-HSCT receiving no treatment, and those who are treated with standard treatment and all other LC patients are treated with standard treatment. RESULTS: 81 and 17 ALK + advanced NSCLC patients were identified in IMSS and ISSSTE, respectively. Total budget impact “without” and “with” one-year time horizon is €50.3 and €52.9 million, respectively, for IMSS. For ISSSTE, total costs were €10.5 versus $11.1 million. The combined incremental budget impact across both public health care institutions is 5.2. CONCLUSIONS: Crizotinib, the only drug approved for the treatment of ALK + Lung cancer patients in Mexico, has a significant incremental budget impact on the overall expenditure within the two main Mexican public health care institutions.
OBJECTIVES: Cancer patients undergo a wide range of laboratory procedures, from simple blood tests to complex molecular diagnostics. In cost-effectiveness analyses, the costs of laboratory testing are often ignored or estimated inaccurately. We present real-world costs of laboratory procedures for non-small cell lung cancer (NSCLC) patients, per category of laboratory testing.

METHODS: In a Dutch academic hospital, all laboratory orders were matched with unit costs per test obtained from the Dutch Health Authority. RESULTS: 1,015 patients were included, with a total of 171,632 laboratory procedures. 392 different types of tests were performed. Mean cost for laboratory testing was €1,175 (95% CI 1,066-1,283) per patient. For cost allocation and modeling purposes, cost per month with laboratory testing (€247,926, 95% CI 247-260) and cost per day with laboratory testing (€246, 95% CI 241-250) are presented. Costs are mainly driven by (molecular) pathology (46%), other (25%), mainly ordering processing fees and clinical laboratories (15%). To high test volumes is 25% of Brazil population). On the other hand, when pegfilgrastim or pegteograstim are not used, the incidence rate of FN is 25% of Brazil population). On the other hand, when pegfilgrastim or pegteograstim are not used, the incidence rate of FN will be underused, thus depriving patients from a technology that could improve their quality of life and using resources that could be freed up for other patients.

OBJECTIVES: To evaluate the budget impact of pneumonia in patients with previous metastatic breast cancer in Brazil. The objective of this study was to estimate the incremental Budget Impact (BI) and survival benefit of utilizing eribulin for treatment of Metastatic Breast Cancer (MBC) in Brazil. The efficacy of pegylated granulocyte colony stimulating factor (pegfilgrastim) to reduce the risk of febrile neutropenia (FN) from chemotherapy for breast cancer with moderate risk compared to a standard treatment with antibiotics and G-CSF after occurrence of FN. METHODS: The efficacy of pegylated recombinant human granulocyte colony stimulating factor (pegfilgrastim) to reduce the risk of FN was 39.5% in the control group, while it was 3.04% in the pegfilgrastim group. Pegteograstim (Neulag®) was shown to be non-inferior compared to pegfilgrastim in the phase three clinical trial, so the resulting incidence rate of FN was 25% of Brazil population).

RESULTS: When assuming an average incidence rate of 20% of FN, the cost of eribulin would be BRL4,884.80 per patient, which is a 6% decrease with pegfilgrastim as per pegteograstim. Therefore, when estimating the sum of the costs of pegfilgrastim, pegteograstim and the average cost of hospitalization, the total cost is €5,757.16 per patient. This is €4,599,687 for NSCLC patients are substantial. Relatively simple blood tests contribute significantly to these costs due to high test volumes. Main cost driver however is molecular testing by the pathologist, for the use of targeted therapies. In pharmacoeconomic evaluations, taking laboratory costs into account significantly impacts results, especially when testing practices differ between treatment alternatives.
of progression-free survival (PFS) curves for dabrafenib and vemurafenib, from their respective registration trials in 1st-line APL treatment. ATO was approved in 2014, rising to €5,318,000 in the scenario with vemurafenib. Budget impact analysis for a 3-year period revealed that introduction of dabrafenib would save the national Sick Fund 900 vs. 2,800 for AIDA. However, direct medical (DM) costs for ATO were €1,109 versus €8,420 (histological review). Of these, 341 patients were found to have a discordant diagnosis. Ten patients were excluded due to missing data. The costs reached €8,420 (histological review) when disease management was based on ATO vs. €7,360 when not. CONCLUSIONS: In addition to the positive impact of centralized histological reviews on the quality of diagnosis for sarcoma, GIST, and desmoids tumors, our model demonstrated that histological reviews lower the cost of disease management for the French NIH.

PCN62 A COST-ANALYSIS OF COMPLEX RADIOTherAPY IN PATIENTS WITH HEAD AND NECK CANCER RESULTS FROM THE ART-OL study
Perrier L1, Morelli M2, Fommi F3, Boisselier P4, Lartigu E5, Gallocher O6, Alfonso M3, Bardet E7, Rives M4, Calaguero V5, Chajon E6, Noel G7, Mecelle H8, Perlot D9, Dussart D10, Girard S11,
1Can’Cercentre Léon Bérard, Lyon, France, 2Can’Cercentre Léon Bérard, Lyon, France, 3Institut Régional de Cancérologie de Montpellier, Montpellier, France, 4Centre Oscar Lecanuet, Lille, France, 5Groupe OncoRad Garonne, Toulouse, France, 6Institut Sainte Catherine, Avignon, France, 7Centre d’Analyses Biologiques, Saint Herblain, France, 8Institut Claudius Regaud, Toulouse, France, 9Institut Curie, Paris, France, 10Centre Eugène Marquis, Rennes, France, 11Centre Paul Strauss, Strasbourg, France, 12Institut de Cancérologie de Lorraine, Vandaveure-lès-Nancy, France, 13Hôpital Européen Georges Pompidou, Paris, France.

OBJECTIVES: A cost analysis investigating TomoTherapy® (Accuray), Elekta Volumetric-modulated Arc Therapy (VMAT®) and Varian RapidArc® was conducted in 21 patients with head and neck cancer. The cost-analysis, funded by the National Institute of Cancer (INCa), was performed prospectively based on a multicenter study. Cost calculations were strictly based on a micro costing approach according to the hospital’s information system. Only resources which are likely to vary between the strategies being compared were considered. Data on consumption of resources were collected from the treatment planning until the last irradiation session. Productivity losses of radiotherapy involved personnel related to organizational constraints or absenteeism, costs of administrative personnel, costs of logistics and general management were not taken into account. All costs were given in 2013 euros. Numbers of irradiation sessions were compared using Kruskal-Wallis test. Uncertainty was captured by one-way and probabilistic sensitivity analyses using a non-parametric bootstrap method.

RESULTS: 174 patients were enrolled in 16 French centers from February 2010 to February 2012. 13 economic questionnaires were exploitable. The mean numbers of sessions were 34.33 (SD: 2.90) for TomoTherapy® (n=73) and 34.33 (SD: 2.57) for Varian RapidArc® (n=92; p=0.0603). Eight patients were treated with Elekta Volumetric-modulated Arc Therapy (VMAT®). For irradiation (all sessions included), the over cost of TomoTherapy® (n=73) reached €1,109 per patient compared to Varian RapidArc® (n=92). Sensitivity analyses showed that the annual operating time of the accelerators played a major role in irradiation costs. CONCLUSIONS: This is to our knowledge the first study highlighting costs incurred by different intensity-modulated Arc Therapy (IMAT) modalities in this setting. Costs of TomoTherapy® appeared more expensive than RapidArc®. The study should be now completed by a cost-effectiveness analysis in order to shed further light on which modality to focus on.

PCN63 COST-CoMPEtITIVE TREATMENT PATHWAYS OF DIFFUSE LARGE B CELL LYMPHOMA IN A UK POPULATION-BASED COHORT: A PATIENT LEVEL SIMULATION MODEL
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OBJECTIVES: Diffuse large b-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma and treatment is usually given with curative intent. Using restricted datasets derived from clinical trials, previous studies examining the cost of treating this cancer have generally focused on first-line therapy alone, meaning...
that their findings can neither be extrapolated to the general patient population nor to treatment pathways based on different clinical settings. Based on the empirical and patient-based cohort, the objective of this study was to develop a simulation model that could predict costs at an individual level and estimate the real medical costs of treating DLBCL. METHODS: All patients newly diagnosed with DLBCL in the UK’s population-based Malignany Research Network (www.hmn.org) in 2007 were followed until 2013 (n=271). The mapped treatment pathways, alongside cost information derived from the National Tariff 2013/14, were used to predict a patient level simulation model to reflect the heterogeneities of patient characteristics and treatment options. RESULTS: The expected total medical costs were £23,184 for the second line and the third line treatments respectively. The predicted costs captured 94% of the actual costs and the proportion of patients simulated in each economic health state was identical to the empirical data, supporting the validity of the model. CONCLUSIONS: This is the first cost modelling study to use empirical data to provide ‘real world’ evidence to estimate medical costs of entire DLBCL treatment pathways. Future application of the model developed here could be used to evaluate new treatment pathways. Support health care decision makers, especially in the era of personalised medicine.

PCN64 Cost-Effectiveness Analysis of an Apoptogen Regimen versus a Standard Antiemetic Regimen: A Sample Size and Power Analysis

Objectives: Prevention of chemotherapy-induced nausea and vomiting (CINV) remains a challenge for patients receiving cytotoxic therapy. The objective of this study was to assess, from the Italian National Health Service perspective, the costs of an antiemetic regimen using aprepitant, a selective neurokinin-1 receptor antagonist, for patients receiving chemotherapy who are at high risk of emetogenesis.

Methods: A decision-analytic model was developed to compare an aprepitant regimen (aprepitant, ondansetron, and dexamethasone) with a standard antiemetic regimen (ondansetron and dexamethasone) using data from controlled clinical trials and cost data from the Italian National Health Service. The model was populated with clinical results from a recent study conducted at a single hospital in Italy, and the costs were based on data from an Italian price database.

Results: The model was used to estimate the cost-effectiveness of the aprepitant regimen compared to the standard regimen over a 5-week period of time. The results showed that the aprepitant regimen was more effective in preventing CINV compared to the standard regimen, but it also had higher costs. The incremental cost-effectiveness ratio (ICER) was found to be £737 per quality-adjusted life year (QALY) gained. This suggests that the aprepitant regimen is cost-effective compared to the standard regimen.

Conclusions: The results of this study suggest that the aprepitant regimen could be a cost-effective option for patients receiving chemotherapy who are at high risk of emetogenesis. Further studies are needed to confirm these findings and to evaluate the long-term cost-effectiveness of the aprepitant regimen.

PCN65 Cost-Effectiveness of Non-small Cell Lung Cancer (NSCLC) Treatment Standards in Vietnam

Objectives: Evaluate and compare the cost of non-small cell lung cancer (NSCLC) treatment by Vietnamese and European standards. The analysis has been conducted based on the perspective of health insurance companies, therefor only medical direct costs, including cost for drugs and medical services has been evaluated. The list of medical services and drugs was derived from NCCN Clinical Practice Guidelines in Oncology (NCCN therapy) and Lung Cancer Therapy of Vietnam National Cancer Hospital (Vietnam therapy) treatment based on clinical researches and consultation with experts. The costs of drugs and medical services has been averaged from the relevant medical services of some major hospitals in Vietnam.

Methods: The total treatment costs increase following the severity of stage whether treatment was implemented by Vietnamese or European standards. Moreover, in all stages of disease, the total treatment costs of NSCLC by Vietnamese standard are less than that by NCCN standard and 74.92% by Vietnamese standard, which is almost 3 times higher than that of medical services.

Results: The highest mean annual costs of melanoma incurred higher expenditures, including carrier ($3,527 vs. $1,324), DME and pharmacy benefits 1 year pre- and post-index date. One-to-one propensity score matching (PSM) was performed to compare follow-up health care costs and utilities between the cohorts, adjusting for demographic and clinical characteristics. The results showed that the Vietnamese cohort incurred higher expenditures than the European cohort, but there was no statistically significant difference in health care utilisation.

Conclusions: Patients diagnosed with melanoma had a higher burden of illness compared to the comparison cohort of non-melanoma patients.

PCN67 Assessing the Economic Burden and Health Care Utilisation of U.S. Medicare Patients Diagnosed with Melanoma

Objectives: To examine the economic burden and health care utilization of melanoma patients in the U.S. Medicare population. Methods: A retrospective cohort study using U.S. National Medicare claims data with study period of 01Jan2008 to 31Dec2012. Melanoma patients were identified using International Classification of Disease 9th Revision Clinical Modification (ICD-9-CM) diagnosis code 172. The first diagnosis date was designated as the index date. A comparator group was created, consisting of patients with the same age, region, gender, and clinical stage as the index cohort. The total medical costs were measured in 2013 and expressed in 2016 constant dollars.

Results: The median total medical costs were $36,378 for the index cohort, $17,157 for the comparator group, and $18,313 for the entire cohort. The total medical costs were higher for both the index and comparator groups compared to the entire cohort, with a 17.1% and 17.9% increase respectively. The median total medical costs were also higher for the index cohort compared to the comparator group, with a 6.3% increase.

Conclusions: Patients diagnosed with melanoma had a higher burden of illness compared to the comparison cohort of non-melanoma patients.

PCN68 Resource Use and Health Care Costs of Cervical Lesions and Cervical Cancer in Slovakia

Objectives: To assess the resource utilisation and cost of cervical lesions and cervical cancer in Slovakia and to provide a basis for cost-effectiveness evaluations.

Methods: The cross-sectional survey was performed to obtain the information on the management of patients with cervical lesions (Low Grade Squamous Intraepithelial Lesion (LSIL), High Grade Squamous Intraepithelial Lesion (HSIL), Atypical Squamous Cells of Undetermined Significance (ASCUS), Cervical Intraepithelial Neoplasia (CIN) I-III) and cervical cancer (clinical stages A1 to IB2) and to estimate the direct costs of the disease management. All types of health care used in the management of cervical lesions/cancer were evaluated (diagnostics, treatment and follow-up). Average costs per patient were assessed on a yearly basis and correspond to the prices in 2013.

Results: Concerning the cervical lesions, the highest mean annual costs were identified in the CIN II (€3,431.23) and CIN III (€3,431.23) stages. Concerning cervical cancer, the highest mean annual costs were identified in the stage IB2 (€11,096.17). The highest mean annual costs were identified in the stage IIIB (€11,096.17) and IVA (€11,096.17). The most expensive treatment (including surgery, radiotherapy, concomitant chemoradiotherapy and palliative chemotherapy) was identified in the stage IIIB (€36,318.23) and IVA (€36,318.23). In the most advanced stages IVA and IVC, the treatment expenses were lower. Follow-up management was the most expensive in the stage IVA (15%, €31,643).

Conclusions:
In the management of cervical lesions/cervical cancer, the most expensive are the costs of treatment.

PCN9 ECONOMIC BURDEN OF MELANOMA IN THREE EUROPEAN COUNTRIES: A RETROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: To estimate cost-of-illness data associated with treatment of patients with stage IIIB/IIIC melanoma with macrometastases involving lymph node involvement in France, Germany and the United Kingdom (UK), whose primary melanoma and regional lymph node metastases had been completely resected. METHODS: This retrospective observational study enrolled patients aged ≥ 18 years, first diagnosed between January 1 October 2009 and 31 December 2011. Data were extracted from medical records and via patient survey. Costs were calculated in Euros (€) via patient survey. Costs were calculated in Euros (€) and 2012. Results: A total of 3,180 deaths in 2012 totaled 25,071 representing 4.5% of years lost generated by all deaths in Portugal in 2012 were caused by NSCLC, which corresponds to 2.0% of the total

A626
PCN75
REAL WORLD MANAGEMENT AND COSTS IN UNRESECTABLE METASTATIC MELANOMA (uMM) PATIENTS TREATED AT THE ANTWERP UNIVERSITY HOSPITAL (UZA)
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OBJECTIVES: To assess the management and associated lifetime costs in uMM patients as from the diagnosis of unresectable metastatic disease until death.
METHODS: We performed a retrospective patient chart review to obtain data on medical consumption related to the management of uMM. A complete registry of all patients diagnosed with melanoma at UZA between 2007 and May 2014 was used. Inclusion criteria for this retrospective registry were: uMM with sufficient data available and who deceased before May 2014. Data on demographics, disease characteristics and management of uMM were collected. Direct costs were calculated by multiplying each item of resource use with its unit cost (2013, €) using the Belgian public health care payer’s perspective (PHCP) and patient’s perspective. Average (bootstrap 95%CI) overall costs per patient were calculated. Costs were presented as median and 95% confidence intervals.
RESULTS: About 87% of the patients received a total of 3 cycles of treatment. Costs per cycle of treatment administration. Mean overall cost/patient was €93,537 (95% CI: 81,710-105,346) for patients treated with “new drugs”, €45,297 (bootstrap 95% CI: 33,905-57,550), of which €44,346 (95%CI: 33,098-56,584) was reimbursed. The PHCP cost was driven by systemic treatments costs (51% of cost). Mean PHCP cost was €93,537 (95% CI: 81,710-105,346) for patients treated with “new drugs”, €36,564 (95% CI: 20,688-32,999) for patients treated with chemotherapy but no “new drugs”, and €7,394 (95 % CI: 5,490-9,472) for patients on best supportive care (BSC) only. Median overall survival was 6 months (9 months, 52 months, 1 month for patients treated with “new drugs”, with BSC only and with “no new drugs”, respectively).
CONCLUSIONS: Management of uMM results in considerable costs for the PHCP, mainly driven by systemic treatment costs.

PCN76
BURDEN OF DISEASE OF THE MASTOCARCINOMA IN AUSTRIA
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OBJECTIVES: Breast cancer or rather called mastocarcinoma, is a malignant growth of the mammary gland. With an incidence rate of 5.105 people in 2010, breast cancer is the most frequent cancer disease in Austria. Annually about 1.500 cases of death are registered, therefore breast cancer is the leading cause for death among women. As a result, enormous costs arise for the health care system. Hence, the aim of the analysis was to perform a disease study, which evaluates all kinds of disease burden, like costs, quality adjusted life years (QALYs) and disability adjusted life years (DALYs) lost, was conducted. This analysis had an incidence based approach and projects costs over a time horizon of one year. Data were based on a literature review, published lists price and hospital records. Costs from published sources were used from the societal perspective. The direct costs cover hospital, treatment and physician consultation costs. Indirect costs cover patient care giver costs as well as work absence. RESULTS: Each breast cancer patient causes direct costs of €6,423.91 and indirect costs of €37,511.87 EUR. Due to the fact that not only costs are important for the health care systems, the mortality rate, QALYs and DALYs were identified. The mortality rate of breast cancer conducts 7.7 percent of all cancer deaths in Austria. Compared to the healthy population, a breast cancer patient has average utility decrements of 0.11. With an incidence rate of 5.105 people in 2010, a breast cancer patient will lose 0.561 quality adjusted life years within one year.
CONCLUSIONS: The analysis showed that the treatment of new diagnosed breast cancer patients causes about 225.5 million EUR. Moreover patients had a lower QALY of 0.561,55 and a loss of 153,15 DALYs within one year.

PCN77
ECONOMIC BURDEN OF ASTHMA IN VIETNAM: AN ANALYSIS FROM PATIENTS’ PERSPECTIVE
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OBJECTIVES: Health care costs of asthma are under pressure in all countries due to high prevalence, incidence and the chronic nature of disease. Estimating the economic burden of asthma from patients’ perspective is necessary not only to understand the value and structure, but also the economic influence of asthma to patients and their families and society is significant. According to the study, determining more public health efforts to better control asthma is the first necessary step to reduce the costs of asthma.

PCN78
ECONOMIC BURDEN OF DISEASE IN FRANCE IN 2012: A TOP-DOWN ALLOCATION OF HEALTH CARE EXPENDITURE BY DISEASE BASED ON THE FRENCH HEALTH INSURANCE DATABASE (SNIIRAm)
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OBJECTIVES: The aim of this study is to assess health care expenditure by disease in order to provide detailed analyses of resource allocations for 2012, based on the French health care system database. METHODS: Using information about 50 million individuals for the French population, we identified all people who received care for each of 56 groups of diseases or medical events or treatments, which are frequent, severe and expensive and applied to each patient’s medical diagnoses. Costs of long-term chronic diseases or hospital stays, specific drugs or medical procedures. Costs of all reimbursed expenditures (outpatient/inpatient care, disablement and disability benefits) were extracted per individual for a top-down method allocated expenditure to each of the 56 diseases based on the average expenditure by disease calculated for individuals with only one disease. All expenditures were thereafter extrapolated to the whole population to fit national health accounts. RESULTS: In 2012, the 146 billion euros (all insurance schemes), 22.1 billion (15%) were related to psychiatric disorders and treatments, 14 (10%) to cancer, 14.6 (10%) to cardiovascular diseases, 7.5 (5%) to diabetes, 6.6 (5%) to vascular-risk treatments, 6.1 (4%) to neurologic disorders, 3.2 (2%) to chronic respiratory diseases, 4.7 (3%) to inflammatory/rare diseases/HIV, 3.5 (2%) to treated chronic renal insufficiency, 1.4 (1%) to liver/pancreas diseases, 1.5 (1%) to chronic pain killer users and 3 (3%) to other long-term chronic diseases. Hospitalizations represented 32.8 billion (23%), basic care 14.6 (10%) and maternity 9.6 (1%). This analysis also provides detailed patterns of expenditures by diseases. CONCLUSIONS: Our study provides helpful information to policy makers by revealing the performance of the French health care system at a disease-based level. This tool will be used to forecast the impact of ageing and epidemiologic patterns on health expenditures.

PCN79
THE BURDEN OF HEALTH CARE COSTS ASSOCIATED WITH PROSTATE CANCER IN IRELAND
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OBJECTIVES: To derive average costs for PCa diagnosis, treatment and follow-up, and stage was estimated at 45,297,867 (CI: 43,010-47,584) for patients diagnosed with prostate cancer (PCa) in Ireland, yielding one of the highest incidence rates across Europe. The focus of this paper was to derive average costs for PCa diagnosis, treatment and follow-up, and to estimate the overall health expenditure for PCa in 2010 in Ireland using a quasi, incidence-based, bottom-up approach. METHODS: A payer perspective using direct costs was adopted and costs were reported in €. Number of new diagnosed PCa (ICD10 C61) incidence and treatment data during 2007-2010 was obtained from the National Cancer Registry Ireland. Estimates of resource use for items not recorded by the NCRI were sourced from the literature and expert opinion. Costs associated with detection, diagnosis, treatment, treatment complications, follow-up until year 4 post-diagnosis and terminal care were estimated using various sources including study-specific survey data, Irish hospital costs (HSE Casemix) and costs published in the literature. RESULTS: The overall expenditure associated with prostate specific antigen (PSA) testing for those diagnosed with PCa in 2010 was €360,016 (average per patient cost (APP) €56 (confidence interval (CI): €45, €67)). Diagnosis including biopsies and staging was estimated at €2,872,333 (APP €804 (CI: €573, €1,114). Treatment costs (for the first year) varied considerably with active surveillance estimated at €423,106 (APP €655 (CI: €520, €814)), external beam radiation therapy (in particular intensity-modulated radiation therapy) estimated at €8,872,037 (APP €6,867,527 (CI: €5,429,823) and radical prostatectomy estimated at €3,549,864 (APP €7,327,527 (CI: €5,797,878)). The total burden of health care expenditure associated with PCa in 2010 in Ireland is approximately €7,377,4m. Conclusions: Calculating health care expenditure from a societal perspective is vital in assessing the true cost and impact of health care services for PCa patients.

PCN80
HEALTH CARE COSTS AND UTILIZATION OF U.S. VETERAN PATIENTS Diagnosed WITH PanCREATIC CANCER
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OBJECTIVES: Many pancreatic cancer patients die of pain and untimely death. Our data show that 79% of pancreatic cancer patients report that their pain interferes with their social activities. This is the aim of this study.
METHODS: A tree-decision model has been developed to estimate the value and structure of the economic burden of asthma in Vietnam. The economic burden of asthma was evaluated by calculating the cost of asthma, including direct and indirect costs. A cohort of 227 asthma patients was selected to be surveyed to identify the direct costs, including costs for drugs and medical services, and indirect costs, including lost work and transportation due to treatment and other costs of patient and caregivers. RESULTS: Annual total cost per patient with asthma accounts for 6,618,682 VND, from which direct costs are 2.5 times more than indirect cost (4,738,682 vs. 1,800,000 VND). The total burden of asthma has increased following the asthma severity with 4,960,278, 9,008,156, 10,759,234, 13,196,280 VND in mild, intermittent, moderate and severe asthma. In the context of total cost, following the asthma severity, the percentage of direct costs increases and indirect costs decreases especially in the mild asthma.
OBJECTIVES: To examine the economic burden and health care utilizations of patients diagnosed with pancreatic cancer in the U.S. veteran population.

METHODOLOGY: A retrospective database analysis was performed using Veterans Health Administration Medical SAS data from 01/01/2007 through 30/06/2012. Patients diagnosed with pancreatic cancer were identified using International Classification of Diseases (ICD) codes on inpatient and outpatient encounters. The first diagnosis date was defined as the index date. A group of patients with similar age, region, gender and index year but without a pancreatic cancer diagnosis and comparable groups using 1:1 propensity score matching (PSM). A total of 10,894 patients were identified for the pancreatic cancer and comparison cohorts. After applying a 1:1 PSM, 3,671 patients were matched from each cohort, and their baseline characteristics and health care costs were compared between the groups. Other costs were more likely to have higher health care resource utilizations, including inpatient admissions (30.83% vs. 2.18%, p < 0.0001), emergency room (ER) (30.67% vs. 5.48%, p < 0.0001), physician office visits (39.57% vs. 59.71%, p < 0.0001) and prescriptions (83.55% vs. 62.82%, p < 0.0001). In addition, pharmacy costs ($2,244 vs. $321, p < 0.0001) and adherence rates were evaluated. The group with pancreatic cancer showed a greater association with ER visits (30.67% vs. 15.87%, p < 0.0001), physician visits (39.57% vs. 30.89%, p = 0.0028), and inpatient care (2.18% vs. 11.51%, p < 0.0001).

CONCLUSIONS: The results of this study indicate that there is a significant, and increasing, health and economic burden associated with head and neck cancers in England, highlighting the need for preventative programmes.

PCN38
THE COST OF NSCLC TREATMENT IN THREE COUNTRIES: FRANCE, GERMANY AND UK

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INTRODUCTION: Lung cancer is a highly prevalent condition with non-small cell lung cancer (NSCLC) representing ~30%. Given its high prevalence and poor survival rates, it is important to understand costs associated with NSCLC treatment. OBJECTIVES: To carry out a study similar to the study by Ramsey (2008) in three European countries: France, Germany and UK. METHODS: Three similar administrative databases were accessed: Hospital Episode Statistics (England), Gesundheitsforen Leipzig (Germany), French Hospital Discharge system (France), using ICD-9/10 codes and treatment/surgery algorithms to identify NSCLC patients. An inpatient cost analysis using National Reference Costs for the latest available year and inflated using the CPI index. Outpatient costs were estimated by grouping consultations by treatment strategy.

RESULTS: The total cost of treatment for all cancers over the entire period was estimated to be around £39 million, at 2011 prices. Indirect costs covered by bundled HRGs accounted for over 50% of this cost, at £280 million. Total costs due to oropharyngeal cancer were slightly higher than those estimated for laryngeal and oral cancer, costing £15 million (37.6%), £6 million (15.1%) and £98 million (31.7%) respectively. There was, generally, an increasing trend in the secondary care burden of all three cancers. Annual costs and patient numbers increased the most for oropharyngeal cancer, with annual inpatient costs increasing from £233,746 in 2006/07 to £2,510 in 2010/11 (p < 0.0001). This study indicates that there is a significant, and increasing, health and economic burden associated with head and neck cancers in England, highlighting the need for preventative programmes.

PCN39
THE ONSET OF SECONDARY CARE COSTS FOR TREATMENT OF HEAD AND NECK CANCERS IN ENGLAND

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OBJECTIVES: To determine the economic burden of medical treatments originating from the upper aerodigestive tract, head and neck cancers are ranked in the top ten for both incidence and mortality among all malignancies globally. This study aims to estimate trends in total secondary care costs associated with the treatment of head and neck cancers in England from 2006/2007 to 2010/2011. METHODS: Data on inpatient and outpatient activity associated with oropharyngeal, oral cavity and laryngeal cancer was extracted from the Hospital Episode Statistics (HES) database. After applying a structured algorithm into spells, a single healthcare resource group (HRG) was derived for each and then cross-referenced with the National Tariff 2010/11 to estimate the associated cost. For specific types of therapy, including chemotherapeutic regimens, these costs were projected using relevant National Reference Costs for the latest available year and inflated using the CPI index. Outpatient costs were estimated by grouping consultations by treatment strategy.

RESULTS: The total cost of treatment for all cancers over the entire period was estimated to be around £39 million, at 2011 prices. Indirect costs covered by bundled HRGs accounted for over 50% of this cost, at £280 million. Total costs due to oropharyngeal cancer were slightly higher than those estimated for laryngeal and oral cancer, costing £15 million (37.6%), £6 million (15.1%) and £98 million (31.7%) respectively. There was, generally, an increasing trend in the secondary care burden of all three cancers. Annual costs and patient numbers increased the most for oropharyngeal cancer, with annual inpatient costs increasing from £233,746 in 2006/07 to £2,510 in 2010/11 (p < 0.0001). This study indicates that there is a significant, and increasing, health and economic burden associated with head and neck cancers in England, highlighting the need for preventative programmes.
for France and Germany in year 1 and 2, were 502 - €126 for France; €1,429 - €1,156 for Germany. Total costs reached €8,096 (yr1), €7,039 (yr2) France; €19,025 (yr1), €13,295 (yr2) Germany; €15,785 (yr1), €19,900 (yr2) England. Two-year costs totalled €25,063 (France); €32,500 (Germany); €17,777 (England). Subgroup analyses showed higher costs for elderly patients, those with non-metastatic disease and smokers.

CONCLUSIONS: The study showed that differences in reported medical costs were observed. In-patient costs dominate in the first year of treatment in all countries. The study highlights the costly nature of NSCLC.

PCN86
COST OF BEST SUPPORTIVE CARE FOR NON-SMALL CELL LUNG CANCER PATIENTS – A GERMAN PERSPECTIVE
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OBJECTIVES: Best supportive care (BSC) is in general individually provided to patients. Thus, the scope of BSC and its costs can vary widely. Only limited information on BSC costs for patients with non-small cell lung cancer (NSCLC) exists. Aim of this research was to estimate annual BSC costs for NSCLC patients in Germany.

METHODS: To estimate BSC costs at first a literature search in PubMed with the key words “best supportive care”, “cost”, “non-small cell lung cancer” and “economic analysis” individual and combined search terms was performed. International publications of economic evaluations including data on single cost items which could be applied to the German health care system were included. Additionally, data on BSC from a NSCLC patient registry (n=193) and prescription data derived from a randomised controlled trial (RCT) were used as further references. Items were extracted from each reference and finally applied to the German inpatient and outpatient reimbursement system.

RESULTS: The literature research yielded 317 records of which 3 met the inclusion criteria (2010-2013). To assess and compare costs for BSC as described by the 3 studies, the RSC patient registry added up to 28,070. The average annual costs for BSC were estimated at 27,864 €. CONCLUSIONS: Since BSC is individually delivered to patients, it leads to a high variance of annual BSC costs for NSCLC patients in Germany. Further, international economic evaluations were extrapolated to the German health care system. Hence, results should be interpreted with caution as international treatment guidelines and reimbursement schemes are not fully applicable to Germany. Future analyses should be based on a German population only.

PCN87
MASTECTOMY DUE TO BREAST CANCER IN BRAZIL: GEOGRAPHIC DISTRIBUTION AND COSTS FROM THE PUBLIC HEALTH CARE PERSPECTIVE
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OBJECTIVES: Treatment for breast cancer is usually based on chemotherapy and radiotherapy, but in unsuccessful cases, mastectomy is required. In Brazil, mastectomy is performed as simple or radical mastectomy. This study aims to relate geographic distribution, temporal trends and economic profile of this procedure in Brazil.

METHODS: Assessments about hospital admissions were performed in Brazil from 2007 to 2012. Furthermore, international economic evaluations were extrapolated to the German health care system. Hence, results should be interpreted with caution as international treatment guidelines and reimbursement schemes are not fully applicable to Germany. Future analyses should be based on a German population only.

RESULTS: The number of mastectomies performed in Amapá, the northern state, was 22,977 procedures, which was the largest number per region, compared with 1,814 in North; 8,443 in South; 2,280 in Midwest and 10,538 in Northeast. In São Paulo, 10,111 procedures occurred in this period, while 8 were performed in Amapá. Total costs with mastectomies due to breast cancer in Brazil during this period were €4,219,235.66 RRL. The value per patient increased about 12.5% over the years with mean costs from 2008 to 2012 of 799.75RBL, €842.62RBL, €853.28RBL, €878.20RBL and €87.25RBL, respectively. In 2010, the mean mortality rate among simple and radical mastectomies was 0.22% and increased until 0.54% in 2012. CONCLUSIONS: Geographic distribution of mastectomy due to breast cancer in Brazil was concentrated in Southeast region, particularly to other regions and from 2008 to 2012 there was no change in this pattern. Although costs elevated, mortality also increased in this period.

PCN88
ESTIMATION OF ECONOMIC LOSSES RESULTING FROM DISEASES ASSOCIATED WITH SMOKING IN MEXICAN INSURED AND UNINSURED POPULATION
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OBJECTIVES: Few data has been published in Mexico related to direct smoking costs. Since the use of isolated limb perfusion and infusion was associated with relatively long hospital stay and high cost. The results of this study may provide source data for economic evaluations of treatment options for regional metastatic melanoma.

RESULTS: Since BSC is individually delivered to patients, it leads to a high variance of annual BSC costs for NSCLC patients in Germany. Further, international economic evaluations were extrapolated to the German health care system. Hence, results should be interpreted with caution as international treatment guidelines and reimbursement schemes are not fully applicable to Germany. Future analyses should be based on a German population only.

PCN90
COST COMPARISON AMONG FIRST LINE MONOClonAL ANTIBOdIES-BASED ONCOLOGY TREATmENT PROTOCOLS
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OBJECTIVES: To estimate BSC costs at first a literature search in PubMed with the key words “best supportive care”, “cost”, “non-small cell lung cancer” and “economic analysis” individual and combined search terms was performed. International publications of economic evaluations including data on single cost items which could be applied to the German health care system were included. Additionally, data on BSC from a NSCLC patient registry (n=193) and prescription data derived from a randomised controlled trial (RCT) were used as further references. Items were extracted from each reference and finally applied to the German inpatient and outpatient reimbursement system.

RESULTS: The literature research yielded 317 records of which 3 met the inclusion criteria (2010-2013). To assess and compare costs for BSC as described by the 3 studies, the RSC patient registry added up to 28,070. The average annual costs for BSC were estimated at 27,864 €. CONCLUSIONS: Since BSC is individually delivered to patients, it leads to a high variance of annual BSC costs for NSCLC patients in Germany. Further, international economic evaluations were extrapolated to the German health care system. Hence, results should be interpreted with caution as international treatment guidelines and reimbursement schemes are not fully applicable to Germany. Future analyses should be based on a German population only.

PCN91
A GUIDELINE-BASED ESTIMATE OF HEALTH CARE RESOURCE USE AND COST OF METASTATIC UNRESECTABLE OSSEROSARCOMA
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OBJECTIVES: To estimate the resource use and costs of a health plan can anticipate during the diagnosis, treatment, and surveillance of a patient with metastatic unmet-
sectable osteosarcoma using national guideline recommendations. METHODS: An economic model was developed based on recommendations of the 2013 NCCN Clinical Practice Guidelines in Oncology for bone cancer. The model quantified resource use for diagnosis, 12 months of treatment, and 12 months of surveillance of a metastatic unresectable osteosarcoma patient. Costs in 2014 dollars were derived from publically available sources for reimbursement of CPT codes, HCPCS codes, and generic WAC prices for medications. Chemotherapy dosing was based on NCCN recommended treatment regimens. RESULTS: The diagnostic cost was €7,796 per patient. Treatment costs, consisting of stereotactic radiosurgery and chemotherapy with drug monitoring, varied widely across the four NCCN recommended regimens due to differences in the price of pharmaceuticals. The chemotherapy regimens were estimated to be the most cost-effective alternative treatments for this disease, thremobrubicin at €1,014.66, and high-dose methotrexate cost €103,051 per patient; doxorubicin and cisplatin cost €17,549 per patient; doxorubicin, cisplatin, high-dose methotrexate, and ifosfamide cost €67,336 per patient. The second most expensive regimen was cisplatin, ifosfamide and high-dose methotrexate. Additionally, stereotactic radiosurgery was estimated at €2,755 per patient, and the cost of drug monitoring during the one year of chemotherapy averaged to €5,899 per patient. Additionally, one year of disease surveillance cost €4,264 per patient, and the cost of health plans to better understand and anticipate the expected diagnosis, treatment, and surveillance resources and costs for unresectable metastatic osteosarcoma patients.

**PCN92**

**RESOURCE USE AND HEALTH CARE COSTS OF METASTATIC MALIGNANT MELANOMA IN SLOVAKIA**

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**OBJECTIVES:** The objective of this cost study was to measure the resource utilisation and the direct costs associated with health care management of metastatic malignant melanoma (MM) in Slovakia as a basis for cost-effectiveness evaluations.

**METHODS:** The cross-sectional survey was performed and included 3 oncologists experienced in mMM management. The survey was performed to obtain the information on the management of patients with mMM and to estimate the direct costs of the management of mMM. The study population was 3 cohorts of mMM patients which are usually identified as the health states in the cost-effectiveness models: "Before progression", "Disease progression" and "Terminal care".

**RESULTS:** Costs of drugs were measured separately from health states and rated particularly according to BRAF positivity. The cost data were assessed for the year 2013. All types of health care used in mMM management were evaluated (outpatient and inpatient visits, diagnostics, prescription drugs and medical examinations). Costs of adverse events (AEs) were calculated for the year 2013. The median cost of the metastatic the first treatment line of BRAF mutant and BRAF negative patients were identical - dacarbazine (94.9% of treated patients), fotemustine (4.5%) and ipilimumab (0.6%). Costs of monthly mMM management in addition to the active treatment in the state "Before progression" cost for 6.64% (€188.51/patient), during the "Disease progression" it was 45.56% (€1,294.31/patient) and during the "Terminal state of patient" 47.80% (€1,358.02/patient). Adverse event (AE) costs were evaluated for grade 3 and 4 events. AEs were noted in 3% of patients (€1,014.56), fever (€364.87) and rash (€230.35).

**CONCLUSIONS:** In the management of mMM (excluding the active drug cost), the most expensive are the costs of hospitalization and symptomatic treatment. The most costly period is the "Terminal state".

**PCN93**

**COST BENEfIT ASSESSmENT OF THE ELECTRONIC HEALTH RECORDS fROm THE TRANSCRIPTASE-POLymERASE CHAIN REACTION RT-PCR ASSAy fROm THE CLINICAL RESEARCH (EHCR4CR) EUROPEAN PROJECT**

Beresniak A, 1Schmidt A, 1 prove fJ, 1Bolanos E, 1Patel N, 1Ammour N, 1Sundgren M, 1Ericson M, 1De Moor G, 1Kahlin D, 2Dunlop D, 3

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**OBJECTIVES:** The EHCR4CR-4 year research partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA) has developed a platform for the trustworthy reuse of hospital electronic health records’ data for clinical research. A cost-benefit assessment (CBA) was conducted from the pharmaceutical industry perspective to assess the value of the first two EHCR4CR clinical research scenarios (S): Protocol feasibility assessment (S1), and the European Institute for Health Records (EuroRec), London, UK

**OBJECTIVES:** The aim was to determine the cost-effectiveness of colonic stent insertion for the management of malignant bowel obstruction. Colonic stents are a minimally invasive alternative to open surgery for patients medically unfit for single stage surgery. METHODS: Two economic models were developed. The first compared patients who received palliative or definitive stents and were not medically fit for ‘a’ one stage surgery. The second compared patients who received two stage surgery and were medically fit for a second stage of two-stage surgery, this included colostomy or Hartmann’s procedure. Results: For patients requiring palliation, the cost of colonic stent insertion was estimated to be €17,809 compared to €20,516 for the one stage surgery. The benefits associated with both procedures were 0.099 QALYs and 0.089 QALYs gained, respectively, an incremental benefit of 0.01 QALYs per patient. For patients requiring a bridge-to-surgery, the cost of colonic stent insertion was estimated to be €29,729, compared to €30,100 for patients that received multi-stage surgery (either a colostomy or a Hartmann’s procedure). This represented a cost savings of €440. The estimated average patient would gain 0.510 QALYs compared to 0.458 QALYs in the multi-stage surgery group. This yields in an incremental benefit of 0.052 QALYs per patient. The main drivers of both models were the technical and clinical success of the stent insertion, and length of hospital stay following the procedures. The probability of a resection with primary anas- tomosis or insertion of a stent and the cost of stenting were also drivers in the bridge-to-surgery model. CONCLUSIONS: In terms of cost-effectiveness, colonic stent insertion for malignant bowel obstruction in patients requiring palliation or a bridge-to-surgery dominated the current alternative surgical procedures.
tests) were based on official reimbursed prices. RESULTS: Out of 4,934 newly diagnosed breast cancer women, 27.5% (1,357) were appropriate for the test application. Only 35% of the women undertaken the oncostype test (N = 1,357) were found as high risk for recurrence (N = 475). The average total cost of chemotherapy treatment was estimated to €8,271 from which more than 80% refer to pharmaceuticals. The total treatment costs for patients who didn’t undergo treatment reached to €10,916, while the relevant cost for women who undertook the test was estimated to €8,118. CONCLUSIONS: The introduction of Oncotype DX® to the Greek health care system had as result annual cost savings of almost €13 million and avoidance of unnecessary chemotherapy treatment (and associated complications) to more than 880 women.

PCN97
CONSEQUENCE COST MODEL INVESTIGATING THE IMPACT OF BOWEL CLEANSING ON PREVENTION OF COLORECTAL CANCER IN A GERMAN SCREENING POPULATION
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OBJECTIVES: The degree of benefit from colonoscopy in the prevention of colorectal cancer (CRC) is highly dependent on the quality of bowel cleansing. In a randomized study of patients undergoing screening colonoscopy in Germany (MODEC), 2L polyethylene glycol with electrolytes + ascorbate components (PEG+ASC) resulted in numerically higher overall polyph/adenoma detection rates (FDR/ADR) and significantly higher right-sided FDR/ADR than sodium picosulfate/magnesium citrate (NaPic/MgCit), together with better bowel cleansing. The objective of the model was to evaluate the economic impact of bowel cleansing on the effectiveness of CRC screening in the eligible German population. METHODS: A cost-consequence model was constructed to compare the total cost of colonoscopy and treatment of subsequent CRC over a 10-year period in a cohort of 10,000 patients aged ≥55 years receiving 2L PEG+ASC or NaPic/MgCit prior to colonoscopy. The rates of successful bowel cleansing, completed colonoscopies, and FDR/ADR were obtained from the study. Published rates of surveillance colonoscopy, with the exception where overall survival (OS) utilized data from longer term clinical registries. The primary model outcome is the ICER per QALY gained in the first-line FTD vs. TD. The following model input main data assumptions applied for the base case analysis: Time horizon: 10 decades; 3) All costs are expressed in 2013 euros; 4) preference for survival; 5) discount rate: annual rate of 3.0% for both, future costs and health benefits. RESULTS: The outcomes over a time horizon show an increase in mean OS time for patients assigned to the FTD group as compared to those in the TD of 0.72 years. Mean QALYS are also higher in the FTD group than in the TD group 0.58 QALYs. The addition of Pertuzumab leads to higher total average treatment costs of €143,529 per patient compared to the TD group. These findings result in an ICER of €200,509 per life year gained and of €249,582 per QALY gained. CONCLUSIONS: Although pertuzumab is not currently reimbursed in Germany, the results exceed commonly applied willingness-to-pay thresholds, but Perutzumab becomes a therapeutic alternative that offers a better health outcome.

PCN101
COST-EFFECTIVENESS OF IPILIMUMAB FOR PREVIOUSLY UNTREATED PATIENTS WITH ADVANCED METASTATIC MELANOMA IN SPAIN
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OBJECTIVES: To assess the cost-effectiveness of ipilimumab compared to dacarbazine as first-line treatment in patients with advanced metastatic melano-

mean compensation adjusting HPV16/18 vac-
cine (AS04V) and the HPV6/11/16/18 vaccine (QV). METHODS: We applied, to the Romanian settings, a population steady state model previously published with a one year horizon (orbit the effective (costs) of vaccination pro-
grame. The number of cases and costs in (RON – Romanian National Currency) were collected from the hospitalization Diagnosis Related Group database for the year 2012. cervical cancer (CC) and genital warts (GW) were considered. Vaccine effectiveness was approximated by comparing vaccine-type and non-vaccine-type efficacy with HPV distribution report for GW (literature) and CC (HPV Centre) for each vaccine. One way sensitivity analysis was conducted on key input param-
eters. RESULTS: HPV vaccination would save 17,706,490 RON with AS04V and 16,432,592 RON with QV. An additional 820 CC-related hospitalisations amounting to a cost difference of 1,273,898 RON was estimated in favour of the AS04V. A total of 205 cases of GW prevented and 153,395 RON associated costs were estimated in favour of the QV. The total cost difference amounted to 1,120,503 RON. Robustness of the results was confirmed by sensitivity analyses”. CONCLUSIONS: Implementing the AS04V would result in +1 million RON saved versus the QV mainly due to a dif-
ference of extra 820 CC cases prevented that completely offset the benefit associated with the prevention of GW. The observed difference is mainly due to higher protection associated with non-vaccine types for AS04V.

PCN98
A COST-CONSEQUENCE ANALYSIS OF HUMAN PAPILLOMAVIRUS VACCINATION IN ROMANIA
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OBJECTIVES: The objective of the study was to estimate the potential cost and epi-
demiological impact of a Human Papillomavirus (HPV) mass vaccination in Romania for 2011. Available evidence and results in the literature led us to believe that the HPV16/18 vac-
cine (AS04V) and the HPV6/11/16/18 vaccine (QV).

OBJECTIVES: To assess the cost-effectiveness of ipilimumab compared to dac-

mean compensation adjusting HPV16/18 vac-
cine (AS04V) and the HPV6/11/16/18 vaccine (QV). METHODS: We applied, to the Romanian settings, a population steady state model previously published with a one year horizon (orbit the effective (costs) of vaccination pro-
grame. The number of cases and costs in (RON – Romanian National Currency) were collected from the hospitalization Diagnosis Related Group database for the year 2012. cervical cancer (CC) and genital warts (GW) were considered. Vaccine effectiveness was approximated by comparing vaccine-type and non-vaccine-type efficacy with HPV distribution report for GW (literature) and CC (HPV Centre) for each vaccine. One way sensitivity analysis was conducted on key input param-
eters. RESULTS: HPV vaccination would save 17,706,490 RON with AS04V and 16,432,592 RON with QV. An additional 820 CC-related hospitalisations amounting to a cost difference of 1,273,898 RON was estimated in favour of the AS04V. A total of 205 cases of GW prevented and 153,395 RON associated costs were estimated in favour of the QV. The total cost difference amounted to 1,120,503 RON. Robustness of the results was confirmed by sensitivity analyses”. CONCLUSIONS: Implementing the AS04V would result in +1 million RON saved versus the QV mainly due to a dif-
ference of extra 820 CC cases prevented that completely offset the benefit associated with the prevention of GW. The observed difference is mainly due to higher protection associated with non-vaccine types for AS04V.

PCN99
ASSOCIATION OF HEALTH CARE COST WITH QUALITY OF LIFE FOR VARIOUS TYPES OF CANCERS
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OBJECTIVES: The new cancer treatment modalities are improving survival rates today. Hence, the main outcomes is the improved health-related quality of life (Qol). Prolonged survival also increases the financial burden of cancer care on health care systems. In this study we aimed to analyze the associations between Qol and direct health care costs in different types of cancers. METHODS: We evalu-
ated 403 (16.7% QoL, 40.9% Q30, and direct medical costs) patients (248 (61.9%) with lung (Lng), breast (Br), hematological (Hm), head and neck (H&N), colorectal (CR), gastric (Gas), gynecological (Gy), and prostate (Pr) cancers. The DMC data of each patient in the following 3-month follow-up period was provided by the hospital finance department database. DMC per Qol point was calculated by DMC/Qol.

score. RESULTS: Mean DMC per Qol was lowest in Pr, and highest in Hem cancers (P<0.001). T1:global template (Q30-Q30 + 0.5 QoL-GG)-l5 (Lng-H&N-Hm). Qol was lowest in Gy in highest in CR (ranged 5:1.6-5.2) (Qy-Lng-Pr-Hm-Hn-GG). Total DMC ranged from 3124-15557 TL (Pr=GY-Br=Gas=CR=Lng-H&N-Hm). Depending on the type of the cancer the association between DMC and Qol could be in negative or positive directions (between DMC and role functioning was positive in Gas, while it was negative in Hn&cancer). CONCLUSIONS: For a fixed period of time the total DMC associated with the management of different types of cancer was rather substantially. As expected the total cost does not however purchase equal amount of Qol for each type of cancer. For those cancers with higher DMC per Qol, we should consider implementing wider psychosocial support measures. Depending on the type of cancer DMC may reflect disease progression leading to decreased Qol, or it may reflect presence of an effective and aggressive manage-
ment leading to increased Qol.
to develop a targeted contrast agent that specifically detects adenomas at increasing risk for progressing to CRC. This may further raise the potential of MR colonography. We explored the potential of conventional and targeted MR colonography in terms of (cost)-effectiveness using the ASCCA model.

METHODS: Thirteen screening strategies were evaluated, differing in primary screening interval and number of screening rounds; contaminated strategies under the assumption that screening was conventional and targeted and MR colonography, coloscopy and CT colonography with two, three and four screening rounds at a ten year screening interval. Further, the statistical validation of the colon chemotest (oCTA) screening was considered. Each strategy was evaluated assuming realistic and perfect participation rates. Incremental costs and effects were estimated from a societal perspective.

RESULTS: All screening strategies were cost-effective compared to no screening. For conventional MR colonography, the ICER ranged between €1,217/LYG and €3,003/LYG for two to four screening rounds at 34% participation per round. For 62% and 100% participation, the ICER ranged from €1,576/LYG to €3,773/LYG and €4,577/LYG to €5,277/LYG, respectively. MR colonography screening was more expensive than other screening strategies at comparable LYG, for all participation rates. Targeted MR colonography was only slightly more effective than conventional MR colonography but considerably more costly, even under more optimistic assumptions regarding test characteristics and costs.

CONCLUSIONS: This is the first study to evaluate the cost-effectiveness of MR colonography screening for CRC. Although conventional and targeted MR colonography are cost-effective compared to no screening, at present they cannot compete with more established screening tests because of the high costs per test.

PCN103

COST-EFFECTIVENESS ANALYSIS OF ABIRATERONE ACETATE TREATMENT COMPARED WITH CABACITABINE IN THE REPUBLIC OF PANAMA, IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER THAT HAVE FAILED TO CHEMOTHERAPY WITH DOXETAXEL

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OBJECTIVES: To assess the cost-effectiveness of Abiraterone Acetate plus Prednisone (A-P) compared with Cabazitaxel plus Prednisone (C-P) in Panama, in patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) that have failed to chemotherapy with Docetaxel. METHODS: A three-health state cohort model was developed as a Markov Model (progression of post-progression disease) was developed based on overall and progression free survival data. The time frame was 10 years. The perspective was that of the Public System of Health of Panama. The outcomes of interest were Quality Adjusted Life Years (QALYs) and Life Years (LYs). Efficacy data was taken from clinical trials (COU-AA-301 for A-P and TROPIC for C-P). Utilities for health states and negative utilities for adverse events were estimated based on quality of life endpoints of the COU-AA-301 trial. The base case analysis was to compare the two treatments in nineteen states (USD). Costs and outcomes were discounted at 5%. Probabilistic sensitivity (PSA) analysis was performed to evaluate uncertainty surrounding the parameters. RESULTS: A-P resulted in 0.79 QALYs and 1.31 LYs per patient against C-P resulted in 0.71 QALYs and 1.28 LYs per patient, respectively. Mean total costs per patient were USD 76,179 for A-P and USD 86,286 for C-P. The results of the probabilistic sensitivity analysis showed that, when compared with C-A, A-P was found dominant (associated with reduced costs and increased QALYs) in the majority of the iterations. A-P had a 73% probability of being cost effective, independent of the willingness to pay, when compared with C-P. When the willingness to pay increases, A-P is more likely to be considered dominant (cost-saving), when compared with C-P, in patients with Metastatic Castration-Resistant Prostate Cancer that have failed to chemotherapy with Docetaxel, from the perspective of the Public System of Health of Panama.

PCN104

EVEROLIMUS PLUS EXEMESTANE COMPARED TO EXEMESTANE AND FULFLOXURINE FOR THE TREATMENT OF ER-HER2- METASTATIC BREAST CANCER IN THE UNITED KINGDOM – A SOCIETAL PERSPECTIVE

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OBJECTIVES: This study evaluated the cost-effectiveness of everolimus plus exemestane (EVE+EXE) versus exemestane (EXE) and fulfloxurine (FUL) in the treatment of postmenopausal women with ER-HER2- metastatic breast cancer in the United Kingdom (UK) from a societal perspective. METHODS: A partitioned survival model was developed to compare treatment with EVE+EXE versus EXE and FUL over a 10-year time horizon. Progression-free survival and overall survival for EVE+EXE and EXE were estimated from the BOLERO-2 trial. Log-istics functions were used to extrapolate trial data beyond the follow-up period. In the absence of head-to-head evidence vs. FUL an indirect treatment comparison was conducted using a Bayesian fixed effect model. Background health state and terminal care resource use were derived from NICE Clinical Guideline 81. Drug costs were taken from the National Drug Tariff of the UK.

RESULTS: A Markov outcome model was developed, included several stages such as: pre-progression on first-line treatment, “post-progression off first-line treatment”, “post progression”, “four weeks to death” and “death”. Data from the MPACT trial were used to estimate overall survival (Life-Years (LYs)) and adverse events. The prices of drugs used in the model per course. The cost of everolimus was estimated at €14,377, and the incremental cost per quality-adjusted life-year (QALY) gained was estimated to be €36,577. Sensitivity and scenario analyses indicated that the model is robust to alternative parameters and assumptions.

CONCLUSIONS: Panitumumab plus mFOLFOX6 can be considered a cost-effective choice compared with gemcitabine alone in Greece.

PCN105

ECONOMIC EVALUATION OF NAB-PAACLITAXEL PLUS GEMCITABINE VERSUS GEMCITABINE ALONE FOR THE MANAGEMENT OF METASTATIC PANCREATIC CANCER IN GREECE

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OBJECTIVES: To estimate the cost-effectiveness of nab-paclitaxel+gemcitabine (Npg) versus gemcitabine (Gem) alone for the first-line treatment of metastatic pancreatic cancer in Greece from a National Health System perspective. METHODS: A Markov model was developed, included several stages such as: “pre-progression on first-line treatment”, “post-progression off first-line treatment”, “post progression”, “four weeks to death” and “death”. Data from the MPACT trial were used to estimate overall survival (Life-Years (LYs)) and adverse events. The prices of drugs used in the model per course. The cost of everolimus was estimated at €14,377, and the incremental cost per quality-adjusted life-year (QALY) gained was estimated to be €36,577. Sensitivity and scenario analyses indicated that the model is robust to alternative parameters and assumptions.

RESULTS: The mean number of QALYs was 0.71 (95%CI: 0.66-0.76) and 0.52 (95%CI: 0.52-0.60) for Npg and Gem, respectively, giving an incremental gain of 0.19 (95%CI: 0.18-0.20) QALYs in favour of Npg. The mean cost of therapy per patient was estimated at €15,628 (95%CI: €14,377 - €17,027) and €8,284 (95%CI: €7,455-€11,912) for Gem, respectively. The incremental cost per QL-Y gained with Npg was estimated at €7,007 and the incremental cost per QALY gained at €47,120. The probability for Npg to be cost-effective at a threshold three times the per capita income (£60,000 per QALY) was 82%. CONCLUSIONS: The severity of pancreatic cancer, in combination with the limited number of effective treatments, results in a high level of unmet need. The high cost of disease management to threshold-hold for an additional QALY is relatively higher for patients with short life expectancy or for diseases with a relatively higher burden, the combination of nab-paclitaxel+gemcitabine could be considered a cost-effective choice compared with gemcitabine alone in Greece.

PCN106

COST-EFFECTIVENESS ANALYSIS OF PANTITUMUBAM PLUS MFLOXOFEX VERSUS BEVACIZUMAB PLUS MFLOXOFEX AS FIRST-LINE TREATMENT OF PATIENTS WITH WILD-TYPE RAS METASTATIC COLORECTAL CANCER

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OBJECTIVES: The purpose of this study was to compare the cost-effectiveness of pantitumumab plus mFOLFOX6 (CETP) versus bevacizumab plus mFOLFOX6 as first-line treatment for patients with wild-type RAS metastatic colorectal cancer (mCRC).

METHODS: Using a French health collective perspective, a lifetime Markov model was constructed, with health states related to first-line therapy (progression-free), disease progression with/without subsequent active treatment, resection of metastases, disease-free after successful resection, and death. Transitions to disease progression and death were estimated using parametric survival analyses of patients with metastatic colorectal cancer (mCRC) who received panitumumab plus mFOLFOX6 (CETP) versus bevacizumab plus mFOLFOX6 (BEV) in first-line treatment of patients with wild-type mCRC. Sensitivity and scenario analyses were performed.

RESULTS: Overall survival in panitumumab plus mFOLFOX6 (CETP) treatment arm was estimated at 26.918, and the incremental cost per quality-adjusted life year (QALY) gained was estimated to be €36,577. Sensitivity and scenario analyses indicate the model is robust to alternative parameters and assumptions.

CONCLUSIONS: Panitumumab plus mFOLFOX6 can be considered cost-effective in first-line treatment of patients with wild-type RAS mCRC.
5-year time horizon, PFS data assessed by independent review, drug doses adjusted by relative dose intensity reported in COMPARE, and a discount rate of 3% for costs and outcomes. Results were expressed as 2014. Deterministic (10-year time horizon, discount rates 0 and 5%, PFS assessed by investigator, and placebo-doses) and probabilistic sensitivity analyses were conducted to determine the robustness of the results. **Results:** In the base case analysis, gefitinib was the dominant alternative, yielding more quality of life adjusted years (0.081) and less total costs ($6,671) vs. suntinib. Base-case results were robust in the alternative scenarios examined and via deterministic sensitivity analyses. In the probabilistic sensitivity analysis (PSA), a 67% of the simulations were plotted in the dominant quadrant of the cost-effectiveness plane. **Conclusions:** In the light of the present analysis, pazopanib should be considered as a dominant alternative vs. suntinib in the first-line mGCC treatment from the Spanish National Health Care perspective.

**PCN108 ECONOMIC EVALUATION OF THE USE OF GEFITINIB FOR THE TREATMENT OF LOCALLY ADVANCED OR METASTATIC NSCLC**

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Non-small cell lung cancer (NSCLC) is the most common type of cancer representing 18.2% of all cancer deaths around the world and in Mexico the estimated mortality rate is 13.4 by 100,000 patients. **Objectives:** Evaluate gefitinib as first and second line treatment of locally advanced or metastatic NSCLC compared to available treatment alternatives in Mexico. **Methods:** A two-way analysis was performed. (1) For the first-line treatment in patients with Epidermal Growth Factor Receptor (EGFR) mutation: (1a) for RAS+ and (1b) for RAS- Non-Small Cell Lung Cancer (NSCC) a cost-minimization analysis was used comparing gefitinib versus erlotinib. (Kim ST, 2012), also a Markov model was developed to perform a cost-effectiveness analysis of evaluating gefitinib versus erlotinib-paclitaxel (Mok TS, 2009), with efficacy measure Progression-free survival (PFS); and (2) For patients in a second-line NSCLC treatment, regardless of EGFR mutation, a cost-minimization analysis was used. Patients started with gefitinib versus erlotinib and, progression-free survival (PFS) (Kim ES, 2008). The costs were obtained from institutional sources. An exchange rate of $13.12 MXN per USD was used. Sensitivity analyses were performed in order to test the robustness of the results. **Results:** For first-line treatment with gefitinib versus erlotinib a cost differential of $9,710 USD in favor of gefitinib. To the same patients gefitinib compared to carboplatin plus paclitaxel generated an additional cost of $2,361 USD per patient, with additional PFS of 0.37 years and an ICER of $7,023. For second-line treatment gefitinib had a lower cost compared to pemetrexed and docetaxel, generating a saving per patient of $927 USD and $21,346 USD respectively. Robustness of results was confirmed with additional deterministic and probabilistic sensitivity analyses. **Conclusions:** The use of gefitinib on metastatic NSCLC is a cost-saving alternative compared to erlotinib, pemetrexed and docetaxel, and also cost-effective compared to carboplatin plus paclitaxel.

**PCN109 COST-EFFECTIVENESS OF OFATUMUMAB PLUS CHLORAMBUCIL IN THE FIRST LINE CHRONIC LYMPHOCYTIC LEUKEMIA IN CANADA**

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**Objectives:** This study aimed to estimate the cost-effectiveness of Ofatumumab plus Chlorambucil (OChl) compared with Chlorambucil (Chl) for patients with Chronic Lymphocytic Leukemia (CLL) who were considered ineligible for, or not responding to, or intolerant to a first-line, second-line, or subsequent therapy. **Methods:** A semi-Markov decision model was developed with a lifetime time horizon. The model comprised two distinct phases. The progression phase was based on the ORR, PFS, and OS of observed in the COMPLEMENT-1 trial. The postprogression phase was based on Canadian treatment practices, treatment patterns identified in clinical guidelines and published literature. The incremental cost per quality-adjusted life year (QALY) gained was calculated using model estimated first- and subsequent-line treatment costs, general disease management costs, and QALYs based on health-state preference utility weights. **Results:** The discounted, lifetime health and economic outcomes estimated by the model showed that first-line treatment with OChl in comparison with Chl in the target population led to an increase in QALYs (0.41) and an increase in total costs (CAD $27,850), resulting in an incremental cost-effectiveness ratio (ICER) of CAD $68,672/QALY gained. Various scenario analyses confirmed that the model’s cost-effectiveness estimates were robust.

**PCN110 COST-EFFECTIVENESS ANALYSIS OF PANITUMUMAB PLUS mFOLFOX FOR BEVACIZUMAB+ mFOLFOX AS A FIRST-LINE TREATMENT FOR METASTATIC COLORECTAL CANCER PATIENTS WITH WILD-TYPE RAS IN GREECE**

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**Objectives:** To conduct a cost-effectiveness analysis of panitumumab plus mFOLFOX as first-line treatment (FLT) of metastatic colorectal cancer (mCRC) patients with wild-type RAS in the Greek health care setting. **Methods:** An existing Markov model consisting of seven health states was adapted from the public third-party-payer perspective. Both efficacy and safety data considered in the model were extracted from the PEAK trial and other published studies. Utility values were also extracted from the literature. Direct medical costs consisting of drug-acquisition costs for FLT, administration costs, subsequent therapy costs and other medical costs were considered. The analysis showed that panitumumab plus mFOLFOX produced greater discounted survival and quality adjusted survival by 0.87 QALYs and 0.65 QALY gained in relation to bevacizumab plus mFOLFOX. mCRC life expectancy was 77.200 and 75.500 with bevacizumab and panitumumab plus mFOLFOX, respectively. This difference was mainly attributed to the higher acquisition cost of panitumumab compared to bevacizumab during the pre-progression health state ($32,223 and $14,730 respectively). Incremental cost-effectiveness ratio (ICER) per QALY gained. Probabilistic sensitivity analysis (PSA) was conducted to account for uncertainty and variability in the parameters of the model. **Results:** The analysis showed that panitumumab plus mFOLFOX being cost-effective over bevacizumab plus mFOLFOX and more costly than bevacizumab plus mFOLFOX resulting in an ICER equal to $34,644 per QALY gained. PSA revealed that the probability of panitumumab plus mFOLFOX being cost-effective over bevacizumab plus mFOLFOX was 81.5% at the pre-determined threshold of €51,000 per QALY gained (3 times the GDP per capita of Greece). **Conclusions:** The results suggest that panitumumab plus mFOLFOX may be a cost-effective alternative relative to bevacizumab plus mFOLFOX as FLT of mCRC patients with wild-type RAS in Greece.

**PCN111 COST-EFFECTIVENESS AND COST-UTILITY OF GLUCOCYTE COLONY-STIMULATING FACTORS IN THE PRIMARY PROPHYLAXIS OF CHEMOTHERAPY-INDUCED FEBRILE NEUTROPENIA (FN) IN BREAST CANCER PATIENTS IN GREECE: A COMPARATIVE ANALYSIS**

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**Objectives:** To conduct a cost-effectiveness analysis comparing pegfilgrastim with filgrastim or lenograstim used either in an 11-day regimen or in a 6-day regimen for the prophylaxis of febrile neutropenia (FN) in breast cancer patients, in the Greek health care setting. **Methods:** A cost-effectiveness model was developed from the public third-party-payer perspective. Efficacy and utility values extracted from published studies were considered in the model. The analysis was conducted for a 6-cycle horizon, to reflect the common clinical practice in Greece. Drug acquisition cost, administration costs and resource costs were estimated. **Results:** The incremental cost-effectiveness ratio was higher in the 11-day regimen in comparison with the 6-day regimen (€3,930/QALY gained). In the 11-day regimen, pegfilgrastim was more cost-effective compared to filgrastim and lenograstim resulting in an ICER equal to €34,644 per QALY gained. **Conclusions:** The incremental cost per additional FN event avoided with pegfilgrastim in comparison with filgrastim was between €1,015 and €27,079 compared to 11-day regimens of originator filgrastim with ICERs of €34,644 per QALY gained. **Results:** The results suggest that pegfilgrastim for the prophylaxis of chemotherapy-induced FN in breast cancer patients is associated with better health gain and is a cost-effective option over either the 6-day or the 11-day regimen of biosimilar filgrastim, in Greece.

**PCN112 COST-EFFECTIVENESS OF VISMODEGIB VERSUS STANDARD OF CARE THERAPY IN THE TREATMENT OF LOCALLY-ADVANCED OR SYMPTOMATIC METASTATIC BASEAL CELL CARCINOMA IN HUNGARY – A GLOBAL COST-EFFECTIVENESS MODEL ADAPTATION**

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**Objectives:** Hungarian adaptation of global cost-effectiveness models of vismodegib vs. standard of care (SOC) in the treatment of locally advanced or symptomatic metastatic basal cell carcinoma (laBCC and mBCC). **Methods:** Global Markov models were developed to conduct the cost-effectiveness of vismodegib vs. SOC in patients with laBCC or mBCC. The model inputs were based on the pivotal phase II clinical study (EUVANCE). **Results:** The life time utility values were based on a time trade off study. To support the reimbursement dossier submission, the adaptation of the global cost-effectiveness model was recalculated based on a questionnaire survey with Hungarian health care professionals. In the model there were two treatment arms, vismodegib and SOC. The model comprised the following states: progression-free survival (PFS) and overall survival (OS) of the phases of the clinical trials. The model was conducted to estimate the OS of patients with laBCC and mBCC, treated with SOC. **Results:** According to the Delphi-panel survey the median OS for patients with laBCC and mBCC was 48 months and 24 months, respectively, on the SOC arm. The average time spent in progression-free health state is longer with vismodegib than with SOC, resulting in a median OS of 48 months for patients with laBCC and mBCC, treated with vismodegib, and 24 months for patients with laBCC and mBCC, treated with SOC. **Conclusions:** The results suggest that vismodegib is a cost-effective alternative relative to bevacizumab plus mFOLFOX as FLT of mGCC patients with wild-type RAS in Greece.
modelgb therapy than with SOC for both, lABC and mABC patients. CONCLUSIONS: Vismodegib could provide an effective treatment for this therapeutic area with high rate of unmet need. During the adaptation process Delphi-panel surveys seemed to be an appropriate method to earn consensus statement to ensure estimation and help interpretation.

PCN113

POtENTIAL vaLue OF PATIENTS wITH AdvANCEd BREAST CANCER wITH POSITIvE ESTROGEN basEd on the threshold stated by world health organization (3xGDP/capita) for study concludes that adding aprepitant to the standard regimen is cost effective. The probability of complete protection and incomplete response of both arms aprepitant plus standard regimen and standard regimen alone were EGP 414.25. Costs and utilities were identified from the literature. The VSS vaccine effectiveness for GW and HPV-related cancers was estimated combining efficacies (AS04-adjuvanted HPV-16/18 vaccine vaccine for HPV-6/11/16/18 vaccine types, (HPV-6/11/16/18) and non-vaccine types (HPV-31/33/35/39/45/52/56/58/59) HPV distribution. Costs and QALYs were discounted at 5.1% and 1.1% respectively. Sensitivity analyses on key variables were performed. RESULTS: The VCE-p in women (men) was: CC £90 v. £20 (E57), AC £323 (E77), VoC £37, VuC £58, (PC £40), GW £6 (E7). Total value of cancer prevention in women (men) was £1,027 (E173), a proportion of 6.1. The value of CC alone is 4.5 times larger than the total value of cancer prevention in men. Sensitivity analyses showed results were robust while influenced by potential hard parameters. CONCLUSIONS: The VCE-p was estimated to be up to 6.5 times higher in women than in men due to the higher burden and frequency of HPV-related cancers in women.

PCN114

COST-EFFECtIVENESS OF APREPITANT IN EGyPTIAN PATIENTs RECEIvING HIGhLY EMETOGENIC THERAPy FROm THE THIRd PARTy PAyER PERSPECTIvE (EPP) in Egypt. The cost-effectiveness of adding aprepitant to the standard Egyptian regimen in patients receiving highly emetogenic chemotherapy (EPP) in Egypt was assessed. Costs and utilities were obtained from the literature. All costs (in 2014 EGP) and outcomes were discounted at 3.5% annually. A 5% discount rate for costs and efficacies was applied. A probabilistic sensitivity analysis was calculated showing its results in a tornado chart. RESULTS: The model showed that everolimus + exemestane results in 0.74 progression free years gained with an incremental cost of €18.6 million (MM) resulting in an incremental cost-effectiveness ratio (ICER) of €26 MM. The PSA showed that the ICER is within the range recommended by WHO. The model showed that AS04V has a 95% confidence interval (CI) of €20,000 per QALY. CONCLUSIONS: This analysis showed that using everolimus plus exemestane in patients with ER +, HER2- advanced breast cancer who have failed on NSAIs is a cost-effective option according to WHO recommendations.

PCN116

COST-EFFECTIVENESS OF 2-DOSE AS04-ADJUvANT HUMAN PAPILLOMAVIrus VACCINATION SCHEDULE IN SlovAKIA. This analysis was prepared by the first-line therapy of adjuvanted NSCLC due to its high clinical efficacy. However, economic effectiveness of BCP has been controversial. This analysis aimed to estimate the cost-effectiveness of BCP versus SOC in the treatment of advanced NSCLC patients from patients’ perspective in Slovakia. METHODS: A previously published Markov cohort model, reproducing the natural history of HPV infection, the impact of screening and vaccination, was adapted to the Slovakian settings. Local data on health care costs and disease severity were used. Costs were accounted for from the third party payer perspective. The incremental cost-effectiveness ratio (ICER) was considered as cost-effective. The univariate sensitivity analyses were carried out on key parameters. RESULTS: Compared to screening alone, adding AS04V to the current screening programme was estimated to reduce the lifetime CC cases by 328 at an ICER of 1,1621 €/QALY gained. Therefore the cost-effectiveness of AS04V was estimated to be an appropriate method to earn consensus statement to ensure estimation and help interpretation.

PCN117

A COST EFFECTIVENESS ANALYSIS OF EVEROLIMUS PLUS EXEMESTANE COMPaRED TO CHEMOTHERAPy AGENT FOR THE TREATMENT OF HER2- mETASTASTIC BREAST CANCER IN THE UNITEd kINGdOm. The value of CC alone is 4.5 times larger than the total value of cancer prevention in men. Sensitivity analyses showed results were robust while influenced by potential hard parameters. CONCLUSIONS: The VCE-p was estimated to be up to 6.5 times higher in women than in men due to the higher burden and frequency of HPV-related cancers in women.

PCN115

COST-EFFECtIVENess ANALYSIS OF EVEROLIMUS + EXEMESTANE FOR PATients wITH AdvANCED transFORMER CANCERS: 6 positive HYDROGEN RECEPTOR (ER +), HER2-, REFRACtORY tO NON-STEROIdAL AROmATASE INHIBITORS (NSAIS) IN chILE. To evaluate the cost-effectiveness of everolimus plus exemestane in UK clinical practice. CONCLUSIONS: This analysis showed that using everolimus plus exemestane (EVE+EX) versus chemotherapy agents (docetaxel (DOX), vinoreline (VIN), doxorubicin (DOX), carboplatin/paclitaxel (PC)) in the treatment of patients with hormone-sensitive breast cancer was cost-effective. However, economic effectiveness of BCP has been controversial. This analysis aimed to estimate the cost-effectiveness of BCP versus SOC in the treatment of advanced NSCLC patients from patients’ perspective in Slovakia. METHODS: A previously published Markov cohort model, reproducing the natural history of HPV infection, the impact of screening and vaccination, was adapted to the Slovakian settings. Local data on health care costs and disease severity were used. Costs were accounted for from the third party payer perspective. The incremental cost-effectiveness ratio (ICER) was considered as cost-effective. The univariate sensitivity analyses were carried out on key parameters. RESULTS: Compared to screening alone, adding AS04V to the current screening programme was estimated to reduce the lifetime CC cases by 328 at an ICER of 1,1621 €/QALY gained. Therefore the cost-effectiveness of AS04V was estimated to be an appropriate method to earn consensus statement to ensure estimation and help interpretation.
Markov model was developed to estimate the health outcome (QALY) and total treatment cost for a given cycle of 21 days. Long-term lifetime horizon and costs data were retrieved from the randomized clinical trial ECOG 4599. Direct costs included costs of drugs, administration, medical services, hospital bed day and adverse drug reaction management. It was estimated that on average, 2 patients remained on treatment for 3.5 years. RESULTS: Adding bevacizumab to PC regimen in first-line therapy of advanced NSCLC patients resulted in incremental QALY gained of 0.26 month compared with PC regimen (7.88 versus 5.62). The total treatment cost with BCP was 3.1 higher than with PC (€49,849 vs €63,717 in 2013 EUR, respectively). ICER of BCP vs PC was €78,798,924 VND, which is 3.35 higher than the Willingness-To-Pay of Vietnam in 2013 (229,424,416 VND). A probability sensitivity analysis was conducted. The model was used to examine the robustness of the results to the model’s parameters. CONCLUSIONS: The results of the probabilistic sensitivity analysis showed that when compared with C-P, A-P was found dominant (associated with reduced costs and increased QALYs) in the majority of the iterations. A-P had a 98% probability of being cost effective, independent of the willingness to pay, when compared to C-P. CONCLUSIONS: A-P can be considered cost effective (cost-saving) when compared with C-P, in patients with Metastatic Castration-Resistant Prostate Cancer that have failed to chemotherapy with Docetaxel, from the perspective of the Public System of Health of Dominican Republic.

PCN121
COST-EFFECTIVENESS ANALYSIS OF ABRITERONE ACETATE TREATMENT COMPARED WITH CARBACITAXEL IN DOMINICAN REPUBLIC, IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER THAT HAVE FAILED TO CHEMOTHERAPY WITH DOXETAXEL
Obando CA, Desanvicente-Celis Z, Gonzalez L, Muschett D, Gonzalez F, Goldberg F, Janssens, Panama, Panama, Janssens, Barrian, NJ, USA
OBJECTIVES: To assess the cost-effectiveness of Abiraterone Acetate plus Prednisone (A-P) compared to Cabazitaxel plus Prednisone (C-P) in Dominican Republic, in patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) that have failed to chemotherapy with Docetaxel. METHODS: A three-health state cohort simulation Markov Model (progression-free, post-progression and death) was developed based on the disease model and patient's transition probabilities. The survival data was taken from clinical trials (COU-AA-301 for A-P and TROPIC for C-P). The results of the probabilistic sensitivity analysis showed that, when compared with C-P, A-P was found dominant (associated with reduced costs and increased QALYs) in the majority of the iterations. A-P had a 98% probability of being cost effective, independent of the willingness to pay, when compared to C-P. CONCLUSIONS: A-P can be considered cost-saving (dominant), when compared with C-P, in patients with Metastatic Castration-Resistant Prostate Cancer that have failed to chemotherapy with Docetaxel, from the perspective of the Public System of Health of Dominican Republic.

PCN119
COST-EFFECTIVENESS SIMULATION OF COLONOGRAPHY VERSUS COLONOSCOPY IN GERMANY: IS LAXATIVE-FREE COLONOGROPHY COST-EFFECTIVE?
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OBJECTIVES: Colorectal cancer (CRC) screening using computerised tomographic colonography (CTC) is preferred to virtual CT colonography, has attracted considerable attention due to its possible impact on high screening uptake rates, especially with a laxative-free preparation before screening. A decision analysis model was constructed in order to evaluate the clinical and economic consequences of performing and discontinuing colorectal cancer screening tests versus performing screening scanography in a population at average risk of colorectal cancer in Germany: colonoscopy, conventional CT-colonography and laxative-free CT colonography. METHODS: A state-transition microsimulation was developed for the evaluation of the different screening strategies using TreeAge Pro Healthcare 2014. A hypothetical population of 100,000 German asymptomatic adults aged between 50 and 100 years was used for the basis of the model. The simulation of the screening strategies was undertaken by assessing the number of screening tests events, costs diagnosed with CRC, sensitivity and specificity of each strategy and the related uptake of each screening method. Sensitivity analysis will be applied to test the impact of parameter uncertainty on model outcomes and recommendations. RESULTS: Initial results of the simulation showed that laxative-free colonography was found to be the most cost-effective screening option, with a total cost of EUR 4,115 per screening patient in the simulation period. CONCLUSIONS: Colonoscopy was found to be the least costly screening method, with total costs of EUR 2,119. The most effective screening was modeled for for laxative-free colonography. The ICER of laxative-free colonography compared to colonoscopy was simulated at 5,221 EUR per life year saved. CONCLUSIONS: Our simulation has shown that using laxative-free colonography has the potential to become a cost-effective screening method for CRC due to its advantage related to improvements in screening uptake.
RESULTS: In the base-case analysis, the estimated incremental cost-effectiveness ratio exceeded the NICE willingness-to-pay threshold of £20,000 per quality-adjusted life-year gained. University and payer perspectives led to much lower and similar estimates to the base case, respectively. Sensitivity analyses to parameter changes, showing greatest sensitivity to variation in overall survival, were conducted. **CONCLUSIONS:** Our model suggests that, from the perspective of the UK NHS, cost-effectiveness of FBC is strongly dependent on mutational status. Step-therapy costs less and offers clinically-equivalent utility (652,388; 2,864 QALYs) compared to physician-choice (71,268; 2,879 QALYs), at an ICER of £59,020/QALY. The effect is robust to changes in the base case. Multivariate probabilistic sensitivity analyses found step-therapy cost-effective in 99.9% of 10,000 Monte Carlo simulations. **CONCLUSIONS:** When imatinib loses patent protection in 2015, treatment in CML should be considered for third-line therapy to maximize cost-effectiveness.

**PCN127**

**LITERATURE REVIEW OF DECISION-ANALYTICAL MODELS USED IN THE ECONOMIC EVALUATION OF EMPERICAL/TARGETED ANTIFUNGAL TREATMENTS FOR INVASIVE FUNGAL INFECTIONS**

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**BACKGROUND:** Invasive fungal infections (IFIs) are an important cause of morbidity and mortality in immunocompromised patients. Based on the pathogen identification status, either empirical (without diagnosis) or targeted (with diagnosis) antifungal therapy is administered to symptomatic patients (e.g. with fever). Several antifungal agents and treatments are available for the different types of IFIs. However, there is no consensus on how to select the most cost-effective treatment strategy in general practice. Therefore, the aim of this study was to review all published economic evaluations of empirical/targeted antifungal treatments for IFIs to identify gaps in evidence and provide an overview of the evidence for empirical versus targeted therapies.

**OBJECTIVES:** The objective was to systematically search and review all published economic evaluations of empirical/targeted antifungal treatments for IFIs in different settings. We conducted a systematic review of economic evaluations of empirical/targeted antifungal treatments for IFIs using a comprehensive literature search strategy of PubMed, EMBASE, and the Cochrane Library.**CONCLUSIONS:** A total of 286 economic evaluations were identified. Of these, 262 were excluded leaving 24 empirical/targeted antifungal treatment evaluations. The majority of studies were conducted in the United States, followed by the United Kingdom, and the Netherlands. The majority of these evaluations (24/24) were conducted in a decision analytic model (DAM) framework. Sensitivity analyses were reported in 13/24 studies. Risk of bias assessments were conducted in 11/24 studies. Univariate and probabilistic sensitivity analyses suggested the results were robust to parameter changes. The results of our review showed that there is a lack of high-quality evidence on the cost-effectiveness of empirical/targeted antifungal treatments for IFIs. Further research is needed to fill this knowledge gap.

**PCN128**

**EVALUATION OF THE NORWEGIAN HPV VACCINATION PROGRAM**

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**OBJECTIVES:** To evaluate the cost-effectiveness of expanding the Norwegian HPV vaccine program to catch-up females and 12 years old boys. **METHODS:** We systematically searched the literature for randomized clinical trials (RCTs) that examined the effect of HPV vaccines on cancer mortality and incidence, precancerous stages and serious adverse events. We assessed selected publications for potential risk of bias, and the overall quality of the evidence for each outcome using GRADE. We adapted a published economic model to the Norwegian setting with respect to incidence of HPV-related outcomes, costs and quality adjusted life years (QALYs) lost from HPV-related diseases. The cost utility analysis reported results in Euros/quality-adjusted life years (QALYs) gained in both a public health budget and a societal perspective. **RESULTS:** We included 46 publications reporting on 13 RCTs for young women, and 3 on 2 RCTs for boys (maximum follow-up period: three-four years). From a public health perspective, HPV vaccination was cost-effective for young women. The long-term effect of such a vaccination, and its effect on cancer incidence and mortality is still unclear.

**PCN129**

**COST-EFFECTIVENESS OF RADICAL PROSTATECTOMY, RADIATION THERAPY AND ACTIVE SURVEILLANCE FOR THE TREATMENT OF LOCALIZED PROSTATE CANCER – A CLAIMS DATA ANALYSIS**

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**OBJECTIVES:** The objective was to compare the cost-effectiveness of radical prostatectomy, radiation therapy and active surveillance for the treatment of localized prostate cancer in primary care patients using claims data. **RESULTS:** The findings of the prospective economic evaluation are as follows: The lifetime cost and QALYs from the patient perspective were €150,000 and 8.97 for radical prostatectomy, €130,000 and 9.05 for radiation therapy, and €65,000 and 11.02 for active surveillance. The incremental cost-effectiveness ratios (ΔC/ΔQALY) from the public health perspective were €30,000/QALY for radical prostatectomy compared to active surveillance, €40,000/QALY for radiation therapy compared to active surveillance, and €15,000/QALY for radical prostatectomy compared to radiation therapy. From a public health perspective, active surveillance was cost-effective compared to radical prostatectomy and radiation therapy. From a patient perspective, active surveillance was the least costly and most effective option. **CONCLUSIONS:** The findings of this study suggest that active surveillance is the most cost-effective treatment option for localized prostate cancer in primary care patients.
OBJECTIVES: Standard treatment for localized prostate cancer is radical prostatectomy or radiation therapy (RT) which frequently cause erectile dysfunction (ED) and incontinence (IC). As tumor progression often is slow, active surveillance (AS) has been proposed as an alternative treatment strategy. This study compares the cost-effectiveness of the three treatment strategies in a German context. The study is based on claims data of a German sickness fund we analyzed. The results were compared to recently published data. Results: Costs and effectiveness were calculated on the basis of data from randomized clinical trials, and the model included progression to metastases. ICERs were calculated with respect to AS, RT, and AS. Conclusions: The simulation results are resistant to increase of the prices for fulvestrant. The results are in line with previously published results. Based on the results, cost-effectiveness analysis is a valid strategy to evaluate the cost-effectiveness of treatment strategies in different countries. METHODS: A three state Markov model was developed. The effectiveness of brentuximab vedotin was obtained from the clinical trial of Gopal et al. 2013. The risk of long-term side effects (ED) and ic (EF) 0.313, RT 0.009, AS 0.084. Cost of fulvestrant was obtained from 3 clinical trial publications. The analysis indicates that RT is associated with better prognosis and higher overall costs compared to AS. Conclusions: The simulation results are resistant to increase of the prices for fulvestrant. The results are in line with previously published results. Based on the results, cost-effectiveness analysis is a valid strategy to evaluate the cost-effectiveness of treatment strategies in different countries. 

PCN130
CRITICAL REVIEW OF COST-EFFECTIVENESS ANALYSES (CEA) OF PREVENTION STRATEGIES AGAINST DISEASES ASSOCIATED WITH HUMAN PAPELMOAVIRUS (HPV) INFECTION
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OBJECTIVES: It is estimated that almost all cervical cancers are associated with HPV infection. In most industrialised countries, cervical screening and vaccination with HPV DNA testing are recommended to prevent the disease. The current study aimed to critically review the results of CEA that have assessed the trade-off between screening and vaccination. METHODS: A systematic literature review was conducted in order to explore the cost-effectiveness of HPV vaccination and other prevention strategies, including different screening approaches, within the geographical context of Western Europe, North America and Australia. Modelling approach, disease considered, vaccination/screening settings and costs were compared. RESULTS: A total of 1,188 citations were identified and 20 studies were included in the review. Heterogeneity was seen across studies in terms of modelling approach, disease and prevention strategies considered. Inclusion of more HPV-related diseases significantly improves cost-effectiveness. The strategy with the greatest impact is the intervention considered when compared to vaccination or screening alone. In terms of screening strategy, HPV DNA testing with cytological triage showed a trend to be the optimal HPV-related diseases significantly improves cost-effectiveness. The strategy with the greatest impact is the intervention considered when compared to vaccination or screening alone. In terms of screening strategy, HPV DNA testing with cytological triage showed a trend to be the optimal strategy for reducing cervical cancer incidence and mortality. CONCLUSIONS: Differences in vaccine costs are substantial across countries due to lack of data. Vaccination costs are influenced by vaccine prices and the number of doses required. Further research is needed to assess the cost-effectiveness of HPV vaccination and other prevention strategies in different settings.

PCN131
COST-EFFECTIVENESS ANALYSIS OF FUVLVESTARN in the TREATMENT of METASTATIC BREAST CANCER in SECOND-LINE CHEMOTHERAPY
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OBJECTIVES: To conduct a pharmacoeconomic analysis of the application of fulvestrant compared with docetaxel and paclitaxel in the treatment of metastatic breast cancer in second-line chemotherapy. METHODS: Literature review of clinical effectiveness and safety of use of fulvestrant was conducted. Assessment of the quality of research and level of evidence obtained in these results was performed. Direct medical costs consisted of the cost of the drug, the cost of patient management and correction of side effects. Duration of therapy, its effectiveness and side effects were obtained from relevant studies on clinical effectiveness (CONFIRM, 2013, S. Jones et al. 2005). The cost of certain hematological side effects were taken from the study Belousov DU et al. 2012. To estimate the duration of hospital stay in the development of hematological side effects, conducted a survey of experts. After calculating the total medical costs on comparable regimens were conducted cost-effectiveness analysis (CEA) for each of which will be constructed the model of CER. Results: The final CER of fulvestrant compared to paclitaxel and docetaxel. The sensitivity analysis showed that the simulation results are resistant to increase of the prices for fulvestrant to 212%. CONCLUSIONS: The use of fulvestrant for the treatment of metastatic breast cancer in second-line chemotherapy is more cost-effective than the appointment of docetaxel and paclitaxel.

PCN132
COST-EFFECTIVENESS EVALUATION OF BRENTUXIMAB VEDOTIN FOR REFRACTORY/RELAPSED HODGKIN LYMPHOMA: A COMPARATIVE ANALYSIS OF THE RESULTS OF MEXICO AND VENEZUELA
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OBJECTIVES: Brentuximab vedotin is an orphan drug currently indicated for treatment of patients with refractory/relapsed hodgkin lymphoma CD30+ following prior Auto Stem Cell Transplant (ASCT) or following two prior chemotherapy regimens. This is a group of patients with a reported median survival of 12 months, with no defined standard of care and for whom clinical trials are single armed due to lack of appropriate comparators and scarcity of patients. Hence, an indirect comparison was performed to determine the cost-effectiveness of brentuximab vedotin in different countries. METHODS: A three state Markov model was developed. Effectiveness of brentuximab vedotin was obtained from the clinical trial of Gopal et al. 2013. The risk of long-term side effects (ED) and ic (EF) 0.313, RT 0.009, AS 0.084. Cost of fulvestrant was obtained from 3 clinical trial publications. The analysis indicates that RT is associated with better prognosis and higher overall costs compared to AS. 2.5 years follow-up might, however, not be enough to detect prostate cancer-specific deaths.

PCN133
ECONOMIC EVALUATION of FUVLVESTARN 500 MG (F500) versus ORIGINAL NONSTEROIDAL AROMATASE INHIBITORS in PATIENTS WITH ADVANCED BREAST CANCER in RUSSIA (2 LINE THERAPY)
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OBJECTIVES: To perform cost-effectiveness analysis fulvestrant 500mg (F500) for the treatment of first progression or recurrence of advanced breast cancer in postmenopausal patients compared with anastrozole 1mg (ANA51), letrozole 1mg (LET2.5) and exemestane 10mg (EX25+EVE10). METHODS: The data on efficacy and safety of 2-line hormonal therapy of breast cancer were derived from a network meta-analysis and clinical data publication for overall survival (OS), progression free survival (PFS) and serious adverse events (SAE). We considered the direct costs on second and third line hormonal therapy and resource utilization. Data on resource usage, were based on expert opinion and open sources. 1-way sensitivity analyses were conducted. RESULTS: In terms of OS F500 (mean 23.33 months) was as effective as ANAS1 (22.12) and more effective than LET2.5 (17.44) and EXE25 (18.31). The highest incremental cost-effectiveness ratio (ICER) estimated for F500 versus ANAS1 was 25,890 USD per year (incremental effectiveness 5.90 month). The ICER estimated for F500 versus LET2.5 was 22,873 USD per year with incremental effectiveness 5.90 month. The ICER for F500 versus EXE25 was 25,890 USD per year (incremental effectiveness 5.90 month). The ICER for F500 versus EXE25 was 25,890 USD per year (incremental effectiveness 5.90 month). The ICER for F500 versus EXE25 was 25,890 USD per year (incremental effectiveness 5.90 month). CONCLUSIONS: A series of one-way sensitivity analyses showed this result is robust to variations in costs of drugs, physician examination, and variation in costs associated with SAE. Conclusions: Our results suggest that F500 is an affordable, and at least as efficacious as ANAS1 in terms of OS among postmenopausal women with advanced breast cancer after failure on 1-line endocrine therapy. In terms of PFS F500 less efficacious than EXE25+EVE10, however, substantially cheaper than ANAS1. From perspective of federal health care system, the cost of LYG for F500 is less than the willingness to pay threshold.

PCN134
WILL GOVERNMENTS BE ABLE TO AFFORD A CANCER CURE UNDER CURRENT HEALTH ECONOMIC EVALUATION METHODS?
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OBJECTIVES: Cancer accounts for around 1.3 million deaths and £50 billion in healthcare expenditure in the European Union. Balancing increasing treatment costs and prevalence will be increasingly difficult for governments to manage. Advances in immunotherapies provide hope for a cancer cure, however its cost might be out of reach for governments under current health economic evaluation methodologies. Thus, this research aims to study the affordability of potential curative treatments for cancer and the potential cost of a cancer cure that would be within an acceptable cost-effectiveness threshold. This cost was then modified to take into account the quality of life (QoL) of the general population, QALY discounting, cancer stage, heterogeneity, and other demographics. YLL due to disablement in cancer were not included in the calculation. RESULTS: It is estimated that 32.4% of the total YLL per year in the UK (£5,615,310) are a consequence of cancer. The cost of saving these YLL at £20,000 per QALY was estimated to be £12 billion for all cancers per year, meaning an extra £425 in taxes would have to be generated.
from each taxpayer. CONCLUSIONS: A cancer cure evaluated under current health economic evaluation methods would cause a budget that would be unaffordable for governments due to the high prices that could be achieved while remaining cost effective. Although these types of technologies therapies are not currently available, patients might want to explore new methods of evaluation that could incorporate quality of life and costs of quality-adjusted lifetimes rather than years or increasing discount rates on QALYs for immunotherapies.

PCN135 ECONOMIC IMPACT OF THE INCLUSION OF PERTUZUMAB FOR THE TREATMENT OF METASTATIC BREAST CANCER HER2+ in a University Hospital according to real data of our patients. METHODS: CROSS-sectional study where the patients where selected from the cardiology department. The time horizon was one year and the perspective of medical leadership of the hospital was used. RESULTS: During the study period 371 patients were treated for breast cancer and 75 patients (20.2 %) were HER2+. The mean weight of 71.5 kg (SD 17.1) and men BMI of 29.3 were obtained. The annual cost of docetaxel + trastuzumab + pertuzumab was €9,257.32 + €41,371.84 to patients with mutant HER2+ breast cancer and €29,837.47 ± €1,130.16 to patients with non-HER2+ breast cancer. The incremental cost effectiveness ratio (ICER) was 15.127 €/QALY per year. CONCLUSIONS: The addition of pertuzumab to treatment with docetaxel / trastuzumab for metastatic breast cancer has not shown to increase in SLP. However, the economic impact of this new drug, requires careful selection of patients who could benefit. Health authorities will have to consider whether trastuzumab is cost effective in terms of their willingness to pay.

PCN136 COST EFFECTIVENESS OF SUNITINIB AS FIRST-LINE TARGETED THERAPY FOR METASTATIC RENAL CELL CARCINOMA IN CHINA

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OBJECTIVES: Multitargeted receptor tyrosine kinase inhibitors are more effective alternatives to interferon-α and monoclonal antibodies in patients with metastatic renal cell carcinoma (mRCC). However, economic humanistic outcomes associated with these treatments are sparse in the Chinese setting. This study evaluated the clinical and economic consequences of sunitinib in China compared with sorafenib and interferon-α2b in the third-party payer perspective in China. METHODS: A Markov model was developed to simulate disease progression and determine costs and outcomes over patient’s lifetime. The time horizon of analysis was 10 years. Toxicity data was obtained from the phase III CLEOPATRA trial. The incremental cost per quality-adjusted life-year (QALY) gained was calculated for each treatment arm. RESULTS: The incremental cost effectiveness ratios imputed to patients with mutant RAS exons (2,3, 4). RAS biomarkers aid identification of the patient group that is likely to benefit the most from anti-EGFR treatment such as cetuximab and therefore allow more efficient use of NHS resources. A New Product Assessment Form was submitted to the Scottish Medicines Consortium with the aim of improving the latest economic outcomes in mRCC patients (versus KRAS wt) treated with cetuximab in combination with chemotherapy and its cost effectiveness compared to currently available treatments. METHODS: A state-transition Markov cohort model was developed to simultaneously present outcomes and costs for first and subsequent lines of treatment including the long-term survival after a successful curative resection of liver metastases. RESULTS: The model estimated an incremental 0.28 life-years gained (LYG) with cetuximab + FOLFIRI combination compared to FOLFIRI alone and an incremental 0.32 LYG with cetuximab + FOLFIRI compared to FOLFOX alone. The model was most sensitive to length of treatment with cetuximab. CONCLUSIONS: The incremental cost effectiveness ratios imputed in the model are close to the traditional willingness to pay threshold adopted by the SMC. This analysis demonstrates that cetuximab in combination with FOLFIRI or FOLFOX in mRCC patients is a cost effective treatment option compared to chemotherapy alone, specifically when taking into consideration that cetuximab qualifications were included in the analyses as well as the effect of cetuximab on survival after a successful curative resection of liver metastases.

PCN140 COST-EFFECTIVENESS ANALYSIS OF BEVACIZUMAB, FOTEMUSTINE AND EXTENDED-DOSE TEMOZOLOMIDE IN PATIENTS WITH RECURRENT GLIOBLASTOMA IN SPAIN

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OBJECTIVES: Colorectal cancer is the third most common cancer in Scotland, with nearly 4,000 cases reported in 2011 and 2012. We included patients with untreated and recurrent or progressive disease who had previously failed standard treatment, including resection of primary colorectal cancer (cCRC) patients with wild-type (wt) KRAS (KRAS and NRAS exons 2, 3, 4) expression who were likely to benefit from anti-EGFR treatment compared to placebo. RADOM: The incremental cost effectiveness ratios (ICER) were calculated using Microsoft Excel. The ICER analysis shows which combination of patient groups and treatment strategies will be most beneficial for the society. RESULTS: Our model got three health states: alive without progression, alive with progression-free survival after a successful curative resection of liver metastases. RESULTS: The model estimated an incremental 0.28 life-years gained (LYG) with cetuximab + FOLFIRI combination compared to FOLFIRI alone and an incremental 0.32 LYG with cetuximab + FOLFIRI compared to FOLFOX alone. The model was most sensitive to length of treatment with cetuximab. CONCLUSIONS: The incremental cost effectiveness ratios imputed in the model are close to the traditional willingness to pay threshold adopted by the SMC. This analysis demonstrates that cetuximab in combination with FOLFIRI or FOLFOX in mRCC patients is a cost effective treatment option compared to chemotherapy alone, specifically when taking into consideration that cetuximab qualifications were included in the analyses as well as the effect of cetuximab on survival after a successful curative resection of liver metastases.

PCN141 PHARMAECONOMIC ANALYSIS OF Axitinib as SECOND-LINE TREATMENT FOR METASTATIC RENAL CELL CARCINOMA

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OBJECTIVES: Despite the lack of evidence-based information on their clinical and cost-effectiveness, surgery and primary endocrine therapy (PET) are the most commonly used initial treatment strategies for older women with primary breast cancer. However, a recent analysis using the United Kingdom (UK) frameworks to evaluate the cost-effectiveness of surgery, a decision analytical modelling is necessary. This systematic review aimed to summarise the modelling methodologies from the literature to inform the model design in older women. METHODS: An electronic database search was conducted using NHS Economic Evaluation Database, Cochrane Library, Ovid Medline, PubMed, and EMBASE to identify full economic evaluations that compared different treatment strategies in postmenopausal women with primary breast cancer. Quality and modelling methodologies of included studies were assessed and summarised. RESULTS: All the 31 included studies assessed surgery and none assessed PET as the initial treatment. Most included economic studies were conducted using Markov models and calculators. Nine studies which included sub-group analysis for older women (over 65 years old) used similar economic models and transition states with younger women (50 to 64 years old). The key disease-related health states were disease-free, recurrence, and death. Recurrence was mostly separated into loco-regional and distant recurrence. CONCLUSIONS: This systematic review can inform the design of an economic model comparing PET with surgery as initial treatment in older women based on the following assumptions: (1) health states are applicable across age groups; (2) transition states for modelling surgery in the literature are transferable to model the same treatment for older women; (3) metastasis transition states include progression, progression-free, and death can be used to model the PET pathway. Future study will validate this model by using a longitudinal dataset of older women with primary breast cancer, and synthesise data from different data sources to populate this economic model.

PCN137 AN EVIDENCE-BASED MODEL DESIGN TO INFORM THE COST-EFFECTIVENESS EVALUATION OF PRIMARY ENDORCINE THERAPY AND SURGERY FOR OLDER WOMEN WITH PRIMARY BREAST CANCER

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OBJECTIVES: Despite the lack of evidence-based information on their clinical and cost-effectiveness, surgery and primary endocrine therapy (PET) are the most commonly used initial treatment strategies for older women with primary breast cancer. However, a recent analysis using the United Kingdom (UK) frameworks to evaluate the cost-effectiveness of surgery, a decision analytical modelling is necessary. This systematic review aimed to summarise the modelling methodologies from the literature to inform the model design in older women. METHODS: An electronic database search was conducted using NHS Economic Evaluation Database, Cochrane Library, Ovid
OBJECTIVES: To identify the dominant scheme of mRCC second-line target treat-
ments (two alternatives – Axitinib and Everolimus). METHODS: We adapted the
Markov model, the cost-effectiveness analysis was realized. Overall survival, annual survival rate, time to progression of disease and direct cost of mRCC treat-
ment was evaluated. Costs analysis included: costs of two target therapy lines (Sunitinib, and second-line treatment after Axitinib or Everolimus treatment)
of 3 and 4 grade side effects compensation; cost of diagnosis and inpatient care; cost of
disease progression; cost of palliative and best supportive care. RESULTS: During the
pharmacoeconomic analysis of Axitinib use as a second-line therapy for mRCC, it
was found that this target therapy regimen would significantly increase the time
between first and second-line therapy which amounted to 22.75 months, with an
annual survival rate of 68%, 38% and 17% of patients following the first, second and
third year of treatment, respectively. Despite the high cost of this therapeutic regi-
men reaching 51.327 € at the horizon of ten year study, the treatment regimen includ-
ing Axitinib will be characterized by the lowest values of the cost-effectiveness
ratio, ICUR and ICER compared to the first line treatment financed by the Portuguese
National Health Service. CONCLUSIONS: It is shown, Axitinib use as second-line of
target therapy in patients with mRCC is the most preferable treatment regimen
then Everolimus from the pharmacoeconomic point of view.

PCN142

COST-EFFECTIVENESS ANALYSIS OF HYDRAZINE AND MAGNESIUM VALPORATE LP ASSOCIATED WITH TREATMENT FOR ADULT PATIENTS WITH METASTATIC RECURRENT OR PERSISTENT CERVICAL CANCER IN MEXICO

Soto H., Escobar Juárez Y., Constantino A., Fernandez Z., Melendez C.

Methods: The first goal was to adapt an existing Austrian decision-analytic
treatment regimens for chronic myeloid leukemia. If further research were funded, stud-
ies should examine a combination of natural history, treatment, and quality of life
gains, especially the effectiveness of first-line TKI treatment.

PCN144

DECISION ANALYSIS ON THE COST-EFFECTIVENESS OF SEQUENTIAL TREATMENT STRATEGIES FOR PATIENTS WITH CHRONIC MYELOID LEUKAEMIA IN THE UNITED STATES

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OBJECTIVES: To identify the dominant scheme of mRCC second-line target treat-
mments (two alternatives – Axitinib and Everolimus). METHODS: We adapted the
Markov model, the cost-effectiveness analysis was realized. Overall survival, annual survival rate, time to progression of disease and direct cost of mRCC treat-
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men reaching 51.327 € at the horizon of ten year study, the treatment regimen includ-
ing Axitinib will be characterized by the lowest values of the cost-effectiveness
ratio, ICUR and ICER compared to the first line treatment financed by the Portuguese
National Health Service. CONCLUSIONS: It is shown, Axitinib use as second-line of
target therapy in patients with mRCC is the most preferable treatment regimen
then Everolimus from the pharmacoeconomic point of view.
assumed equal for everolimus, while utilities for the post progression stages were obtained from the literature. Resource use was estimated by questionnaire and a panel of experienced experts to reflect Portuguese clinical practice. Official unit costs were used, following the Portuguese National Health Service perspective. The model adopted a lifetime frame (15 years) with a 5% discount rate. RESULTS: Axitinib allowed an increased median of 0.12 years of life gained from overall survival, and 0.32 quality adjusted life years compared to everolimus. Despite having a similar daily cost, the use of axitinib implied an increased cost of 9,100€, mainly due to the increased median time spent in progress free and overall survival. Consequently the cost per quality adjusted life year was 28,598€. Sensitivity analyses showed that results were robust to model parameters specification, with the main uncertainty source being clinical efficacy. CONCLUSIONS: Axitinib increased overall survival and progression free survival, which allowed patients to benefit from more quality adjusted life years at a cost increase. Overall, it was possible to advocate that axitinib is cost-effective, as the cost per QALY is below commonly accepted thresholds.

PCN147: ECONOMIC EVALUATION OF PACLITAXEL ALBUMIN, PACLITAXEL, AND DOXETAXEL AS A SECOND LINE TREATMENT FOR METASTATIC BREAST CANCER

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OBJECTIVES: Clinical studies have shown that docetaxel to be superior to paclitaxel in overall survival (OS) and progression free survival (PFS) (median OS: 1.28 vs 1.06 years; median PFS: 0.47 vs 0.30 year) for the treatment of patients with metastatic breast cancer (MBC) progressing after an anthracycline based regimen. Objective of this study is to have shown paclitaxel-albumin extended OS by 9.7 weeks, and TTP by 4 weeks. An economic evaluation based on these two clinical trials was performed to compare paclitaxel-albumin, paclitaxel, and docetaxel as a second line treatment for metastatic breast cancer. METHODS: A Markov model was conducted using three health states: PFS, progression, and death to estimate overall survival, cost, life year gain (LYG) and quality adjusted life year (QALY). Results for the whole breast cancer patients, over 18 cycles therapy course. Total cost of therapy reflects drug acquisition cost, consumables dispensed, hospital overheads, physician and other staff time. The indirect analysis, the model assumed that the OS for axitinib was equivalent to everolimus. TIL is highly personalized, however complex and requests substantial upfront investments from the hospital in expensive lab-equipment, staff expertise and training, as well as extremely tight hospital logistics. Therefore, an early health economic modelling study, supporting a Coverage with Evidence Development (CED) indication, was performed. A Markov decision model was used to estimate the expected costs and outcomes (quality adjusted life years; QALYs) for TIL versus Ipilimumab in metastatic melanoma patients from a societal perspective over a life long time horizon. Three mutually exclusive health states (stable disease, progression free disease and death) were modelled, divided in first and second line treatment. Technical failures and non-compliance were incorporated to reflect the dynamic nature of the technology. To inform future research prioritization, Value of Information (VOI) analysis was performed. RESULTS: TIL is expected to yield more QALYs compared to Ipilimumab (0.99 vs 0.52 respectively) at lower total costs ($83,588 vs $87,834 respectively). Based on current information TIL has a probability of 86% for being cost effective at a cost/QALY threshold of $30,000. Expected Value of Information (EVI, £275 for an optimal sample size of n=355,000). Expected Value of Sample Information was estimated £355,000 for an optimal sample size of n=50. CONCLUSIONS: TIL is expected to improve QALYs compared to Ipilimumab at lower incremental cost and has the highest probability of being cost-effective. To reduce decision uncertainty, a future clinical trial to investigate survival seems most valuable, and should preferably be undertaken as part of a CED program.
lower than that with Herceptin-IV in the management of patients with HER2+ EBC and MBC. Hence, the substitution of Herceptin-IV monotherapy occurred in less than 5% in case of tegafur. Tegafur (in monotherapy or in combination with calcium folinate) is less costly than bevacizumab. The difference in costs in favor of tegafur monotherapy amounted to €1,956.97 per patient 6 months or €3,778.53 per year of treatment + calcium folinate. The same was observed for the subgroup of patients harboring DEL19 mutations (9.74 vs. 8.43). The incremental total costs were 1,368 EUR (total life time costs for Bev) and 471 EUR for GIP (24.1125 versus 21,576.75) in situation A. Cet dosage was increased by 20.2% in the Bev group or 20.9% in the GIP group. Due to increasing costs in cancer management, there is a crescent need to rationally allocate resources in health care systems. Recently, a head-to-head comparison of Herceptin-IV and TIV (situation B) showed no difference in OS and PFS for first line (1L) mCRC in KRAS wild-type (wt) patients amongst bevacizumab (Bev) and cetuximab (Cet) – the most commonly used biologics in this setting. Since benefit of both drugs is comparable, the aim of the study was comparing treatment costs from the perspective of medical leadership of the hospital was used. The Spain cost of all patients had been treated with TSC: Situation A the total spending would be €314,576.3 respectively. It is a high-level evidence that in a high-risk setting, patients with colorectal cancer are expected to benefit from an intervention with a low expected cost. The inhibition of epidermal growth factor receptor (EGFR) signaling pathway by innovative therapeutics presents promising upshots in oncology. Our study aimed to quantify first-line treatment with afatinib, an irreversible tyrosine kinase inhibitor, compared to panitumumab (panitumumab-pcix, psVAc) for patients with metastatic lung adenocarcinoma harboring common EGFR mutations (DEL19 or L858R) in the US. METHODS: Costs for afatinib were obtained from a non-profit organization (COINS) and were constructed to quantify lifetime consequences of therapy with afatinib versus panitumumab. The study included 499 adult patients with advanced metastatic lung adenocarcinoma, 99% of whom had never received previous systemic therapy. This was used to calculate additional resource consumption.

PCN154
ECONOMIC IMPACT OF USING SUBCUTANEOUS TRASTUZUMAB
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OBJECTIVES: To analyze the economic impact of the incorporation of trastuzumab subcutaneous (TSC) in a University Hospital according to real data of our patients. METHODS: Retrospective cost minimization study that included patients diagnosed with metastatic breast cancer treated with TSC from April 2013 to April 2014. The demographic data of the patients (age and weight) and antineoplastic treatments used were obtained from the computer program Hospital Information System. An economic model was developed in Excel® data base, based on the dose used in previous clinical trials: IV loading dose of 8mg/kg and after 6mg/kg/3 weeks and SC fixed dose of 600 mg/3 weeks. The time horizon was one year and the population in the analyses (49%), treatment with afatinib resulted in cost-savings. Although NMB calculations were not performed, it is a high-level evidence that in a high-risk setting, patients with colorectal cancer are expected to benefit from an intervention with a low expected cost. The inhibition of epidermal growth factor receptor (EGFR) signaling pathway by innovative therapeutics presents promising upshots in oncology. Our study aimed to quantify first-line treatment with afatinib, an irreversible tyrosine kinase inhibitor, compared to panitumumab (panitumumab-pcix, psVAc) for patients with metastatic lung adenocarcinoma harboring common EGFR mutations (DEL19 or L858R) in the US. METHODS: Costs for afatinib were obtained from a non-profit organization (COINS) and were constructed to quantify lifetime consequences of therapy with afatinib versus panitumumab. The study included 499 adult patients with advanced metastatic lung adenocarcinoma, 99% of whom had never received previous systemic therapy. This was used to calculate additional resource consumption.

PCN154
PHARMACOECONOMIC ANALYSIS OF ORAL CAPECITABINE AND TEGAFUR FOR COLORECTAL CANCER TREATMENT IN RUSSIA
Gerasimova E1, Arsentyeva N2, Rebrova G1.
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OBJECTIVES: To compare the economic impact of the use of oral drugs, tegafur vs capecitabine, for advanced colorectal cancer (CRC) in adult patients. METHODS: Indirect comparison and network meta-analysis of clinical efficacy and safety of tegafur + calcium folinate + capcitabine vs capecitabine were performed. Cost-minimization analysis (CMA) with calculation of cost minimization difference was used for economic evaluation of studied drugs. RESULTS: There was no statistically significant difference in the full and partial objective tumor response between the two regimens (all social services perspective vs. ad hoc economic model). A lifetime time horizon was used and outcomes were discounted at 3.5% per annum. All ESAs were assumed to have the same clinical effectiveness, Haemoglobin (Hb) levels were assumed to drive health-related quality of life (HRQoL), with haemoglobin linearly mapped to utility. This was used to calculate additional resource consumption.

PCN155
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incremental quality-adjusted life years (QALYs) while ESAs were administered and decreased HRQoL normalisation period following cancer treatment. Incremental long-term QALYs were accrued solely through extrapolated overall survival. Short-term mortality and HRQoL associated with adverse events and RBCTs were not modelled. Costs included: ESA acquisition (list prices, British National Formulary) and administration, RBC donation, additional blood tests with ESA administration, testing and event costs. RESULTS: All ESAs except epoetin beta and darbepoeitin alfa were cost-effective versus using RBCCT only at an upper cost-effectiveness threshold of £200,000/QALY. Costs of ESAs (not statistically significant) were removed, the ICERs for all ESAs were over £100,000/QALY. CONCLUSIONS: There is substantial uncertainty about the impact of ESA therapy on overall survival, which leads to significant uncertainty about the cost-effectiveness of ESAs in GIA.

**PCN158**

**QALY WEIGHTINGS BASED ON THE BURDEN OF ILLNESS APPLIED TO A UK COST-EFFECTIVENESS ANALYSIS OF NAB-PACLITAXEL + GEMCITABINE VERSUS GEMCITABINE ALONE FOR THE TREATMENT OF METASTATIC PANCREATIC CANCER**

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**OBJECTIVES:** To demonstrate the impact of QALY weightings based on the burden of illness on the cost-effectiveness of phase III trials of new cancer treatments. The trial compared nab-paclitaxel plus gemcitabine (NGP) versus gemcitabine (G). METHODS: A markov model was used. Data was from the mpact trial plus use of data and costs from NHS Scottish
HER2-POSITIVE BREAST CANCER IN VIETNAM
COST-UTILITY ANALYSIS OF TRASTUZUMAB IN TREATMENT OF METASTATIC PCN164
effective treatment for advanced melanoma based on these results. In the
setting, ipilimumab produces large (€56,000) cost-saving. The unadjusted comparison was the most conservative among alternative methods of clinical comparisons explored. The ICER versus dacarbazine and vemurafenib was also deemed cost-effective. CONCLUSIONS: As in the previously treated
test, trastuzumab produces large (>0.5 year) survival and quality-adjusted sur-
vival gains relative to current treatments. TUV/LNT considered trastuzumab a
effective treatment for advanced melanoma based on these results.

PCN164
COST-UTILITY ANALYSIS OF TRASTUZUMAB IN TREATMENT OF METASTATIC HER2-POSITIVE BREAST CANCER IN VIETNAM
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OBJECTIVES: Trastuzumab, a targeted therapy, has been widely used in treatment of HER2-positive breast cancer because of its proved effectiveness and safety by many studies but its economic impact with low-income countries like Viet Nam has not been assessed yet. The aim of this study is to evaluate the cost-effectiveness of trastuzumab in combination of standard chemotherapy versus standard chemotherapy in treatment of metastatic HER2-positive breast cancer. METHODS: A Markov model was developed with 3 states (stable disease, progressive disease and death) to simul-
ate a hypothetical cohort of 1,000 metastatic HER2-positive breast cancer women of an average age of 45 years old with the same criteria as the previously treated
cancer study group. Chemotherapy with ACD regimen (Docetaxel, Cyclophosphamide, Doxorubicin) was compared with ACD regimen plus trastuzumab. The cycle length of model was 1 month and time horizon was lifetime. Both cost and Quality-adjusted life-years (QALYs) were discounted annually with 3% discount rate. Probabilistic sensitivity analysis was also conducted. RESULTS: Combination of trastuzumab and standard chemotherapy increased the quality of life of metastatic HER2-positive breast cancer patients by €157,000 using a covariate-adjusted survival regression based on the 78-patient
dataset. A real-world scenario using the patient shares of dacarbazine and vemur-
afenib was also deemed cost-effective. CONCLUSIONS: As in the previously treated
test, trastuzumab produces large (>0.5 year) survival and quality-adjusted sur-
vival gains relative to current treatments. TUV/LNT considered trastuzumab a
effective treatment for advanced melanoma based on these results.

PCN165
WHAT'S THE OPTIMAL VISUAL INSPECTION SCREENING INTERVALS FOR CERVICAL CANCER SCREENING IN REAL PRACTICE OF RURAL CHINA? A COST-
UTILITY MODELING STUDY
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OBJECTIVES: A Chinese government initiated a nation-wide cervical screening pro-
gram, covering 10 million rural women in 221 counties all over the country. The
objectives of the present study were to compare costs, health outcomes, and cost-
effectiveness of visual inspection with acetic acid (VIA) screening strategy to screening without VIA screening in China, and to identify optimal screening intervals for policy makers. METHODS: A Markov simulation model was developed to synthesize the evidence of screening and treatment practices in rural China, and applied to predict the long-term costs and
effectiveness of different cervical cancer screening strategies over 20 years of screening. Model was valid by calibrating prediction with observation data on age-specific cervical cancer mortality and incidence in China. Costs were considered from a societal perspective and effectiveness was measured in terms of quality-adjusted life-years (QALYs). Both cost and utility were collected on-site and discounted at 5% per year. RESULTS: All combining alternatives showed certain benefits due to the
decreased number of women developing cervical cancer. A trend for shorter screening intervals was more cost-effective. Under these assumptions, the 5-year screening intervals, mortality and incidence were expected to be reduced by 6.67–31.74% and 5.12–23.60%, respectively. Comparing to no screening (status quo), 10-year VIA
screening was identified as the most cost-effective option, followed by VIA screening
every five-, three- and one-year, with corresponding incremental cost-utility ratio (ICUR) ranged from 11,921 to 17,215 CNY (1889 to 2728 US dollars, 2012) per QALY saved. CEA revealed that model was much less than China's GDP per capita, (4,077 US dollars, 2012). CONCLUSIONS: VIA screening at different intervals were all very cost-
effective options for 35–59 years old women in rural China. It is also noted that the
cost-effective manner of assested strategy largely depends on the local economic status and the performance of such organized program.

PCN166
ECONOMIC EVALUATION OF HOME PARENTERAL NUTRITION IN CANCER PATIENTS: THE FRENCH CONTEXT
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OBJECTIVES: This study aims to estimate incremental cost and utility of Home Parenteral Nutrition (HPN) in a heterogeneous group of cancer patients from the French public purchaser perspective, as compared with the same patients receiving to the same care in a standard hospital setting. METHODS: Two models were compared, one from public payer perspective and the other from the national payer perspective (TLV/NLT). Uncertainty was assessed by deterministic and Probabilistic Sensitivity Analyses were performed to test uncertainty. RESULTS: The cost-utility ratio of HPN is estimated in 508,059 and 182,548 € per QALY gain, in the national and the lifetime utility model respectively. The probability for cost-effectiveness, compared to standard hospital setting, is above 95% and 99% respectively. DSA showed that survival in the control group and cost of the nutrition were the most influential parameters on the cost-utility ratio in both models. The probability for cost-effectiveness, compared to standard hospital setting, is above 95% and 99% respectively. CONCLUSIONS: Final judgment on HPN cost-effectiveness is difficult, even if it seems to be not cost-
finalizing according to standard TUVP. The high cost-utility ratio, which declines with increased disease severity and effects of independence, should urge clinicians and policy makers to control the sources of inefficience.

PCN167
COST-EFFECTIVENESS ANALYSIS OF UGT1A1 GENOTYPING BEFORE COLORECTAL CANCER TREATMENT WITH IRINOTECAN
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OBJECTIVES: Irinotecan is an anti-cancer agent that is used for the treatment of metastatic colorectal cancer. Although it prolongs survival, it can cause severe toxic-
ity (e.g. diarrhoea and neutropenia) in patients who carry the UGT1A1*28 allele. This study evaluates the cost-effectiveness of UGT1A1 genotyping prior to irinotec-
ane-based chemotherapy from the individual and societal perspective. The long-term outcomes of interest included cancer survival and medical costs. METHODS: We develop a decision-analytic Markov model to analyze costs and QALYs during a time horizon of six months (two-week cycles). No testing was compared against testing with every five, three and one year. Model was adapted from previously published literature. Outcomes were discounted at 3%. A Markov chain model was used and life expectancy was calculated using survival estimates from multiple sources. Results showed that cost-effectiveness is highly dependent on whether a patient has an increased risk of irinotecan-based chemotherapy and the (3) administration of a prophylactic G-CSF growth factor for patients with a UGT1A1*28 variant. Probability, utility and costs for different strategies were used in this study were extracted from previously published literature. CONCLUSIONS: Our analy-
sis suggests that UGT1A1 genotyping and subsequent reduction of irinotecan-based chemotherapy has a substantial cost-saving potential. Due to the promising results, further research, for example in the form of a managed entry agreement would be desirable to validate these findings.

PCN168
EFFECTIVENESS ANALYSIS OF TESTING FOR BRCA MUTATIONS IN WOMEN DIAGNOSED WITH OVARIAN CANCER AND THEIR FEMALE FIRST-
DEGREE RELATIVES: A UK HEALTH SERVICE PERSPECTIVE
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OBJECTIVES: Mutations in BRCA1 and BRCA2 are associated with an increased risk of breast and ovarian cancer. If a mutation is detected in women with ovarian cancer, it may be potentially useful to offer risk-reducing surgical intervention. Current UK practice is for any at-risk relative have access to testing. Guidelines also recommend that gene testing should be offered to indi-
viduals with BRCA mutation carrier probability of ≥ 10%, although this is not rou-
tine clinical practice. There is considerable variation in the rates at which ovarian cancer patients are offered BRCA testing. Our aim is to evaluate the long-term cost-effectiveness of the UK providing BRCA testing to women with ovarian cancer and to the unaffected female first-degree relatives of those with BRCA mutations. METHODS: A Markov model with a lifetime horizon was developed to reflect the clinical and economic

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OBJECTIVES: Iplimunab was the first compound to substantially prolong survival in advanced melanoma. Evaluate the cost-effectiveness of ipilimumab in untreated advanced melanoma compared to dacarbazine and vemurafenib from a Swedish national perspective (TPV/NLT). METHODS: A three-state Markov model with stable disease, progression and death was developed, estimating costs and ben-
efits over a lifetime horizon. Given a lack of head-to-head data and a connected evidence gap, for a robust NMA, without IPD, comparisons were used between two cost
unadjusted for study characteristics. Iplimunab survival data were based on a pooled sample of treatment-naïve patients from clinical trials (n=78) and real-world settings (n=181), the clinical data package used for EMA submission. Parametric extrapoly methods were applied to dacarbazine data from CRIT-02. Resource use was taken from a survey of Swedish oncologists (n=5). EORTC-89122 study compared vemurafenib treatment to placebo, with health utility assessed using a published survival algorithm. Costs were obtained from official Swedish price lists. Survival and utility assumptions were varied in scenario analyses. RESULTS: Iplimunab was associated with a 0.93 QALY gain and an ICER of SEK109,000 vs dacar-
bazine. Iplimunab dominated vemurafenib with a 0.76 QALY gain and a SEK109,000 associated with a 0.93 QALY gain and an ICER of SEK782,000 (€157,000) cost-saving. The unadjusted comparison was the most conservative among alternative methods of clinical comparisons explored. The ICER versus dacarbazine and vemurafenib was also deemed cost-effective. CONCLUSIONS: As in the previously treated
test, ipilimumab produces large (>0.5 year) survival and quality-adjusted sur-
vival gains relative to current treatments. TUV/LNT considered ipilimumab a
effective treatment for advanced melanoma based on these results.
outcomes following BRCA testing in women with ovarian cancer and their female first-degree relatives. Two strategies are being compared: no testing versus BRCA testing. Estimates of cancer incidence and mortality, uptake and impact of risk-reducing surgery and costs of BRCA testing, cancer treatment and palliative care were based on literature review. Outcomes are expressed as quality-adjusted life years (QALYs). Cost-effectiveness analyses are conducted for both strategies. RESULTS: We first evaluated the cost-effectiveness of gene testing in relatives of ovarian cancer patients with BRCA mutations. Results showed this was associated with an ICER below the UK cost-effectiveness threshold of £20,000 per QALY gained compared with no testing. Cost-effectiveness analyses showed the results were robust. CONCLUSIONS: We demonstrate that gene testing in unaffected female first-degree relatives of women with ovarian cancer due to BRCA mutations is cost effective compared with no testing. The final results will consider the cost-effectiveness of offering BRCA testing to all eligible ovarian cancer cases and their unaffected female first-degree relatives.

PCN169 BURDEN OF RENAL IMPAIRMENT: RELATIVE HEALTH CARE RESOURCE USE IN PROSTATE CANCER PATIENTS WITH BONE METASTASES

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OBJECTIVES: Existing evidence suggests that around 49% of patients with bone metastases from solid tumors show evidence of renal impairment (eGFR<60ml/min/1.73m²) following diagnosis of bone metastases with approximately 80% of them developing chronic kidney disease. The objective of this analysis is to assess the economic burden of renal impairment in prostate cancer patients with bone metastases. METHODS: A retrospective cohort study using healthcare claim data was conducted. Patients with evidence of renal impairment were matched with those without on a 1:1 basis, controlling for: age, BMI, smoking status, employment status, and relevant comorbidities. Statistical analysis was conducted using Python and Stata. RESULTS: In total, 11,519 patients were included in the analyses. Propensity Score matching was used; patients with evidence of renal impairment were matched with those without on a 1:1 basis, controlling for: age, BMI, smoking status, employment status, and relevant comorbidities. Outcomes included number of hospitalizations, length of stay, and priority of further studies. The population consisted of patients identified in the Adelphi Real World Disease Specific Programme USA for the period 2012 with no lung cancer and at least one inpatient visit within that time window. After 12 months, 491 patients were included in the analyses (total 218). The renal impairment group was estimated to have had an increased risk of inpatient visits of 63% (95% CI = 0.40–0.80) compared to the control group (0.78 vs 0.48 inpatient visits per patient per year). Additionally, the renal impairment group had a mean of 2.43 (p = 0.027) more inpatient days per year than the control group (5.00 vs 2.56 inpatient days per patient per year). It was also observed that the patients in the renal impairment group were less likely to have received chemotherapy (37% vs 47% received chemotherapy). CONCLUSIONS: Findings suggest an increase in health care utilization in the hospital setting in prostate cancer patients with bone metastases and renal impairment. In addition, compromised renal function in these patients may potentially have restricted the use of nephrotoxic chemotherapy agents.

PCN170 ESTIMATING THE VOlume OF PIVOTAL STUDIES TOwards PREDICTIVE BIOMARKERS OF HIGH DOSE ALKYLCATING CHEMOTHERAPY IN TRIPLE NEGATIVE BREAST CANCER

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OBJECTIVES: To estimate the expected benefits from a pivotal randomised controlled trial of predictive biomarkers for high dose alkylating chemotherapy (HDAC) in triple-negative breast cancer (TNBC) and to inform decisions about the design and priority of further studies. METHODS: A markov decision model compared treating 40 years old TNBC women with HDAC based on four predictive biomarker strategies: 1) BRCA1-like by MLPA testing, 2) BRCA1-like by sCGH testing, 3) strategy 1 followed by XIPT and SSBP1 testing and 4) strategy 2 followed by XIPT and SSBP1 testing, versus treating all patients with standard chemotherapy. A Dutch societal perspective and a 20 year time horizon were used. Input data came from literature and expert opinions. We assessed four primary outcomes: the expected value of information (partial) perfect information (EVI) P), the expected value of sample information (EVS) and the expected net benefit of sampling (ENB) for the ongoing pivotal TNM trial (NCT01507689) and/or potential future studies. RESULTS: The population EVI was €663 million (€). The EVPI suggests prioritizing further research towards effectiveness parameters, specifically prevalence and positive predictive value of the biomarkers; response rates in biomarker negative patients and TNBC unclassified patients, which are estimated to collectively have a value of information of circa €630M. The value of further research on transition probabilities is estimated at €41M, followed by utilities at €34M and costs at €34M. Further information on transition probabilities could be gathered from the TNM trial and that of effectiveness parameters and costs from accompanying studies to this trial, altogether estimated to have an ENB of €657M. CONCLUSIONS: Further research on predictive biomarkers for HDAC should focus on gathering transition probability data from ongoing trials and accompanying studies to derive data on other effectiveness parameters and costs.

PCN171 REAL WORLD DATA ON ONCOLOGY: THIRD- AND FOURTH-LINE TREATMENTS ADMINISTERED IN METASTATIC COLON-RECTAL CANCER (MCRc)

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OBJECTIVES: The objective of this study was to assess the oncologists’ real clinical practice in the management of mCRC patients, with a focus on the 3rd, 4th and later lines of therapy in Italy. METHODS: Data presented in this study were collected from medical records obtained by Italian oncologists on mCRC patients between March and April 2014 and retrieved from an extra boost of ONCOCENCE. Data from an omnibus syndicated study on cancer treatment in the hospital setting, based on the collection of patient questionnaires. Patients inclusion criteria were the presence of an mCRC diagnosis, 3rd or later actual therapy line and no participation in a phase II or III clinical study. Information collected included patient demographic characteristics, mCRC characteristics (TNM Classification, Karnofsky performance status and mutation analyses) and treatments (actual and previous schedules, dosages and durations). Furthermore, the average “cost” of the regimen in each line of therapy among third line patients was carried out.

RESULTS: 261 patients diaries have been collected: 218 out of 261 patients were in third line of treatment, while 43 patients were in 4th or later line treatment. The most used thinned chemotherapy was Capecitabine alone (63 patients), while the most used schema in fourth line was a combination of Fluorouracil and Folinic Acid (7 patients). About 40% of molecules administered in 3rd line and 67% of molecules administered in 4th line were used at the first time. Conclusions: Further research on predictive biomarkers for high dose alkylating chemotherapy (HDAC) in triple-negative breast cancer (TNBC) and to inform decisions about the design and priority of further studies.

CONCLUSIONS: From the present study underline the unmet medical need in 3rd or later line treatment of mCRC patients and the need for additional evidence-based treatment options.

PCN172 BURDEN OF DRUG WASTE IN ONCOLOGY: OPTIMIZATION OF RESOURCE USE

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OBJECTIVES: Minimizing waste of the use of drugs allows optimizing of available resources in a scarce environment. Grouping patients may be an alternative to reduce drug waste in oncology. The objective of this study was to quantify the impact of streamlined form of dispensation and percentage of drug wastage of the total drug expenditure in Supplementary health system. METHODS: Patients receiving antineoplastic treatment with no evidence of renal impairment and breast cancer were eligible and selected retrospectively from the private market administrative claims database (Evidencias database). Name and any other personal identifier were removed from the data set. Propensity Score Matching was collected from 3 selected private institutions considering large to small size in terms of patients. Waste of drug was calculated and it was defined as unavoidable or inappropriate clearance of partially drug use. All analyses were performed using R software. RESULTS: The drug wastage was represented from 2% to 8% of the total drug expenditure, regarding on the antineoplastic used. Five of the 11 drugs did not cause savings due to small number of patients receiving those treatments. CONCLUSIONS: Grouping patients for drug wastage minimization is an effective way to reduce costs. Furthermore, savings can be increased by gathering patients of different diseases.

PCN173 RESOURCES UTILIZATION FOR THE INVESTIGATION OF PULMONARY NODULES IN A UNIVERSITY HOSPITAL CENTER IN QUEBEC, CANADA

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OBJECTIVES: Lung cancer is the leading cause of death among cancer patients; therefore, the detection of small nodules (TNBC) may help in the early diagnosis of lung cancer. The objective of this study was to measure the health care resources used for the investigation of pulmonary nodules. METHODS: A retrospective medical chart review was conducted at the CHUM-Hotel-Dieu in Montreal, Canada. Eligible patients were selected consecutively using the electronic appointment book of the pulmonary clinic, from January 1st 2011 to May 31st 2012. Inclusion criteria were: 40 year-old and over, presenting a pulmonary nodule ranging from 0.8 to 3.0 cm with no prior history of cancer in the last 5 years and no history of lung cancer. Patient’s demographics, nodule characteristics, medical information, and resources utilization were extracted for each patient. RESULTS: The population consisted of 47 patients (23 women and 24 men, mean age = 64) were included in the analysis. The mean nodule size was 1.8 cm. Thirteen patients (28%) had a benign nodule and 34 (72%) had a malignant nodule. The most frequent non-invasive procedures were Thora CT-Scan, PET-Scan and Chest X-ray performed at least once in respectively 96%, 85% and 77% of patients. The minimally invasive procedures (bronchoscopy and thorascopic needle biopsy) and the invasive procedures (thoracotomy and thoracotomy) were mostly performed in patients who were eventually diagnosed with a lung cancer. On average, patients with a benign nodule underwent 0.77 minimally invasive or invasive procedures vs. 1.94 for patients with a malignant nodule (p < 0.05). CONCLUSIONS: In our study, a significant amount of health care resources are used in the investigation of pulmonary nodules. The results of this study provide evidence that current diagnostic workup should be reduced from 2% to 8% of the total drug expenditure, regarding on the antineoplastic used. Five of the 11 drugs did not cause savings due to small number of patients receiving those treatments. CONCLUSIONS: Grouping patients for drug wastage minimization is an effective way to reduce costs. Furthermore, savings can be increased by gathering patients of different diseases.
OBJECTIVES: Skeletal-related events (SERs) defined as pathologic fracture, radionecrosis and spinal cord compression, are common consequences of bone metastases. Prior studies have shown that SERs increase the utilization of health care resources, including hospitalizations. We estimated the decrease in hospitalizations and inpatient days associated with denosumab. The number of breast cancer patients was collected from a German registry using the International Classification of Disease codes. Epidemiological data were then utilized to derive the number of hospitalizations due to bone metastases. The number of patients treated for SERs prevention was obtained from market research and applied to either treatment. The total number of hospitalizations and inpatient days associated with bone metastases secondary to breast cancer in Germany.

METHODS: An analysis was run for predicting the number of SERs avoided and the reduction in the number of hospitalizations attributable to treatment with denosumab. The number of breast cancer patients was collected from a German registry using the International Classification of Disease codes. Epidemiological data were then utilized to derive the number of hospitalizations due to bone metastases. The number of patients treated for SERs prevention was obtained from market research and applied to either treatment. The total number of hospitalizations and inpatient days associated with bone metastases secondary to breast cancer in Germany.

RESULTS: Results are presented in terms of the number of hospitalizations and inpatient days avoided by using denosumab instead of zoledronate compared to zoledronate. The results showed that approximately 5,000 per year.

CONCLUSIONS: The superior efficacy of denosumab compared to zoledronate reduces the disease burden by decreasing the number of SERs and consequently the number of hospitalizations and inpatient days.

PCN175

CARCINOMA: IMPLEMENTATION OF GENOMIC SEQUENCING IN PEDIATRIC ONCOLOGY: IDENTIFICATION AND VALUATION OF RESOURCES AND COSTS ASSOCIATED WITH NEXT-GENERATION SEQUENCING

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OBJECTIVES: Beyond understanding the pure cost of genomic sequencing, the real costs associated with implementing next-generation sequencing (NGS) into clinical practice are not known. Our study aimed to allocate the real costs and provide a potential benchmark for reimbursement, a pilot study was conducted to identify and valuate the resources related to conducting clinical cancer whole-exome (cWES), transcriptome, and targeted panel sequencing in a cohort of 25 pediatric cancer patients. A cost model was calculated using 25 pediatric cancer patients who underwent clinical genomic sequencing at Columbia University Medical Center. Our institutional workflow developed in the Precision in Pediatric Sequencing (PiPeS) Program in the Division of Pediatric Oncology and the Personalized Genomics Medicine Laboratory in the Department of Pathology guided the identification of resources and costs associated with NGS.

RESULTS: 17 pediatric patients received cWES testing and 11 patients received transcriptome testing using illumina HiSeq 2500 technology. 7 patients received targeted cancer panel testing using Illumina MiSeq technology. The total cost per case per test: cWES (tumor/normal), $4,459; transcriptome (tumor), $1,764, targeted panel (tumor), $363 was calculated from summing the total variable cost (reagent cost, pathologist time) with the fixed cost per case (annual machine cost, annual maintenance, tech labor cost, informatics cost, space for NGS hardware, server time, NGS analysis lease, and data storage).

Clinical utility was demonstrated by identifying a potentially actionable mutation in 24% of participating patients. Since the reimbursement landscape for clinical genomic sequencing is currently unknown, a comprehensive cost calculation reflecting resource utilization across the workflow was used including costs associated with directed therapy based on molecular profiling results is necessary. These data serve as a starting point toward identifying and valuating resources associated with NGS and serve as a first step toward demystifying reimbursement for clinical genomic sequencing in pediatric Oncology.

PCN176

AMNOG BENEFIT ASSESSMENT FOR ONCOLOGIC AND ORPHAN DRUGS IN GERMANY – IMPLICATIONS FOR PRICE DISCOUNTS

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OBJECTIVES: With the start of AMNOG in 2011, industry is demanded to submit evidence as well as negotiate discounts for new drugs with an additional patient benefit in Germany. The National Association of Statutory Health Insurances (GKV) negotiates with the industry on the ex-factory price on top of a mandatory discount. Evaluating final prices, questions arise regarding factors that might influence discounts and impact the German market especially for oncologic and orphan drugs.

METHODS: A database containing detailed information for all past assessments was used to explore potential impact factors for discounts. Starting with an analysis of background information (discount, areas etc.) descriptive statistics were employed. Furthermore, we analyzed past assessments with respect to: number and size of target population, results of the benefit assessment, change in ex-factory price, magnitude of discount, incorporation of quality of life evidence, and acceptance of comparator therapy among others.

RESULTS: Until June 2014 24 price negotiations were conducted under or not receiving treatment. With the start of AMNOG in 2011, the number of hospitalizations and inpatient days associated with bone metastases secondary to breast cancer in Germany was 5,000 per year.

CONCLUSIONS: The superior efficacy of denosumab compared to zoledronate reduces the disease burden by decreasing the number of SERs and consequently the number of hospitalizations and inpatient days.

PCN177

TARGETED LITERATURE REVIEW OF MEDICATION EVENT MONITORING SYSTEMS TO EVALUATE ADHERENCE IN OBSERVATIONAL REAL-WORLD STUDIES

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OBJECTIVES: To identify and review methods employed to evaluate medication adherence in studies of oral antineoplastic agents, with particular interest in the opportunities and challenges associated with medication event monitoring systems (MEMS) implemented in observational studies.

METHODS: A targeted literature review was conducted. The identify studies that have measured adherence with antineoplastic agents. Our review included studies that were published between January 1990 and May 2014. Key data abstracted from each study included patient characteristics, study design and type, treatment, adherence monitoring, and results. Based on preliminary results, a second targeted review was conducted to evaluate the literature on the use of the Hawthorne effect in observational studies utilizing MEMS in any therapeutic area.

RESULTS: We identified 69 studies, 16 of which were exclusively observational and excluded from further review. Of these remaining 63 studies, 29 (44%) were prospective, 25 (40%) were retrospective, and 10 (16%) were cross-sectional. A total of 15 studies used MEMS to evaluate medication adherence. Among observational studies that utilized MEMS and evaluated the Hawthorne effect (n=3), mixed results were observed. In two studies, patients reported their behavior was affected by their awareness of being evaluated. This was demonstrated by a significant decrease in adherence in one study conducted over 12 months. In the third study, no change in adherence scores were observed.

CONCLUSIONS: There is limited health-state utility data for advanced ovarian cancer and no published HSUVs for advanced ovarian cancer. There is limited health-state utility data for advanced ovarian cancer and no published HSUVs for advanced ovarian cancer. Given the limitations of the current evidence base additional methods, such as mapping algorithms should be considered.

PCN178

A SYSTEMATIC REVIEW OF HEALTH STATE UTILITY VALUES FOR ADVANCED OVARIAN CANCER

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OBJECTIVES: Identifying appropriate utility values to inform cost-effectiveness analysis is a common problem. The aim of this study was to review health-state utility values (HSUVs) for patients with advanced ovarian cancer and make recommendations on how to use these data. A systematic review was conducted in June 2013 for studies reporting direct (standard gamble (SG) or time trade off (TTO)) or indirect (EQ-5D, SF-6D, or HUI-3) utility values for patients with advanced ovarian cancer. HTA agency websites were also searched. Study design, country, HSUV elicitation method, health state (HS) description, and who valued the HS were extracted. Mean (SD) utility scores, or medians (ranges), if means were unavailable, were recorded for each HS.

RESULTS: A total of 16 publications were found, representing primary sources of utility values. Two were derived from trial-based patient-reported EQ-5D utility values. One derived utility values from patients with ovarian cancer and utility values from a sample of the general population using a SG; two derived HSUVs from a sample of women without cancer using a TTO. These studies reported utility values for 18 different health states. Comparisons were possible, utility values differed widely: clinical remission 0.83-0.977; progression-free after recurrence 0.50-0.715; progressive disease 0.40-0.725. None of the studies reported values for patients receiving maintenance therapy.

CONCLUSIONS: There is limited health-state utility data for advanced ovarian cancer and no published HSUVs for advanced ovarian cancer. Given the limitations of the current evidence base additional methods, such as mapping algorithms should be considered.

PCN179

HEALTH-STATE UTILITY VALUES IN BREAST AND PROSTATE CANCER MEASURED USING THE EQ-SD: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: In cost-effectiveness analyses (CEA), a paucity of health-related quality of life (HRQoL) data often necessitates use of utility values from populations which may be ill-matched with the disease modelled. Use of the most pertinent data is essential to provide accurate results.

METHODS: A targeted literature review was conducted for localisation PC (2 studies), worse performance status or undergoing palliative care. For localised PC (2 studies),
values ranged from 0.81–0.90. Pain, severity of disease, urinary and bowel function and performance status attributed utility values in patients with PC. CONCLUSIONS: For BC and PC, disease progression, exposure to CT and worsening performance status were associated with decreases in utility values. For corresponding disease stages, utility values tended to be lower for BC than PC, although heterogeneity of data for BC studies may have contributed to making conclusions about BC utility values according to response to treatment. Further research is warranted to improve the evidence available for CEAs.

PCN180 HEALTH STATE UTILITY VALUATION IN RADIO-IOINEDE REFRACOTORY DIFFERENTIATED THYROID CANCER (RR-DTC)
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OBJECTIVES: The study is designed to capture health related quality of life (HRQoL) weightings for radio-iodine refractory differentiated thyroid cancer (RR-DTC) health states. Current treatment options for RR-DTC are limited, with generally poor prognosis. As new treatments emerge for RR-DTC, associated cost-effectiveness evaluations require appropriate preference-weighted HRQoL values. METHODS: Vignette studies were conducted, illustrated that quality of life was substantially higher in patients with RR-DTC. Three techniques were used to inform qualitative work conducted with RR-DTC patients in the US and interviews with 6 clinicians and nurses in the UK and US with RR-DTC treatment experience. Health states included: stable disease, treatment response, progressive disease, stable + grade III diarrhoea, stable + grade III fatigue, stable + grade III hand foot syndrome (HFS), stable + grade I-II alopecia. The vignettes were reviewed by the UK and US clinical experts and piloted with UK general public participants in cognitive debrief interviews (n=5). All vignettes were valued by a UK general public sample (n=100) using a visual analogue scale (VAS) rating and time trade off (TTTO) interview. Data were analysed using descriptive and regression methods. RESULTS: The mean TTTO health utilities for RR-DTC states ranged from treatment response (0.86; 95% confidence intervals (CI) 0.83; 0.89), through stable disease (0.80; CI 0.77, 0.84); to progressive disease (0.50; CI 0.45, 0.56). AEs had a significant effect on HRQoL, e.g. alopecia (0.45; CI 0.31, 0.59); hand foot syndrome (0.33; CI 0.19, 0.47). CONCLUSIONS: Three existing mapping algorithms can be used to generate HSUVs from other algorithms. Comparable HSUVs were generated using OLS and Tobit algorithms. OLS to Cheung were 0.915 and 0.851, respectively. The CCCs comparing Dobrez and Longworth were 0.994 and 0.974, respectively. The lowest and highest mean predicted HSUVs were estimated using OLS and Dobrez, respectively. CONCLUSIONS: HSUVs can be estimated from FACT-G using FACT-G mapping algorithms. Comparing CAROL, HSUVs, and FACT-G mapping algorithms, whilst Cheung and Dobrez generated distinct HSUV profiles. Without trial data directly comparing EQ-5D to FACT-O, it is difficult to identify the optimal mapping algorithm.
The functional scales for QL-C30 showed a good quality of life, however symptom scales related to sexual function showed a diminished QoL, satisfaction with doctors and nurses is good, but not for other personnel.

PCN186

BREAST EUROPEAN PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS THE BURDEN OF DISEASE AND TREATMENT IN METASTATIC BREAST CANCER (MBC) PATIENTS TREATED WITH ORAL VINOSELINE (NVBORAL) OR INTRAVENOUS VINOSELINE (IVVINO)

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OBJECTIVES: MBC is an incurable disease for which NVBORAL is a standard treatment available in 45 countries. The burden of disease, treatment patterns and motivation to choose across treatments and their consequences are seldom described in the real world.

RESULTS: A prospective observational study was conducted to assess the global burden of disease and treatment with NVBORAL or IVvino. NVBORAL is a currently marketed first-line chemotherapy for breast cancer patients receiving treatment in a tertiary referral hospital.

Conclusions: NVBORAL and IVvino are both efficacious treatments for breast cancer patients, but NVBORAL is preferred to IVvino for several reasons.

PCN187

HEALTH RELATED QUALITY OF LIFE (HRQL) IN MULTIPLE MYELOMA PATIENTS TREATED IN A TERTIARY REFERRAL HOSPITAL


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OBJECTIVES: To determine HRQol scores in multiple myeloma patients who are receiving treatment in a tertiary referral hospital. METHODS: Outpatients at a breast cancer clinic in a tertiary referral hospital were surveyed. Patients were surveyed at the beginning of the follow-up treatment and at any other stage of treatment. We interviewed through EORTC questionnaires: QL0, MY20 and INFATSAT2. The medians and percentiles were calculated. Questionnaire scores were calculated according to formulas and instructions of the EORTC scoring manual.

CONCLUSIONS: Multiple myeloma patients treated in this hospital showed favorable results on scores of quality of life in terms of symptoms, activity and treatment-related side effects, especially in the fatigue. These results can be compared satisfactory according with other reports from the international literature.

PCN188

HEALTH RELATED QUALITY OF LIFE AND PATIENT SATISFACTION IN MULTIPLE MYELOMA PATIENTS TREATED IN A TERTIARY REFERRAL CLINICAL DEPARTMENT

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OBJECTIVES: To determine HRQol and patient satisfaction scores in colorectal cancer patients treated through radical surgery with a curative intent.

METHODS: Colorectal cancer patients treated through radical surgery for colorectal cancer were selected. One month after the surgery we applied EORTC questionnaires QL-C30, CR-25, and IN-PATSAT2. The scores for each questionnaire were calculated according formulas and instruction in the EORTC Scoring Manual. We calculated mean and standard deviation for each score.

RESULTS: Global Health Status/QOL has a mean score 74.80 (±20.74); the functional scales: physical 87.4 (±18.08), emotional 80.3 (±17.23), role 76 (±12.37), pain 76.86 (±27.63), emotional 76.86 (±27.63), physical 76.86 (±27.63), social 76.86 (±27.63), fatigue 15 (±15.80), insomnia 27.3 (±30.00), urinary symptoms 32.5 (±21.57), symptoms related with herbal therapy 15.7 (±14.13), incontinence support 29.2 (±38.24). About scores for IN-PATSAT2, for doctors: Personal professional skills 88.30 (±16.72); technical skills 87.33 (±19.95); capacity to bring information 89.01 (±17.29); availability 88.56 (±16.85); necessity of information 87.41 (±16.74) technical skills 86.52 (±18.51); capacity to bring information 84.40 (±19.08); availability 79.26 (±20.89); other personnel kindness 80.85 (±20.89); incontinence support 29.2 (±38.24). About scores for IN-PATSAT3, for nurses: Information provided 92.05 (±15.44); comfort 86.80 (±21.62) and general satisfaction 84.57 (±18.46).

CONCLUSIONS: The functional scales for QL-C30 showed a good quality of life, however symptom scales related to sexual function showed a diminished QoL, satisfaction with doctors and nurses is good, but not for other personnel.
function showed a diminished QoL, satisfaction with doctors and nurses is good, but not for other hospital and doctors office conditions.

PCN190

INVESTIGATING THE FRAMING-EFFECTS OF RISK ATTRIBUTES IN DISCRETE CHOICE EXPERIMENTS: A PILOT STUDY

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OBJECTIVES: To understand how the communication of risk in a discrete choice experiment (DCE) affects respondents’ choices. METHODS: An online pilot DCE was designed to understand the preferences of female members of the public (recruited via an internet panel provider) for a breast screening programme described by three attributes (probability of detecting a cancer, risk of unnecessary treatment, and out-of-pocket cost) each with four levels. Two versions were used that presented the risk attributes (probability of detecting a cancer and risk of unnecessary treatment per 100 women screened) as: (A) a percentage or (B) a percentage and risk image (icon array). The DCE was blocked into four surveys, each containing 10 choice sets.

The design, generated using Ngene, included an internal validity test through the inclusion of a dominant choice set. The DCE data were analysed using conditional logit models. RESULTS: A higher proportion of women with higher education recognized therapeutic options in the respondents who received the percentages only version, almost 20% failed the validity test (compared to only 3% of those who received the risk image). Probability of detecting a cancer was the most important attribute. Willingness-to-pay (WTP) for an additional cancer detected was £175 for respondents presented with the risk image compared to £207 in the percentages only group. Significant differences were found between the two versions of the DCE (p<0.05). The data analysis was performed with SPSS 20.0. CONCLUSIONS: The UK hypothetical EQ-5D reimbursement authority (TLV) states that experience-based valuation of QALY weights are preferred before a hypothetical valuation. The UK hypothetical EQ-5D valuations, the “on treatment” utility of 0.66 was used as a benchmark since 2013 an extensive analysis of “tariff” exists for the general population in Sweden [Burstrom 2013]. This study explores the implications on IECRs by applying the two different version sets. This pilot study highlights the impact attribute framing can have on respondents’ choices in a DCE. The use of risk images also resulted in fewer “irrational” responses implying respondents had a greater understanding of the task.

PCN191

RESULTS AND IMPLICATIONS OF USING A NEW EQ-5D VALUE SET FOR COST-UTILITY ANALYSES IN SWEDEN. AN APPLICATION USING ENZALUTAMIDE (XTANDI®) VERSUS CUMPARATIVE CARE IN THE TREATMENT OF METASTATIC CAstration RESISTANT PROSTATE CANCER (mCRPC)

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OBJECTIVES: The guideline on economic evaluations from the Swedish price and reimbursement authority (TLV) states that experience-based valuation of QALY weights are preferred before a hypothetical valuation. The UK hypothetical EQ-5D valuations, the “on treatment” utility of 0.66 was used as a benchmark since 2013 an extensive analysis of “tariff” exists for the general population in Sweden [Burstrom 2013]. This study explores the implications on IECRs by applying the two different version sets. This pilot study highlights the impact attribute framing can have on respondents’ choices in a DCE. The use of risk images also resulted in fewer “irrational” responses implying respondents had a greater understanding of the task.

PCN192

POSSIBILITIES OF BREAST CANCER PREVENTION

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OBJECTIVES: Aims to gain knowledge about the rate of breast screening among Hungarian women. In addition are they familiar with the concept of self-examination, with procedure and if so, whether it is used and how often. Also would like to develop an educational program based on results, which would target risk groups and younger generations. Surveys were used to assess breast cancer prevention.

METHODS: A descriptive, cross-sectional, prospective and qualitative study made with women living in and around Sárvár, Hungary. Inclusion criteria was continuous internet users over 6 years of age. At the beginning of the study 150 surveys were applied with 100 women, between January and June, 2013. Data collected with a questionnaire of 31 questions. Descriptive statistics with frequency range, Chi²-test was performed with Microsoft Excel 2007.

RESULTS: There is a significant difference between cervical screening and the distance from medical centre (p<0.001). A higher proportion of women with higher education recognized therapeutic options for breast cancer than those with lower education (p<0.05). For women where breast cancer was diagnosed in family history, 80% of them regularly attend screening. The women participate in less complex programs for the prevention, because they did not receive information about it (p<0.001).95.74% of women to arouse the attention on breast cancer prevention advised their friends. CONCLUSIONS: Results show that long graduates are less appear on screening contrary to lower. Rate of self-examination is higher if family history of breast cancer known. Based on results, it is important to reach women who have not yet participated in preventive performances. The reduced activity can be a problem if it is to be improved. The importance of organizing a training program, especially for the correct application of the method and breast self-examination with usage of questionnaire.

PCN193

KNOWLEDGE OF HUMAN PAPILLOMAVIRUS AMONG UNIVERSITY STUDENTS IN HUNGARY

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OBJECTIVES: The main objective of our study was to assess the knowledge of HPV among the female university students in Hungary and also learn their attitudes about the vaccine. METHODS: The quantitative cross-sectional questionnaire survey was conducted among 300 university students. RESULTS: Knowledge about HPV was very low (49.6%). The female students were more informed about HPV than the male students (p<0.05). The main reason for non-vaccination was fear of complications, however, the most of the respondents thought that HPV vaccination is important and should be recommended to others (95.3%). The recommended groups for HPV vaccination were sexually active girls (84.7%), 61.7% thought that vaccination is economically acceptable. CONCLUSIONS: It is important to give information about HPV vaccination among the university students.

PCN194

PATIENTS’ PREFERENCES FOR BONE METASTASES TREATMENTS IN TURKEY

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OBJECTIVES: To assess patient preference for the currently available bone-targeted agents (XTANDI®) used to prevent skeletal-related events (SREs; commonly defined as pathologic fracture, radiation to bone, surgery to bone and spinal cord compression) in Turkey. METHODS: Adult patients with a self-reported physician diagnosis of bone metastases secondary to a solid tumor were recruited in several hospitals in Turkey to complete a pencil and paper discrete-choice experiment survey consisting of a series of 10 choices between pairs of hypothetical medication profiles. Each profile was defined using five attributes with several levels (based on prescribing information for XTANDI®) for 10,18 and 28 months: time until worsening of pain, time until first SRE (10,18 and 28 months); annual risk of osteonecrosis of the jaw (ONJ), 1%, 3%, 5%; annual risk of renal impairment, 0, 4 and 10%; and mode of administration (daily oral tablet, or subcutaneous injection, 15-minutes or 120-minute intravenous infusion). RESULTS: A total of 91 patients were included in the analysis and provided demographic information. Among the attributes included in the survey, annual risk of renal impairment, time until worsening of pain and delaying SREs were the three most important attributes, with better levels of outcomes preferred to worse levels. Daily oral administration was the preferred mode of administration and there was no statistically significant difference between injection and infusion of different durations. Annual risk of ONJ was judged by patients to be the least important attribute. CONCLUSIONS: When considering treatment choices, patients in Turkey focused mainly on the risk of renal impairment, the delay of pain worsening and delaying SREs.

PCN195

WHAT MATTERS TO PATIENTS AND THEIR CAREGIVERS: USING SOCIAL MEDIA AND PATIENT FORUMS TO OBTAIN VALUABLE INFORMATION FROM A PATIENT AND CARER PERSPECTIVE

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OBJECTIVES: The aim of this study was to assess whether social media and disease-specific websites or forums could be useful sources of information for patients and caregivers about their disease and its management. METHODS: We investigated the accessibility of such information in breast cancer and schizophrenia. We used disease-specific media websites and forums dedicated to sufferers of the two diseases were examined. RESULTS: Breast cancer was more frequently mentioned in general social media websites than schizophrenia, with more charities, large organisations and fundraising events dedicated to breast cancer. Searches for breast cancer and schizophrenia were conducted on general social media websites and on thousands of adults, but these are mainly posted by advertisers or pharmaceutical companies, or contain non-patient opinions or news articles. Patients tend not to discuss their condition openly on general social media sites, whereas disease-specific forums contain daily entries on the patient experience. While searches within forums lead to fewer results, these are
much more accessible and informative, and require less filtering through irrelevant posts. For example, posts from breast cancer patients typically discuss side effects of investigations and treatments and how to manage them, as well as offering emotional support. The limitations of using this type of information include the lack of a mechanism to confirm that contributors really do have the relevant disease, although the number of patients contributing is likely to be outweighed by "true" patients and caregivers.

CONCLUSIONS: This study showed that more valuable information can be found in patient-to-patient correspondence in forum threads than in general social media. Breast cancer patients appear to be more vocal in patient forums than schizophrenia patients, possibly due to the stigma attached to mental health problems. Little was found on what matters to breast cancer caregivers, since patients tend to present their own personal experience.

PCN196
PAiNTING AND DISEASE CHARACTERISTICS ARE IMPORTANT DETERMINANTS OF QUALITY-OF-LIFE OF PATIENTS WITH METASTATIC RENAL CELL CARCINOMA: RESULTS FROM A POPULATION-BASED REGISTRY

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OBJECTIVES: Limited data are available on the health-related quality of life (HRQOL) of patients with metastatic renal cell carcinoma (mRCC) in daily practice. The aim of this study was to estimate the HRQOL of patients with mRCC in daily practice, and to assess the influence of patient- and disease characteristics, such as comorbidities and adverse events on HRQOL.

METHODS: Patients with mRCC were selected from a Dutch population-based registry (PERCEPI). In this registry, registry data were collected from patient and disease characteristics, comorbidities and adverse events to measure HRQOL. A generic questionnaire (EQ-5D-5L) was used to evaluate EQ-5D utility score, this factor was not significant after adjustment for other factors.

CONCLUSIONS: This is one of the first studies that provides insights into the HRQOL of patients with mRCC in daily practice. In contrast to previous studies, this study also identified patient- and disease characteristics that influence HRQOL. Presence of comorbidities, number of metastatic sites, radiotherapy and presence of severe toxicity related to targeted therapies were significantly associated with a lower EQ-5D utility score. Although presence of bone metastases significantly lowered the EQ-5D utility score, this factor was not significant after adjustment for other factors.

PCN197
DEVELOPMENT OF A CONCEPTUAL MODEL FOR PEDIATRIC ONCOLOGY REVIEWS: RESULTS OF A REVIEW OF QUALITATIVE RESEARCH LITERATURE AND CLINICIAN INTERVIEWS

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OBJECTIVE: This study aimed to develop a conceptual model to guide the design of prospective pediatric oncology review reviews.

METHODS: The child's age, cancer type and stage, and severity of other side-effects/impacts. Adolescents appeared to be most impacted by cancer, due to their grasp of the condition to confirm that contributors really do have the relevant disease, although the number of patients contributing is likely to be outweighed by "true" patients and caregivers.

CONCLUSIONS: This study showed that more valuable information can be found in patient-to-patient correspondence in forum threads than in general social media. Breast cancer patients appear to be more vocal in patient forums than schizophrenia patients, possibly due to the stigma attached to mental health problems. Little was found on what matters to breast cancer caregivers, since patients tend to present their own personal experience.

Objective: Instanyl® (fentanyl nasal spray) received European market authorisation for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain, with precise instructions on indications for use and dosage. The study objectives were to evaluate patient-reported misuse, abuse, and diversion of Instanyl® in real-life in France. METHODS: Centers for Disease Control and Prevention (CDC) guidelines were applied at a non-hospital pharmacy. An anonymous self-administered questionnaire was distributed to patients at the time of drug dispensation between 27 July 2011 and 12 November 2011. The questionnaire collected breakthrough pain through patient interviews with five pediatric oncologists. Data were analyzed using grounded theory methodology. Cognitive debriefing results are also presented.

RESULTS: The questionnaire collected data on indication, contraindication misuse and 86% at least one posology misuse. Widening the definition of use for breakthrough pain to use for both breakthrough and chronic pain in cancer patients, reduced the indication/contraindication misuse (63%), but when posology misuse was also considered this did not markedly change overall misuse (93%). Abuse of Instanyl® (using the drug for emotional reasons, relaxation, and diversion (passing the drug to another person) concerned 2 patients (1 with cancer and 1 without).

CONCLUSIONS: Misuse of Instanyl® was widespread. Nearly half reported not to have cancer, and among those who did, only a few used this drug correctly. There seems to be a communication deficit as to the proper prescribing of this drug, and its proper use when prescribed.

PCN199
DEVELOPMENT OF A PATIENT-LED END OF STUDY QUESTIONNAIRE TO EVALUATE THE EXPERIENCE OF CLINICAL TRIAL PARTICIPATION

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OBJECTIVE: To obtain feedback from participants in clinical trials using a structured method is a valuable opportunity to identify strengths and weaknesses of trial design and conduct, highlight improvement opportunities and provide patient insight to help future recruitment. This study aimed to develop a questionnaire to provide a structured approach to evaluate patients’ experience of clinical trial participation.

METHODS: A draft questionnaire assessing patients’ experiences before, during and after the trial was developed in collaboration with oncology patient advocates before being qualitatively reviewed by individuals who have participated in a clinical trial or who have provided support to trial participants. A literature review informed these draft concepts. Three interviewer-led focus groups involving clinical trial participants (on-going or completed within the last 12 months) were performed to evaluate the developed questionnaire. Further concepts for questionnaire inclusion. An updated questionnaire was developed based on combined insights from the focus groups and literature review. Content validity of the revised measure was considered using cognitive debriefing interviews (n = 12). This testing aimed to identify the relevance and clarity of the instrument.

RESULTS: A literature review confirmed the relevance of the concepts assessed by the draft questionnaire. Aspects of the draft questionnaire included the trial enrolment and consent process, logistics of study participation and dissemination of results. The focus group participants provided further evidence on the relevance of the concepts included in the draft instrument and the clinical context of capturing patients’ experience from the patient perspective.

CONCLUSIONS: The draft questionnaire included evidence on the content validity of the post-trial questionnaire. Assessing the clinical trial experience from the patient perspective using a robust questionnaire may offer patients an improved trial design and ensure subjects stay engaged throughout the trial process.

PCPN20
PATIENT-REPORTED OUTCOMES ASSESSED USING THE BREAST-Q INSTRUMENT IN WOMEN UNDERGOING BREAST RECONSTRUCTION POST-MASTECTOMY: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Assessing the effects of breast reconstruction (BR) on patient-reported outcomes (PRO) is important as BR becomes increasingly common after mastectomy. A systematic literature review was conducted to assess the clinical use of a well-validated PRO instrument, the BREAST-Q (BQ) in women undergoing BR. METHODS: Searches using PubMed, ScienceDirect, Cochrane Library, and references in plastic surgery journals were conducted from when BQ was developed in 2008 to May 2014 using the term, ‘breast-q OR breast’. Non-English, reviews, letters, protocols, and single-patient case reports were excluded. BQ module unrelated to reconstruction (e.g., Augmentation or Reduction) were also excluded. Each BQ scale score ranged from 0-100 with a higher score representing better PRO. RESULTS: After applying exclusion criteria, 35 studies were retrieved. Majority of studies were conducted in North America (54%, 19/35) or Europe (29%, 10/35). Study sample size ranged from a single administration post-BR. Only 4 studies reported the change from pre- to November 2012. The questionnaire collected data on indication, contraindications, instructions in July 2009 for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain, with precise instructions on indications for use and dosage. The study objectives were to evaluate patient-reported misuse, abuse, and diversion of Instanyl® in real-life in France.

CONCLUSIONS: This study established the trial enrolment and consent process, logistics of study participation and dissemination of results. The focus group participants provided further evidence on the relevance of the concepts included in the draft instrument and the clinical context of capturing patients’ experience from the patient perspective.

CONCLUSIONS: The draft questionnaire included evidence on the content validity of the post-trial questionnaire. Assessing the clinical trial experience from the patient perspective using a robust questionnaire may offer patients an improved trial design and ensure subjects stay engaged throughout the trial process.
especially in comparative and longitudinal studies is recommended in order to enhance use of BQ in clinical decision making around BR modalities.

PCN201

PATIENTS’ PREFERENCES IN THE TREATMENT OF NEUROENDOCRINE TUMOURS: AN ANALYTIC HIERARCHY PROCESS

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OBJECTIVES: Neuroendocrine tumours (NET) are relatively rare, usually slow-growing malignant tumors. So far, there is no data on the patient preferences/priorities regarding the therapy of NET. This empirical study aimed at the elicitation of patient preferences in the drug treatment of NET.

METHODS: Qualitative patient interviews (N=9) were conducted. To elicit patient’s perspective regarding various treatment aspects of NET, a self-administered questionnaire using Analytic Hierarchy Process (AHP) was developed. The data collection was carried out using paper questionnaire and personal interaction. The response system is a group discussion approach. The patient-relevant outcomes, the eigenvector method was applied. RESULTS: N=24 patients, experts and relatives participated in the AHP survey. In the AHP all respondents had clear priorities for all considered attributes. The attribute “overall survival” was the most significant feature of a drug therapy for all respondents. As in the qualitative interviews, “efficacy attributes” dominated the side effects in the AHP as well. The evaluation of all participants thus showed the attributes “overall survival” (Wglobal: 0.16) to be most relevant. “Occurrence of abdominal pain” (Wglobal: 0.051) was ranked last, with “tiredness/fatigue” and “risk of a hypoglycaemia” (Wglobal: 0.034) on a shared seventh place.

CONCLUSIONS: The results thus provide evidence that how much influence a treatment capacity has on therapeutic decision. Using the AHP major aspects of drug therapy from the perspective of those affected were captured, and positive and negative therapeutic properties could be ranked against each other. Based on the assessment of the patient’s perspective, further investigation must elicit patient preferences for NET drug therapy. In the context of a discrete choice experiment or another choice-based method of preference elicitation, the result obtained here can be validated and the therapeutic features weighted according to their preference.

PCN202

WHAT RELAPSED/REFRACTORY CLL/MCL TREATMENT OUTCOMES DO GERMAN PATIENTS AND PHYSICIANS FIND MOST IMPORTANT? RESULTS FROM QUALITATIVE INTERVIEWS

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OBJECTIVES: Despite the availability of a wide number of treatments for relapsed/refractory chronic lymphocytic leukemia (CLL) and t/r mantle cell lymphoma (MCL), no standard of care has emerged. There are no studies evaluating preferences for treatment outcomes for t/r CLL and t/r MCL. This study was designed to elicit preferences for t/r CLL and t/r MCL treatment outcomes among patients, the general public and physicians experienced in treating CLL/MCL in Germany.

METHODS: Interviews (90 minutes) in German of 6 CLL/6 MCL hematologists, 6 t/r CLL and 5 t/r MCL patients were conducted (total 23 interviews). Participants were asked to state their most important treatment outcomes. Transcripts were translated to English and analyzed by counting the number of times each outcome was mentioned. We present here results of patient and physician preferences.

RESULTS: t/r CLL patients stated the most relevant treatment outcomes were as follows: (1) response rate (4); (2) quality of life (QOL) aspects (4); (3) progression free survival (PFS) (4). A tolerable side effect profile (4) and control of disease symptoms (4) were considered important. t/r MCL physicians mentioned OS (4), QOL (4) and PFS (4). t/r MCL patients mentioned efficacy-benefit as cure (4) and OS (2), QOL (3), various QOL aspects (5) and a tolerable SE profile (4). t/r MCL treatment outcomes were long-term organ damage (2), hair loss, nausea and night sweats (1 each). MCL physicians mentioned OS (6), QOL (5) and a tolerable SE profile (4).

CONCLUSIONS: Extending life, disease control, maintaining QOL and avoiding SE are important t/r MCL/CLL treatment outcomes to German patients and physicians.

PCN203

PATIENTS’ PREFERENCES IN LATE STAGE TREATMENT OF NON- SMALL-CELL LUNG CANCER: A DISCRETE-CHOICE EXPERIMENT

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OBJECTIVES: Lung cancer is a major cause of cancer-related deaths and thus represents a global health problem. To date, decisions on which treatment to use are often driven by health care professionals’ opinions. The perspective of patients with metastatic non-small cell lung cancer (NSCLC) on the importance of different treatment criteria and the ranking of these decision criteria are rarely taken into consideration. Aim of the study is the evaluation of the patient-relevant characteristics of NSCLC patients. METHODS: The literature review, and 30 qualitative interviews revealed seven patient-relevant treatment attributes. A Discrete Choice Experiment (DCE) was used to evaluate the patient-relevant treatment characteristics of NSCLC patients. RESULTS: The literature review and the statistical data analysis used random effect logit and GLAMM latent class models for subgroup identification. In total: N=211 patients with metastatic NSCLC participated in the computer-assisted personal interviews. The patient-relevant characteristics in this study. The sole consideration of the “progression-free survival” as foundation for decisions is not sufficient from the patients’ perspective and multiple criteria are important. Subgroup analysis revealed that the importance of “progression-free survival” increased with increased therapy experience. Basically, the results give insight into how much a deciding factor affects the treatment decision from the perspective of patients. In addition, the results of this study provide a basis for patient-oriented evaluation of treatment options in NSCLC.

PCN204

CARER PERCEIVED BURDEN AS A PREDICTOR OF HEALTH-RELATED QUALITY OF LIFE: THE CASE OF COLORECTAL CANCER

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OBJECTIVES: This study aimed to (i) investigate the impact of subjective and objective factors on colorectal cancer carer physical and mental health, and (ii) identify key subjective burden predictors of these two domains.

METHODS: 228 colorectal cancer carers were posted a questionnaire which included questions on socio-demographic characteristics, relationship with the care recipient, the caregiver reaction assessment (CRA) scale and the SF-12v2. Multivariate linear regression was used to assess whether five CRA domains (family support, finances, schedule and health, esteem) predicted carer mental or physical health, controlling for age and other confounders.

RESULTS: 153 carers (82% female) completed the questionnaire (response rate = 68%). Carers’ mean physical component score (PCS) was 48.56 (SD=10.38) and mean mental component score (MCS) was 49.22 (SD=9.7). The most negatively affected CRA domain was disrupted schedule (mean=-3.0), followed by financial problems (mean=-2.9) and physical health (mean=-2.3) and lack of family support (mean=-2.0). Multiple regression analysis showed health burden was the strongest predictor (β=−.54, p<.001) of carer PCS, followed by having a comorbid condition (β=−.34, p<.001), age (β=−.19, p<.001), social isolation (β=−.16, p=.001), and estimated life expectancy (β=−.16, p=.05).

CONCLUSIONS: Our results demonstrate the need to recognize the different aspects of the impact of caring on caregivers (i.e. physical and mental), and that different domains of subjective caregiver burden impact differently on each of these.

PCN205

IMPACT OF BRAIN METASTASES ON QUALITY OF LIFE AND ESTIMATED LIFE EXPECTANCY IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG CANCER

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The majority of patients with advanced non-small cell lung cancer (NSCLC) are diagnosed with advanced disease (Stage IV). The site of the metastasis as well as the underlying disease influences the outcome and the patient’s quality of life.

OBJECTIVES: To evaluate the impact of brain metastases compared with other metastatic sites on health-related quality of life (EQ-SD) and physician- perceived life expectancy in stage IV NSCLC patients.

METHODS: Data were drawn from the Adelphi NSCLC Disease-Specific Programme (DSP), a cross-sectional survey of 120 pulmonologists and oncologists and their NSCLC patients conducted between July and September 2010 in France and Germany. Each physician completed detailed record forms on 10 advanced patients being actively treated for NSCLC. Patients were invited to complete an equivalent patient self-completion questionnaire (PSC) which included the EQ-SD Analysis. Patients were conducted on patients with only one metastatic site, either brain, contralateral lung, adrenal gland, bone or liver. Mann-Whitney tests were used to test the differences between metastatic sites.

RESULTS: 498 patients with one metastatic site were identified of whom 325 (65%) completed a PSC. The higher the EQ-SD score the better the health state, EQ-SD was significantly lower for patients with brain metastases (mean 0.52, SD=0.29) compared with contralateral lung metastases (mean 0.69, SD=0.26) and adrenals (mean 0.69, SD=0.19) and liver (0.71, SD=0.46, p=0.0191). No significant difference was observed between brain and bone metastases (0.53, n=92, p=0.8219). Estimated life expectancy was significantly shorter for brain metastases (25.3 weeks) compared with contralateral lung (50.5 weeks), bone (49.4 weeks), adrenal glands (48.7 weeks) and liver (44.9 weeks) (all p<0.01).

CONCLUSIONS: The development of brain metastases in patients with advanced NSCLC is associated with a significant reduction in quality of life and estimated life expectancy compared with other metastatic sites.

PCN206

SEXUAL-RELATED EVENTS (SREs) IMPACT SIGNIFICANTLY THE HEALTH-RELATED QUALITY OF LIFE (HRQoL) OF CHEMO-NAIVE MENS WITH METASTATIC CASTRATION RESISTANT PROSTATE CANCER (mCRPC)

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OBJECTIVES: Men with mCRPC are at risk of experiencing SREs, defined as pathologic bone fracture (“fracture”), spinal cord compression (“compression”), and the need for radiotherapy or surgery to bone (“radiotherapy/surgery”). We examined the patient and clinical relevance of SREs for HRQoL in men with mCRPC.

METHODS: We conducted a questionnaire using a random sample of patients (n=587), irrespective of treatment in PREVAIL - a phase 3 trial of enzalutamide (n=872) vs. placebo (n=845) in asymptomatic/mildly symptomatic chemono naive mCRPC patients. For patients with multiple SREs, only the first event was included. HRQoL was assessed using the FACT-P and EQ-5D tools. Impact of first SRE on HRQoL was evaluated as follows:
1) estimate each patient’s longitudinal HRQoL trajectory before the first SRE, using repeated measures analysis, 2) calculate how SREs affect HRQoL changes. RESULTS: We found statistically significant declines in utility scores after all three types of SREs (tumor progression, soft tissue failures and bone metastasis), i.e., a number of FACT-P domains and total score to a clinically meaningful and statistically significant extent. Compression had the broadest impact, affecting 7 out of 9 FACT-P domains, significantly reducing or delaying the occurrence of SREs may slow down the observed HRQoL declines in mCRPC patients.

PCN207 SUSTAINABLE MEASUREMENT OF RESPONSE SHIFT IN PROSTATE CANCER PATIENTS: ADJUSTING HEALTH RELATED QUALITY OF LIFE WITH THE THEN-TEST

OBJECTIVES: Patients diagnosed with prostate cancer (PCa) have similar survival rates across treatments, making treatment choices based on health related quality of life (HRQoL) the most objective criterion. However, HRQoL usage, sustainability and reliability measurement over time for use in cost-effectiveness analyses by investigating the occurrence of response shift (RS) in PCa patients. Never before has RS been measured for this long a time period and on a population level. M ETHODS: A prospective sectional cohort study was started in January of 2012 with 1,720 CAPSURE patients using the SF-36 and UCLA-Prostate Cancer Index (PCI). In January of 2013 PCI was sent to questionnaires aspi nting to their perceived HRQoL at time of diagnosis (then score) and current HRQOL (post-score). These scores were matched to previous collected scores at baseline (pre-score), ranging from 3 months to 20 years. RS (then-pre-score), True test–true score, False test–true score were calculated and compared with t-tests in different questionnaire domains. Linear regression was used to explore relations between scores and patient characteristics. RESULTS: RS and PCI are found to be negative overall for SF-36 (3.6/-14.5 TF – 8.1/8 FC–3.0/-22.7) and PCI (RS=4.0/-3.0 TC–2.0/0.7 FC–3.6/-4.9), showing significant difference (P<0.05). Significant difference was also seen over the whole time range between post-scores and RS-adjusted-post-scores for SF-36 and PCI. A difference was found in patients with recurrence and non-recurrence groups (ranging 0–4.0), although not significant. RS over time did not show change. CONCLUSIONS: Mean negative RS scores were found in this population using SF-36 and PCI, indicating over reporting in retrospective collected data. It is recommended physicians and researchers adjust found HRQoL scores with RS values found in this study, to increase usage, sustainability and reliability of retrospective collected HRQoL-scores. Further research is needed to investigate RS dependency on other variables or characteristics.

PCN208 QUALITY OF LIFE IN PATIENTS WITH MULTIPLE MYELOMA IN SLOVAKIA

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OBJECTIVES: Multiple myeloma is common in older adults and its incidence increases after the age of 60 (under the age of 40, it occurs rarely, < 2%). In SK approx. 400 new cases have been diagnosed and in the treatment there is in average 1500 patients. Research aim was to find out the impact of the disease on particular items of Quality of patients’ lives. METHODS: Sample: research consisted of patients diagnosed with the disease of multiple myeloma. We distributed 120 questionnaires and compiled 82 questionnaires (68,33%). There were 36 men (43,00%) and 46 women (56,10%). Their age was between 40 and 71 years. We utilised standardised questionnaire of quality of life. Quality of Life-BREF (WHOQOL-BREF). Its first part included 24 items in four domains (physical health, psychological health, social relationships, and environment) and two items of overall evaluation. Numerical scales were signed in the answers in the follow ing way: the least auspicious answer had the smallest value and the most auspicious answer had the biggest numerical value (range 1–5). The results of respondents were compared to population norms of the WHOQOL-BREF domains. RESULTS: In majority of items, the answers of the respondents do not differ very much in comparison with the average score of WHOQOL-BREF. Two items mostly differ from the average score most: domain of physical health – pain, where the average of 2.5 lowered in comparison to population norm of 4.0. The domain psychological health – negative emotions: where the average of 2.00 was lower in comparison to the population norm of 3.47. CONCLUSIONS: Prompt diagnostics of multiple myeloma significantly increases the possibility of the treatment to be successful. It also prolongs and improves quality of patient life. Research finding points out the reality that MM does not have the same impact on all domains of quality of life.

PCN209 QUALITY OF LIFE IN PATIENTS WITH LUNG CANCER IN THE SLOVAK REPUBLIC

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OBJECTIVES: The current incidence and mortality of lung cancer (LC) in adult patients in Slovakia ranges from 16.7 to 7.3 resp. 50 in men and 10.8 resp. 7 in women per 100000 inhabitants. The lung cancer has a great impact on quality of life (QoL) and the ability to work (WA) too. Till now in the Slovak Republic there was not realised the study oriented on the both mentioned categories. METHODS: 102 patients with LC were studied. The average age of was 50.3 y., weight – 78.3 kg, height – 175.1, duration of illness – 2.4 y., symptoms of illness before diagnosis – 1.2 y. Metastases were present in 72 patients. 4 patients were mentioned as strong pessimists, 6 patients as other pessimists or optimists, 18 strong optimists, and 18 optimists. QoL and the ability to work were evaluated by means of the numeric scale from 0 to 10 (0-the worst, 10- the best) by patients themselves. RESULTS: The QoL was evaluated in these domains: in the time of good health – 82.1, in the time of diagnosis – 2.82, in the current time – 5.71. The WA had these results: in time of good health – 8.89, in the time of diagnosis – 5.08, and in the current time – 2.17. The impact of treatment on the QoL was 2.49 and on the patients’ ability to work 2.79. The willingness to pay for perfect cure was 92.95 € per month (the average salary in Slovakia in 2013 was 824 €). CONCLUSIONS: LC has a great impact on QoL and on the WA too. There was a strong correlation between QoL and QoL, although the WHOQOL-BREF was the last on the list. Our research confirmed the importance of early diagnosis and high effective treatment of this disease.

CANCER – Health Care Use & Policy Studies

PCN212 EVIDENCE-BASED MEDICINE AS A DRIVER OF IMPROVING COLORECTAL CANCER SCREENING IN UKRAINE

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OBJECTIVES: To validate the short version of the QLQ-C30 obtained for patients with non-small-cell lung cancer in patients with head and neck, prostate, breast or cervix cancer. METHODS: We analysed data of 636 patients distributed: 237 diagnosed with lung cancer, 140 diagnosed with head and neck cancer, 121 diagnosed with cervix cancer and 113 diagnosed with prostate cancer. The analysis followed a 4-step approach. First, we conducted a Mokken nonparametric item response analysis to assess the reliability and separation of the current version and the shortened version. Second, we conducted a parameter Samejima’s graded response model (GRM) to assess the item characteristics and information for each domain. Third, we did a test of the test the scalability of the questionnaire by obtaining standardised factor loadings to suggest a reduced version of the QLQ. Finally, we assessed the discriminatory validity of the reduced version using receiver-operator curve (ROC) analysis. RESULTS: Mokken analysis of the QLQ-C30 resulted in a unidimensional latent structure over the whole QLQ-C30 (CIT = 0.98; RMSRE = 0.05) with modification indexes pointing to important redundancy of information. The selection of items with standardized factor loadings > 0.70 led to a 6-item QLQ that showed good discriminatory validity against independent criteria of quality of life (ROC area = 0.76; 95% CI = 0.72 to 0.80) as compared with the values for the whole scale (ROC area = 0.70; 95% CI = 0.66 to 0.74). CONCLUSIONS: The EORTC reduced scale was validated in this study; it presents good psychometric properties and includes a unidimensional structure of patient-perceived quality of life.

PCN211 SOCIAL DECISION-MAKING IN WOMEN WITH EARLY STAGE BREAST CANCER AND IMPLICATIONS FOR LONG-TERM HEALTH-RELATED QUALITY OF LIFE

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OBJECTIVES: Surgery for breast cancer has a substantial impact on a woman’s health-related quality of life (HR-QoL). The NIH and EORTC advocate treatment decision-making that involves women in the decision-making process. The aim of this study was to understand the shared surgical decision-making process from the patients’ perspective by implementing qualitative methods. METHODS: All participants were recruited and consented from a single center. Inclusion criteria included women who selected BCT over mastectomy. Utilising an interview guide, women were asked to share their experience with all aspects of decision-making related to breast cancer treatment. Interviews were audio-taped, transcribed, and coded with NVIVO8. Qualitative data were further analyzed to identify factors influencing decision-making regarding BCT. A comparative matrix analysis was conducted to further evaluate women’s appraisal of their surgical decision-making process and how this impacted their long-term HR-QoL. RESULTS: Nineteen patients were included in the analysis. The mean age was 58.6 (± 12.6) years, 52.9% were married, 84.2% were Caucasian, 68.4% were currently employed and 31.6% had a family history of breast cancer, 10.4% diagnosed with Stage 0, 52.6% stage I and 36.8% stage II breast cancer. Factors contributing to decision-making were dichotomized into satisfied (n=11) or dissatisfied (n=8). Satisfied patients were further categorized as either (i) positive outlook n=2; or (ii) acceptance of choice n=9. Dissatisfied patients were further categorized as (i) experiencing regret n=6; or (ii) fear of recurrence n=4. CONCLUSIONS: As decision-making needs vary by individual women, a personalized decision-making approach is an essential factor to improve HR-QoL among women with early stage breast cancer. Additional prospective qualitative research into the decision-making process of pre-operative and post-operative HR-QoL is necessary, as these findings may complement existing outcomes research.
OBJECTIVES: Colorectal cancer (CRR) is an important public health problem. The human lifetime cost of this disease is vast. In the UK, the total cost is $79.9 billion. In addition, CRR is a high-risk adenoma, identified in 1 in 3 UK adults. The objective was to understand the economic burden associated with CRR.

METHODS: We undertook a systematic review of the economic literature to estimate the cost of CRR. We identified 45 studies that met our eligibility criteria. We then performed a meta-analysis of the literature to estimate the cost of CRR in the UK. We also performed a sensitivity analysis to determine the effect of uncertainty on the cost estimate.

RESULTS: The estimated cost of CRR in the UK is $19.9 billion. The majority of this cost is attributable to medical care costs. The cost of CRR is expected to increase over time due to an aging population and an increase in the prevalence of CRR.

CONCLUSIONS: CRR is a significant economic burden in the UK. Future research should focus on developing new treatments to reduce the cost of CRR.
0.2% (pancreas cancer) to 16.6% for females. Inconsistent changes were noticed for either incidence or mortality of different cancers. There were no statistically significant correlations between change in 5-year survival, and change in incidence and mortality for either male or female cancers during this period. When other time periods were considered for analysis, statistically significant correlations (between changes in mortality) of male cancers from 1981 to 1995 (Pearson r = 0.68, P = 0.03) and from 1986 to 1995 (Pearson r = 0.78, P = 0.007). However, when the two mostly diagnosed cancers (prostate and breast) were separated, there were no correlations between changes in 5-year survival, and change in incidence and mortality for the three time periods.

**Conclusions**: Our study shows no reliable relationships between changes in 5-year survival and incidence or mortality. The increase in 5-year survival might not represent progress in cancer control, but instead indicate improved diagnosis and treatment in clinical practice.

**PCN218**

**ASSESSMENT OF LUNG CANCER TREATMENT BY DISEASE PHASE USING NATIONAL CANCER REGISTRY DATA LINKED WITH TREATMENT PATHWAY COST DATA IN AUSTRIA**

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**Objectives**: Pilot study for evaluation of record linking and potential analysis of combination of epidemiologic cancer registry data and personalized pathway of care identified by billing data using lung cancer as test illness for Austrian data sets in the years 2006 till 2011. **Methods**: Data sets are linked by anonymized distinct social insurance numbers of approximately 85 percent of all detected incident cases in Austria in the years 2006 till 2011 in the billing data on single person level. The calculated dataset deals as starting point for the analysis of the remaining lifetime distribution depending on age and TNM - stage. Analyzing the data by eight main categories given in hospitals coded by the MEL-system in combination with treatment using defined drugs is analysed and reported for further interpretation by the experts. An exploratory data analysis on the survival and regional and economic differences in Austria were used to complete the pilot study. **Results**: Data for the whole Austrian health insured population, including incident cases for lung cancer over a time span of two years were analysed for the following chronic diseases detected by predefined rules on hospital diagnoses and drug prescription in the year preceding patient history: COPD, diabetes and psychiatric illnesses. For the detected 6616 patients the probability of surviving is calculated and visualized by Kaplan-Meier-Curves. Exemplarily the one year survival is given: 75.47% and the 5-years life expectancy: ~1% Further results combining different influence factors on survival including data from the cancer registry information table are performed. **Conclusions**: Combining data collected by the national epidemiologic cancer registry system and population based data of patients treated in clinical practice in Austria provides a broad basis for analysis concerning real world pathway comparison of cancer patients. This work can unlock potential in respect of defining clinical national cancer registries.

**PCN219**

**ITALIAN ONCOLOGY RESEARCH TO EVALUATE ADHERENCE TO CLINICAL GUIDELINES FOR CANCER TREATMENT: THE RIGHT PROGRAM**

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**Objectives**: Clinical oncology societies develop and regularly update evidence-based guidelines to achieve more equal and uniform care for patient management. In 2004 AIO (Italian Association of Medical Oncology) created the RIGHT program: Research for the identification of the most effective and highly representative of 230 AIOM centers. Site sampling from AIOM database was stratified by geographic distribution (North, Center, South). Indicators were identified to verify the concordance between AIOM guidelines and clinical practice about staging and treatment. Patients were included if they had their first visit at the site after guideline emission. Patients were then followed-up for at least 6 months. **Results**: Patients enrolled for the breast, colorectal and lung cancer guidelines were 324, 326, and 708 respectively. Adherence was on average 69% for BC, 76% for CRC and 69% for LC. For CRC adherence was 78% for colon, 69% for rectal cancer and 83% for advanced disease. For BC, the lowest degree of compliance (0%) was observed for the follow-up indicator in asymptomatic patients. For LC, on average 67% and 81% of stage I-II-III, IBIB and IV patients respectively received recommended care according to defined cancer indicators. **Conclusions**: The RIGHT program showed that guidelines adherence is generally good in the case of the guideline on breast cancer treatment. Guidelines adherence monitoring and update represent crucial activity to get more useful instrument to plan health care interventions.

**PCN220**

**WHICH IS MORE IMPORTANT FOR DOCTORS IN A LOW-MIDDLE INCOME COUNTRY: A NATIONAL GUIDELINE OR THE MEDICAL LITERATURE? A GUIDELINE ADHERENCE SURVEY OF TRASTUZUMAB USE FOR BREAST CANCER IN IRAN**

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**Objectives**: Most national standard therapeutic guidelines recommend a 52-week trastuzumab regimen for breast cancer treatment. In contrast, the Iranian national guideline (published by the Ministry of Health) recommends a nine-week regimen. We assessed the differences between current routine practice amongst Iranian specialists and the guidelines for trastuzumab treatment and HER2 receptor testing in breast cancer patients. **Methods**: 128 Iranian oncologists from patients with breast cancer from 1981 to 1995 were asked to complete an online anonymous questionnaire. Concurrently, a 3-year retrospective claims database analysis was conducted using data from the Social Security Organization, a health insurer which covers approximately 60% of the Iranian population, to enable comparisons with the questionnaire results. **Results**: With a 41% (21/52) response rate, doctors reported a relatively high absolute adherence (86%) to the guideline for HER2 receptor testing but a low rate of absolute adherence (46%) (28/62) to the trastuzumab guideline for duration of trastuzumab treatment. Doctors indicated that the planned duration was 9 weeks in only 32% of patients; in most cases, the plan was 52-week treatment. Patients with a 9-week treatment plan received trastuzumab for 37.43 weeks on average while with 52-week plans received it for 29.2 weeks. The general trends found in the survey were confirmed in the claims database analysis of 830 HER2 positive patients. **Conclusions**: When it comes to trastuzumab use, Iranian doctors appear to rely more on the medical literature than on the national guidelines developed by the Ministry of Health. Policy makers, doctors and the general public should try to reach some consensus about the optimal way to treat eligible patients. This is particularly necessary in low-middle income countries, whose limited budget cannot easily accommodate all of the innovative technologies that are available.

**PCN221**

**TIME SAVINGS WITH TRASTUZUMAB SUBCUTANEOUS (SC) INJECTION VERSUS TRASTUZUMAB INTRAVENOUS (IV) INFUSION: A TIME AND MOTION STUDY IN 3 RUSSIAN CENTERS**

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**Objectives**: Trastuzumab (TRA) subcutaneous (SC) injection is an alternative to intravenous (IV) administration for the treatment of HER2+ early breast cancer (EC). The objective is to quantify health care professional (HCP) time and patient chair time associated with the TRA treatment, in contrast to a transition from IV to SC. **Methods**: A multi-centre, prospective time-and-motion study was run in three Russian centres participating in the SafeHer clinical trial (MO28048). Case report forms listing pre-specified tasks for IV, SC, and pharmacy management in chronological order and tailored to site practices were used for data collection. Trained observers recorded patient chair time and durations that HCPs spent on IV and SC process time was calculated as the sum of the mean time task intervals. IV vs. SC process time was associated with increased patient chair time and reduced IV process time. **Results**: Mean reduction in HCP time per patient session was 18.6 mins (48%)(IV 38.7 mins vs. SC 20.1 min), of which 61% of time reduced was achieved in the treatment room. Per treatment session (total 18 sessions), the estimated saving was 5.6 hours (range across centres: 2.6-9.3 hours). Reduction in mean chair time was 29.5 mins (-8%) (IV 57.6 mins vs. SC 76.8 mins). **Conclusions**: The monetary value of HCP and patient chair time saved was 1.175 and 6.314p, respectively, for 18 treatment sessions. **Conclusions**: Transition from IV to SC leads to substantial reduction in chair time, saving HCP time and associated costs. This allows more time to be used for other patient care activities, increasing the number of patients who could be treated and thus increasing the overall efficiency of treatment centers.

**PCN222**

**PROCESS MAPPING TO CAPTURE BREAST CANCER PATIENTS’ JOURNEY IN GREEK PUBLIC ONCOLOGICAL HOSPITALS**

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**Objectives**: The present study aimed to examine how breast cancer patients proceed through the public Greek health care system by using process mapping to identify constraints and bottlenecks and unnecessary process steps. **Methods**: The sample of the study were 86 patients diagnosed with breast cancer at two large public oncological hospitals. A process mapping study, by applying PERT (Program Evaluation Review Technique) analysis, was conducted. **Results**: The total time spent for obtaining the treatment (per os or chemotherapy) is higher up to 7 times compared with the time spent in activities contributing directly towards the patient’s outcome. The average time needed to complete the procedure (e.g., physician consultation, waiting times, prescribing, obtaining pharmaceuticals) in Hospital A was 78.65 minutes (SD= 37.43) while waiting time was 51 minutes (SD= 21.58). In Hospital B, the average time was 86.8 minutes (SD= 23.49) while waiting time was the waiting time. Similarly, the average time required for chemotherapy at Hospital A was 4 hours and 27 minutes (SD= 106.61) while the waiting time was 2 hours and 15 minutes (50.84%). **Conclusions**: Among the main reasons for the delays were the lack of electronic records and poor function of the Central Information Prescribing System. **Conclusions**: Waiting time represented a higher percentage of the total time needed to complete the process for obtaining the treatment. As it represents one of the main causes for patient dissatisfaction, applying process mapping is a critical step for Health care organizations to improve the beneficial time and the overall quality of the services offered.
and P&R demands and tightening budgets negatively impact prescribing of costly regional/local budget planning are specified as uptake levers.

prescribing of erlotinib and gefitinib for non-small-cell lung cancer. Interviewed ≥

Some 68-83% of surveyed oncologists in France, Italy, Spain, and the UK, and 44%
restrictions impede uptake; e.g., 18% of German hematologists surveyed report

EU5: SURvEyED ONCOLOGIST ANd INTERvIEwED PAyER INSIGHTS

PCN223

A COMPARISON OF MARKET ACCESS EVALUATIONS FOR NEW ONCOLOGY THERAPIES IN FRANCE, IN GERMANY AND THE UK: AN ANALYSIS USING THE PRISMAccess DATABASE

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OBJECTIVES: In recent years (2011-2014) various new oncology therapies were launched and evaluated by the different market access authorities: The international Prismaccess database includes all evaluations and decisions by the respective authorities in France, Germany and the UK. METHODS: All decisions for new oncology therapies which were evaluated by the authorities in France, Germany and UK, were systematically searched for. A comparison was executed with a focus on reimbursement decision, basis of decision, acceptance of submitted clinical endpoints, study designs, comparator, quality of life and indirect treatment comparison (ITC). RESULTS: In total there were 23 new oncology therapies being evaluated in the three countries. In France 10 decisions were positive (ASMR I-III), further 6 of minor improvement (ASMR IV), 20 were positive in Germany (n=3 ‘significant’, n=6 ‘considerable’, n=9 ‘minor’, n=2 ‘non-quantifiable’ added because the decision were positive in England and 5 in Scotland. In 2 cases, respectively the assessment was positive (different magnitude) or negative in all countries. 26% (n=6) it was similar in at least three countries. (n=5 positive decisions; n=1 negative decision). In case overall survival was the primary endpoint the likelihood was higher in all countries for a positive decision. Key differences in terms of decisions were given in acceptance of ITCs, comparator as standard of care and ratings for cost-effectiveness. CONCLUSIONS: Using the Prismaccess database the analysis shows that there might be key differences in terms of evaluation criteria between the three countries analysed. In Germany a key focus is given on the appropriate comparator(s) and patient-relevant endpoints. In the UK and Scotland cost-effectiveness is a key positive benefit assessment. In France the key drivers are not only the severity of the pathology (for tumours, >25% of SMR are not substantial), but also efficacy/adverse events ratio, Effective amount, Comparator choice and Therapeutic strategy.

PCN224

CURRENT STATUS OF REIMBURSEMENT DECISIONS FOR ORPHAN DRUGS OR CANCER DRUGS: IMPLEMENTATION FOR ACCESS SCHEMES IN KOREA

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OBJECTIVES: The Korean Reimbursement Assessment has been made to evaluate the access of orphan drugs or cancer drugs to patients since it is difficult for these drugs to be reimbursed due to its high price or lack of clinical evidence. We aim to investigate the current status of reimbursement and reviewed related schemes in Korea. METHODS: The reimbursement results for orphan or cancer drugs during 7 years (2007~2013) were included and recommendation rate, final listing rate and order of entry among 8 countries were analyzed. RESULTS: Total 331 were recommended to be reimbursed in overall 467 appraisal results (71%), whereas 74 was recommended to be reimbursed among 121 results for orphan or cancer drugs (61%), indicating that it was less likely to be recommended for those drugs. Fifty eight orphan or cancer drugs (48%) were finally listed through NHIC negotiation process. For cancer drugs, the final listing rate (54%) was inferior to the orphan drug (81%) but due to constant shortage of registered BCG from May 2012, non-registered BCG was also listed (price: not defined). Still there was no import, due to worldwide shortages. The absence of the treatment encouraged the Serbian health authorities to consider other alternatives. CONCLUSIONS: The price as proposal for new medicine would be 55,436, expenses per patient per year would be 498,876 and total costs for 520 patients would be 259,412,40 €, it is projected that total savings would be 111,150,000 € per year. Market share of domestic BCG (orphan medicine) is expected to be 20% of total market. The future aim is to develop, register and list domestic BCG that would provide lower costs per patient, high quality, availability and the continuous immunotherapy.

PCN227

THE EXPLAIND VALUE FOOTPRINT OF ONCOCLOGICAL TREATMENTS

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OBJECTIVES: To provide a better understanding of: how changes in the use of an oncology medicine can affect its aggregate value; how different HTA systems have assessed these value expansions; and whether there is a link between value expansions and use. METHODS: We examine all oncology medicines approved by the EMA between 2003 and 2005 – giving a sample of 10 medicines. Our framework sets out five value types: 1) price, 2) value-adding services, 3) different Interventions, 4) different cancer type, different disease stage; different treatment line/stage, different treatment regimen, orphan designation; patient sub-population; and new route of administration. We then assessed how HAS (France), NICE, England and Wales), and Asta (US) have recognised these value expansions. Finally, we analysed IMS data (2004-2013) on prices, volumes and sales for the five of the medicines. RESULTS: Significant medicinal value has been added to patients via the following initial indication. Many are now used for indications that are very different from their original indication. Most of the HAS assessments resulted in the drug being reimbursed but the rewards to the manufacturers were in many cases relatively low because few of the recommended drugs were given by the Department of Health service” (ASMR) levels. The majority of NICE appraisals (63%) resulted in the drug/ indication not being recommended for use in the NHS. Generally, the UK had lower prices, volumes and sales than France and the US (with some exceptions). The comparisons between France and the US were a little more equivocal. There is a mixed picture in terms of the correlation between NICE/HAS recommendations and sales in the UK/France. We observe a link between expansions in licensed indications and changes in sales. CONCLUSIONS: Health systems and policy makers need to recognise how patient life-cycle considerations affect the value of medicines, and in particular, oncology medicines.

PCN228

IMPACT OF INTRODUCING COSTS/QALY THRESHOLD ON ACCESS TO ONCOLOGY MEDICINES IN SLOVAKIA

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OBJECTIVES: In December 2011, a threshold value of costs/QALY was introduced into the Slovak practice via a qualitative survey among oncologists. The objective of the analysis was to assess the pricing and reimbursement possibilities, as well as the budget impact, of a new medicine for bladder cancer immunotherapy. METHODS: We investigated the number of medicines for bladder cancer immunotherapy that were registered and listed in the period between March 2011 and March 2014, in Serbia. We also made pharmacoeco- nomics analysis that would be a part of the Health Insurance Fund submission. RESULTS: Acc. to the assessment was positive (different magnitude) or negative in all countries. 6) it was similar in at least three countries. (n=5 positive decisions; n=1 negative decision). In case overall survival was the primary endpoint the likelihood was higher in all countries for a positive decision. Key differences in terms of decisions were given in acceptance of ITCs, comparator as standard of care and ratings for cost-effectiveness. CONCLUSIONS: Using the Prismaccess database the analysis shows that there might be key differences in terms of evaluation criteria between the three countries analysed. In Germany a key focus is given on the appropriate comparator(s) and patient-relevant endpoints. In the UK and Scotland cost-effectiveness is a key positive benefit assessment. In France the key drivers are not only the severity of the pathology (for tumours, >25% of SMR are not substantial), but also efficacy/adverse events ratio, Effective amount, Comparator choice and Therapeutic strategy.

PCN222

REIMBURSEMENT DECISIONS FOR ORPHAN AND INVESTIGATIONAL DRUGS: IMPLEMENTATION FOR ACCESS SCHEMES IN KOREA

Kim Y1, Na Y1, Yim E1, Kim J1, Yoo MY

Health Insurance Review & Assessment Service, Seoul, South Korea

OBJECTIVES: The Korean Reimbursement Assessment has been made to evaluate the access of orphan drugs or cancer drugs to patients since it is difficult for these drugs to be reimbursed due to its high price or lack of clinical evidence. We aim to investigate the current status of reimbursement and reviewed related schemes in Korea. METHODS: The reimbursement results for orphan or cancer drugs during 7 years (2007~2013) were included and recommendation rate, final listing rate and order of entry among 8 countries were analyzed. RESULTS: Total 331 were recommended to be reimbursed in overall 467 appraisal results (71%), whereas 74 was recommended to be reimbursed among 121 results for orphan or cancer drugs (61%), indicating that it was less likely to be recommended for those drugs. Fifty eight orphan or cancer drugs (48%) were finally listed through NHIC negotiation process. For cancer drugs, the final listing rate (54%) was inferior to the orphan drug (81%) but due to constant shortage of registered BCG from May 2012, non-registered BCG was also listed (price: not defined). Still there was no import, due to worldwide shortages. The absence of the treatment encouraged the Serbian health authorities to consider other alternatives. CONCLUSIONS: The price as proposal for new medicine would be 55,436, expenses per patient per year would be 498,876 and total costs for 520 patients would be 259,412,40 €, it is projected that total savings would be 111,150,000 € per year. Market share of domestic BCG (orphan medicine) is expected to be 20% of total market. The future aim is to develop, register and list domestic BCG that would provide lower costs per patient, high quality, availability and the continuous immunotherapy.
to reimbursements, causing a significant growth in costs. Expenses for oncology in 2003-2011 increased by 718% (from €14.5 million in December 2011, a cost/QALY threshold was introduced to legislation, creating a barrier to the inclusion of oncology drugs to the Reimbursement list. Following adoption of this legislation, of the 12 drugs registered by the EMA, only 3 oncology drugs were included. The other 9 drugs, which were withdrawn, included 5 non-oncology drugs that were prevalent, and the outcomes of such schemes.

Methods: The research was conducted through in-depth interviews with payers and clinicians across 10 EUA markets. Results: Of the 10 markets studied, 5 countries were identified to have either easier or quicker routes to access for new biopharmaceuticals (e.g. ATU in France, approval in 6-18 months, no regulatory approval in Saudi Arabia, and the “white list” in Norway). Most of these routes were reserved for products with orphan indications or products that were believed to significantly impact current standard of care. One hundred and twenty-nine different biopharmaceuticals and two hundred and thirty-three different routes are often significant restrictions imposed on the product, as well as a reduction in volume. If companies elect for the standard route to approval and reimburse, the review process is often more rigorous, however, the decision is likely more timely. A number of products with product volumes of product is larger. Frequently, if products opt for the faster route to access, this will serve as additional evidence for getting the product reimbursed at a later date for use in a wider population.

Conclusions: New pharmaceutical products that are likely to dramatically change the treatment landscape or are active in orphan diseases should take advantage of these schemes. Physicians grasp at the opportunity to use efficacious products as early as possible and companies need to leverage the opportunity for streamlined access to products.

PCN229

INNOVATION MAY DRIVE STREAMLINED ACCESS TO NEW BIOPHARMACEUTICALS ACROSS SOME EMENA MARKETS

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Objectives: Objectives: The purpose of the study was to analyze the availability of innovative oncological treatment. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

Conclusions: In Slovakia, the willingness to pay for an additional unit of medication is limited by legislation and the availability of innovative oncological treatment. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

PCN230

HEALTH ECONOMIC IMPACT OF VOLUME DOUBLING TIME AS BIOMARKER IN LUNG CANCER DIAGNOSIS

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Objectives: Lung cancer has a continuously bad prognosis in terms of survival and quality of life, usually because of late detection of malignancies. Given an expected increase in the incidence, overall mortality will increase. Early detection and efficient diagnostic planning may offer additional gain in survival. Diagnosis of lung cancer is complicated by a cascade of different imaging and diagnostic modalities. The main objective of this study is to estimate the health economic impact of diagnostic procedures and the expected gain by volume-doubling time on low-dose CT as biomarker in suspected lung cancer (NELSON protocol). Methods: A state-transition model is created to simulate the pathway of lung cancer diagnostic procedures, including x-ray, diagnostic CT, PET-CT, bronchoscopy, mediastinoscopy and more. Hospital registries and data from the National Cancer Registry were used to estimate the amount of diagnostic procedures in a cohort of lung cancer patients. Systematic literature search was performed to estimate the diagnostic performance of different modalities. Patient cohort is defined and the pre-test probability for malignancy is estimated through the Swensen criteria. Probabilistic sensitivity analysis is performed using Monte Carlo simulations. Results: Diagnostic procedures for patients with suspected lung cancer can count up to almost €3,000 per patient. Pathway was modeled in a microsimulated cohort through Swensen criteria, leading to a mean chance of malignancy of 40%. Costly steps in the pathway include cervical mediastinoscopy and mutation analysis. Inclusion of NELSON protocol can lead to a reduction in costs. Decision making per patient can reduce overall of diagnostic modalities. Conclusions: The diagnostic procedure for suspected lung cancer patients is a costly pathway and can be improved with use of the NELSON screening protocol or personalized selection of diagnostic procedures.

PCN231

HOW SUCCESSFUL HAVE PEDIATRIC INVESTIGATION PLANS BEEN IN STIMULATING RESEARCH FOR PEDIATRIC CANSERS?

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Objectives: The European Pediatric Medicine Regulation was created in 2007 to encourage further drug development for pediatric diseases, by requiring pharmaceutical companies to submit pediatric investigation plans (PIPs) when submitting the marketing application for a new drug. The objective of this study was to determine how successful this legislation had been in stimulating research in pediatric cancers. Methods: Current oncology PIPs were manually extracted from the EMA database for 2014. Primary data was collected from the application, decision, action date, and date of expected completion. Indications for approved PIPs were classified into five categories: brain tumors, diagnostics, leukemias/lymphomas, side effects, and solid tumors. Results: A total of 105 PIPs were found, 25% of which were indications for orphan indications or products that were believed to significantly impact current standard of care. Objectives: The objective for this study was to describe current chemotherapy patterns for OC in the Netherlands. Currently, the EMA offers no standardized criteria for the treatment of ovarian cancer (OC) in the Netherlands. The current study is to determine the effect of the FDA black box warning on ESA use patients taking chemotherapy. The objective for this study was to describe current chemotherapy patterns for OC in the Netherlands. Currently, the EMA offers no standardized criteria for the treatment of ovarian cancer (OC) in the Netherlands.

Conclusions: The objective for this study was to describe current chemotherapy patterns for OC in the Netherlands. Currently, the EMA offers no standardized criteria for the treatment of ovarian cancer (OC) in the Netherlands. The current study is to determine the effect of the FDA black box warning on ESA use patients taking chemotherapy.
OBJECTIVES: NAT for eBC have potential benefits in reducing tumor size, permitting better surgical candidates, identifying the adenovirus program, and providing prognostic information. This study investigated the characteristics of eBC patients, real-world utilization patterns of NAT, and health care costs from diagnosis to primary surgery (neoadjuvant phase) using a US claims database. METHODS: A cohort of 57,032 patients was identified from the IMS PharMetrics Plus database, including female patients aged 18–75 with the first (index) breast cancer (BC) diagnosis (ICD-9-CM 174.x, 233.x) between July 2006 and September 2012, primary surgery (mastectomy or lumpectomy) after index, continuous enrollment from 180 days before index (pre-index) to 90 days after surgery, no pre-index diagnosis for BC or other primary cancer, and no secondary malignancy from pre-index to surgery. Systemic therapies used by this cohort in neoadjuvant phase were assumed as NAT. Patients with eBC with trastuzumab use were presumed HER2+. RESULTS: Of 57,032 eligible eBC patients, 1,016 (3.5%) received NAT. Patients who received NAT had primary surgery in a median of 166 days after index diagnosis vs. 21 days for patients who did not receive NAT. Among patients in the Republic of Korea, breast cancer burden was highest. The Riyadh program revealed higher rate of breast cancer in the region than pre-index. Data visualization readily identified regions for the KSA female population, BC burden and existing health system and project (KSA).

Conclusions: The modeling and phased studies will guide the national program development and establish a care pathway for accurate diagnosis and treatment. The Riyadh program revealed higher rate of breast cancer in the region than previously reported, emphasizing the need to ensure access for accurate diagnosis and create a national program. Data visualization readily identifies regions for prioritized expansion. Real world data will continue to inform the ABMS model to identify investments required to establish a national breast cancer program across KSA.

PCN237
DIFFERENTIAL PHARMACEUTICAL PRICING: ARE PRICES CO-RELATEGED WITH GDP?
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OBJECTIVE: To assess co-relations of GDP per capita (purchasing power parity) on pharmaceutical pricing. METHODS: Based on empirical research, 12 drugs were selected and grouped into seven therapeutic categories: (1) Blood Based Disorders; (2) Cardiovascular Disorders; (3) Inflammatory Disorders; (4) Oncology; (5) Respiratory Disorders; (6) Antihypertensive drugs; and (7) Viral Diseases and Antivirals. For each drug per unit (mg, IU, U) at ex-factory level data was collected from IMS PharOnline International (GOL) Database across 41 countries (Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, India, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Morocco, The Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, and United States). RESULTS: World Bank was used as the reference point for the same period of time. We fit the regression equation for the log price per unit (dependent variable), log GDP per capita, generic status, strength, percentage of population aged 65 and above, an indicator for the US market, and year (independent variables) as follows: Y (Price per Unit) = a + b 1 X1 + b 2 X2 + b 3 X3 + b 4 X4 + b 5 X5 + b 6 X6 + b 7 X7 + b 8 X8 + ε. The coefficient b1 was statistically significant GDP (PPP) coefficients at the 0.01 level, whereas Dasigna, bezazemuz, dabigatran, rivaroxaban, exenatide, longrateg, saxagliptin, and interferon alpha were not significant at 0.01 level. CONCLUSIONS: Our model finds varying degrees of co-relation between GDP per capita and price per unit. Nonetheless, sitagliptin, cetuximab, filgrastim, Stovoza, Truvada, and adalimumab exhibited highest co-relation; they are thus most differentially priced.

PCN238
HEALTH CARE RESOURCE UTILIZATION (HCRU) IN HOSPITALIZED FEMALE NEUROPATHIC (FN) PATIENTS TREATED WITH CHEMOTHERAPY FOR SOLID TUMORS (ST) AND HEMATOLOGIC MALIGNANCIES (HM) IN BULGARIA
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OBJECTIVES: Chemotherapy-induced FN is associated with increased morbid- ity and mortality and frequently leads to hospitalization. This analysis aimed to describe HCRU in patients hospitalized for FN in Bulgaria in 2006-2012. METHODS: Eleven Bulgarian centers contributed to this international, retrospective, observational study conducted in Bulgaria, Czech Republic, and Slovakia. Adult patients with ST or HM receiving the chemotherapy leading to the first FN episode between 01/01/2006 and 12/31/2010 were identified (the first observed diagnosis date as the index event). The number of approved off-label regimens by year and cancer type, and the regimen of the most widely used included. RESULTS: From 2006 to 2013, total 203 off-label regimens were approved for use in 63 hospitals (number of cumulative cases: 16,566). From 2006 to 2012, the number of approved off-label regimens was increased (1, 3, 3, 14, 93, 37, 67, respectively). In 2013, only 38 regimens were approved. Compared with the other cancer, non-Hodgkin lymphoma (50 regimens, 15%), ovarian cancer (10 regimens, 5%), colorectal (10 regimens, 5%), and breast (20 regimens, 6%) cancers were the most widely used regimens (~3 weekly ~5-6 instills) for gastrointestinal cancer was the most widely used regimens (59 hospitals, number of cumulative cases: 2,283). CONCLUSIONS: The use of off-label regimens has increased in Bulgaria since 2006. The number of approved off-label regimens by year and cancer type, and the regimen of the most widely used included. RESULTS: From 2006 to 2013, total 203 off-label regimens were approved for use in 63 hospitals (number of cumulative cases: 16,566). From 2006 to 2012, the number of approved off-label regimens was increased (1, 3, 3, 14, 93, 37, 67, respectively). In 2013, only 38 regimens were approved. Compared with the other cancer, non-Hodgkin lymphoma (50 regimens, 15%), ovarian cancer (10 regimens, 5%), colorectal (10 regimens, 5%), and breast (20 regimens, 6%) cancers were the most widely used regimens (~3 weekly ~5-6 instills) for gastrointestinal cancer was the most widely used regimens (59 hospitals, number of cumulative cases: 2,283). The results suggest that the development of new drugs and the more clinical trials should be needed in cancer disease.

PCN236
USING INNOVATIVE MODELING ANALYTICS WITH REAL WORLD DATA TO DEVELOP A NATIONAL BREAST CANCER SCREENING PROGRAM IN THE KINGDOM OF SAUDI ARABIA
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OBJECTIVES: To develop a national breast cancer (BC) screening program through phased regional expansion using an advanced investment decision support simulation model informed by real world data in the Kingdom of Saudi Arabia (KSA). METHODS: An agent-based modeling simulation (ABMS) tool will represent the KSA female population, BC burden and existing health system and project impact of infrastructure investment options. Data are drawn from existing sources including census, registries and health surveys, phased studies will generate real world data on the outcomes of new clinical interventions. In Phase 1, a mobile BC screening program was deployed in Riyadh with three mobile clinics equipped with appropriate technology and medical staffing with the goal to screen 10,000 women during 2012-2014 and establish a care pathway for accurate diagnosis, modeling the phased studies will guide the national program development by evaluating the impact of investments on BC screening rates, outcomes and economic impact. RESULTS: The ABMS model will be used to simulate BC screening programs in different regions of KSA. Baseline female and established a care pathway modeling led to 83 confirmed BC diagnoses (rate: 6.4 per 1000). Data visualization plotting breast cancer disease prevalence and mortality across regions and base identified areas for future BC care expansion. CONCLUSIONS: The Riyadh program revealed higher rate of breast cancer in the region than previously reported, emphasizing the need to ensure access for accurate diagnosis and create a national program. Data visualization readily identifies regions for prioritized expansion. Real world data will continue to inform the ABMS model to identify investments required to establish a national breast cancer program across KSA.

PCN239
WHAT ARE THE HEALTH CARE RESOURCE UTILIZATION AND COST MEDICATION OF UNTREATED PATIENTS WITH NEUROENDOCRINE TUMORS IN THE UNITED STATES?
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OBJECTIVE: The use of off-label medication is restricted by government in some countries, because using off-label anticancer drugs has some concerns about its efficacy and toxicity. HIRA (Health Insurance Review & Assessment Service) has the process of the assessment and control of the use of anticancer drugs in South Korea. We would introduce the controlling for the off-label use of anticancer drugs and evaluate the trend of off-label use in anticancer drugs. METHODS: Since Dec. 2006, HIRA has permitted off-label use for which there is adequate evidence for the efficacy, toxicity, and cost effectiveness. We collected the patient’s medical record data (briefly recorded response rate, major adverse effects etc) which updated every year from hospital. We defined 37 cancers (36 cancers, other cancer) and project the number of approved off-label use of anticancer drugs from 2006 to 2013. RESULTS: The number of approved off-label regimens by year and cancer type, and the regimen of the most widely used included. RESULTS: From 2006 to 2013, total 203 off-label regimens were approved for use in 63 hospitals (number of cumulative cases: 16,566). From 2006 to 2012, the number of approved off-label regimens was increased (1, 3, 3, 14, 93, 37, 67, respectively). In 2013, only 38 regimens were approved. Compared with the other cancer, non-Hodgkin lymphoma (50 regimens, 15%), ovarian cancer (10 regimens, 5%), colorectal (10 regimens, 5%), and breast (20 regimens, 6%) cancers were the most widely used regimens (~3 weekly ~5-6 instills) for gastrointestinal cancer was the most widely used regimens (59 hospitals, number of cumulative cases: 2,283). The results suggest that the development of new drugs and the more clinical trials should be needed in cancer disease.
performed to assess evolution of HRQoL and medical costs over time. Similar analysis was conducted for Medicaid-eligible patients. RESULTS: Of the 3,940 commercially insured and 1,658 Medicare-eligible individuals with NETs, 63.0% (n=2,484) and 67.0% (n=1,111) were untreated, respectively. Among untreated commercially insured individuals with NETs, carcinoid syndrome (20.9%), nausea/vomiting (14.2%) and liver metastasis (11.6%) were the most prevalent symptoms/co-morbidities in the 12-month post-index period, 37.7% had hospitalization admissions and 31.4% had emergency department (ED) visits, and the mean annual number of physician office visits was 42.2% had hospitalization admissions and 35.0% of those diagnosed had ED visits, and the mean annual number of physician office visits was 4.8 cm³ per dose in a 2-dose-vial and for 6/11/16/18V 15 cm³ per dose for a 2-dose-vial. Additionally, a buffer factor of 10% as well as a wastage factor (5% for a 1-dose-vial and 10% for a 2-dose-vial) were also accounted for as an assumption. Two vaccines were considered: the AS04-adjuvanted HPV-16/18 vaccine (AS04v) ≥ 12 years of age (A-D, U) representing the strength of evidence. The ICER score comprises of a number indicating the clinical profile of the drug and the letter indicating whether the evidence is of high, moderate or low quality. The ICER per indication was sourced from literature published between 2013 until March 2014 were analysed and mapped to the national May CDF list. Each year, the NHS based on the pre-calculated score. For industry the market opportunity is compelling, however market access across routine cohort CDF criteria for rare diseases or, in cases where a decision has been made not to fund a cohort, for patients whom clinical exceptionality from this cohort can be demonstrated. ICDFRs are screened to ensure that the request is appropriate and are then appraised by one of four regional CDF panels to determine whether access to oncology through ICDFRs varies by region. METHODS: ICDFR outcomes data (April 2013–March 2014) was extracted from the NHS website and stratified by NHS estimates of the resident population by age and sex in England for each region. All 5.5 ICDFRs were accepted per million children aged < 5 years, between regions varying from six-fold (range 1.9 (East and Midlands) to 12.0 (South England)). CONCLUSIONS: The notable variations in ICDFR screening, acceptance, and population level approval rates, which are larger than what we may expect based on regional variations in case mix and the level of evidence are the most important factors for the CDF inclusion while cost-effectiveness is not a standard part of the decision-making process. The findings can also support manufacturers in estimating the likely outcome of the CDF application based on the pre-calculated score. The result of this research confirms that the clinical profile and the level of evidence are the most important factors for the CDF inclusion while cost-effectiveness is not a standard part of the decision-making process. The findings can also support manufacturers in estimating the likely outcome of the CDF application based on the pre-calculated score.
pcn248
DILEMMA OF CROSS-OVER TRIALS AND THEIR IMPACT ON BENEFIT ASSESSMENT IN ONCOLOGY

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OBJECTIVE: The cross-over design is widely used for the conduct of clinical trials in oncology. However, it is not uncommon to encounter situations where high patient cross-over rates may lead to the conclusion that a certain treatment is ineffective. At the same time, cross-over designs are often the only practical way to ethically conduct a clinical trial, especially in oncology where disease progression may be so rapid that delayed intervention may result in the death of the patient. The aim of this study was to assess the impact of cross-over designs on the benefit assessment in oncology.

METHODS: A systematic review of clinical trials in oncology that utilized cross-over designs was performed. The primary outcome measure was the impact of cross-over rates on the assessment of treatment benefit.

RESULTS: A total of 24 clinical trials were included in the study. The cross-over rates ranged from 20% to 80%. The impact of cross-over rates on the assessment of treatment benefit was found to be significant in 12 of the 24 trials. In 10 of these trials, the cross-over rates resulted in the conclusion that the treatment was ineffective, whereas in 2 trials, the treatment was found to be effective.

CONCLUSIONS: Cross-over designs are widely used in oncology clinical trials. However, high patient cross-over rates may lead to the conclusion that a certain treatment is ineffective, even though it may be beneficial. Therefore, careful consideration should be given to the design of clinical trials in oncology to ensure that the benefits of treatments are accurately assessed.
recommendations. Its Dutch counterpart, ZI, issued only 8% of negative decisions to TCTs. The mode for a success rate in the Netherlands was special policy that enabled reimbursement of TCTs without CEA.

**PCN251**

**THE CANCER DRUGS FUND: A SYSTEMATIC ANALYSIS OF THE REQUIREMENTS FOR INCLUSION ON THE ENGLISH NATIONAL LIST OF DRUGS FOR PRIORITY FUNDING**

**METHODOLOGY:**

- HERON Commercialization, London, UK

**OBJECTIVES:**

- The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access therapies that are not routinely available on the National Health Service (NHS). In April 2013, NHS England became responsible for the management of the CDF with a single national list of drugs for prioritised funding. As the CDF has recently been extended to 2016, it is increasingly important to understand the key criteria for inclusion on the CDF list.

**RESULTS:**

- 56 CDF decision summaries were available, 14 (25%) scored full approval, 10 (18%) received conditional/restricted approval, 28 (50%) were rejected, and 4 (7%) were referred to commissioning. The key clinical attributes of each oncologic were given a numerical scoring that sum to a possible maximum of +21 and minimum of -4. The maximum score of any drug appraised was +8 and the minimum was -1. Excluding approvals referred to commissioning, 16/18 appraisals scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2 (4/5 primarily due to trial comparator choice). There were no scored due to a lack of appropriate (SACCT) data (30% of all submissions). 7/25 (28%) were rejected on the basis of quality of life (QoL) submissions, efficacy scores were halved), 5 of which were approved.

**CONCLUSIONS:**

- A score of >2 seems to be the key clinical threshold above which most drugs are accepted below which most are rejected. Given that 43/47 scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2, this means that 3 points are typically required, which can come through a 4-5 month Progression Free Survival or Overall Survival gain (or a 2-3 month gain in both), but this must be versus the clinically relevant comparator.

**PCN252**

**TESTING THE UTILITY OF THE NHS’S SYSTEMIC ANTI-CANCER THERAPY DATA SET FOR MULTICATION PRICING**

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Roche Products Ltd., Weylun Garden City, UK

**OBJECTIVES:**

- The price of a medicine should reflect the value it offers to patients, the health care system and society more broadly. However, with current pricing manufacturers can only set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as being too high, or too low, or where a response is not given.

**RESULTS:**

- An analysis of all oncology assessments will reveal key drivers responsible for the maximum score of any drug appraised was +8 and the minimum was -1. Excluding approvals referred to commissioning, 16/18 appraisals scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2 (4/5 primarily due to trial comparator choice). There were no scored due to a lack of appropriate (SACCT) data (30% of all submissions). 7/25 (28%) were rejected on the basis of quality of life (QoL) submissions, efficacy scores were halved), 5 of which were approved.

**CONCLUSIONS:**

- A score of >2 seems to be the key clinical threshold above which most drugs are accepted below which most are rejected. Given that 43/47 scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2, this means that 3 points are typically required, which can come through a 4-5 month Progression Free Survival or Overall Survival gain (or a 2-3 month gain in both), but this must be versus the clinically relevant comparator.

**PCN253**

**ONCOLOGY PRODUCTS IN THE AMNOG PROCESS – LEARNINGS FOR A SUCCESSFUL DOSSIER SUBMISSION**

Dehnen J, Goldhagen K

HERON Commercialization Group, Munich, Germany

**OBJECTIVES:**

- Since AMNOG reform has taken effect 3.5 years ago, 78 dossiers have been evaluated by the G-BA. Especially with oncology agents, 28 products have started the process and G-BA has finalized decisions for 25 dosis. In 20 cases additional benefit was granted. Therefore, the success rate of oncology products is 80% and much higher than the success rate of non-oncology products (29%).

**RESULTS:**

- An analysis of all oncology assessments will reveal key drivers responsible for the maximum score of any drug appraised was +8 and the minimum was -1. Excluding approvals referred to commissioning, 16/18 appraisals scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2 (4/5 primarily due to trial comparator choice). There were no scored due to a lack of appropriate (SACCT) data (30% of all submissions). 7/25 (28%) were rejected on the basis of quality of life (QoL) submissions, efficacy scores were halved), 5 of which were approved.

**CONCLUSIONS:**

- A score of >2 seems to be the key clinical threshold above which most drugs are accepted below which most are rejected. Given that 43/47 scoring >2 were rejected (89%) compared to only 5/25 (20%) scoring >2, this means that 3 points are typically required, which can come through a 4-5 month Progression Free Survival or Overall Survival gain (or a 2-3 month gain in both), but this must be versus the clinically relevant comparator.

**PCN254**

**MEDIA COVERAGE OF THE NICE FIRST DRAFT CONSULTATION GUIDANCE FOR TRASTUZUMAB EMANTANISME (Kadcyla) IN BREAST CANCER**

**Macarly R**

HERON Commercialization, London, UK

**OBJECTIVES:**

- The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criterion. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncology) where the most memorable example of which relates to the funding of Herceptin in early-stage breast cancer in 2005. This research aimed to evaluate how the media currently report NICE decision-making, focussing on the NICE appraisals for trastuzumab emtansine (Kadcyla) during a further public consultation.

**METHODS:**

- A total of 78 decision notices were collected between 23rd-25th April 2014 regarding this NICE draft guidance from which key criteria were extracted and compared. RESULTS: 19 articles were extracted (6 national newspapers, 6 regional newspapers, 3 broadcasters, and 4 other), 19 articles were extracted and compared.

**RESULTS:**

- All articles included at least one of the following criteria (in which patients were denied access to medicine in certain indications).

**CONCLUSIONS:**

- ONCLOGIES not to fund oncology drugs still seem to be predominantly faced by a hostile media reception that focus more on patient reactions than the difficulties of how to allocate finite health care resources to best optimize care in the NHS.

**PCN255**

**COMPARING HOW SINGLE ARM PHASE II TRIAL DATA CAN SUPPORT APPROVAL OF ONCOLOGIES BY EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODIES**

**Macarly R**

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**OBJECTIVES:**

- The European Medicines Agency (EMA) approved 15 oncologies across 24 indications based on pivotal single-arm Phase II data (Macaulay, ISPOR Dublin 2013). Approval was typically granted for indications in which there was no therapeutic alternative (where a response is achieved).

**METHODOLOGY:**

- This joint working project to validate and test the utility of the Systemic Anti-Cancer Therapy (SACT) data set for the Personalised Reimbursement Service (NHS). In April 2013, NHS England became responsible for the management of the CDF.

**RESULTS:**

- Following completion of this work we hope SACT will be used to introduce MIP in England – this will enhance the administrative burden of drug data collection for commercial schemes for cancer medicines, enabling manufacturers to set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as being too high, or too low, or where a response is not given.

**CONCLUSIONS:**

- STIPULATE STRICTER CLINICAL CRITERIA BUT WILL ALSO APPROVE FUNDING TO SUBMIT RECOMMENDATIONS ON WHICH DRUGS THE NATIONAL HEALTH SERVICE (NHS) SHOULD FUND, WITH COST-EFFECTIVENESS BEING A KEY CRITERION. THERE HAVE BEEN CRITICAL MEDIA REACTIONS TOWARD NICE APPRAISALS THAT RECOMMEND AGAINST FUNDING DRUGS (PARTICULARLY ONCOLOGY) WHERE THE MOST MEMORABLE EXAMPLE OF WHICH RELATES TO THE FUNDING OF HERCEPTIN IN EARLY-STAGE BREAST CANCER IN 2005. THIS RESEARCH AIMED TO EVALUATE HOW THE MEDIA CURRENTLY REPORT NICE DECISION-MAKING, FOCUSING ON THE NICE APPRAISALS FOR TRASTUZUMAB EMANTANISME (KADCYLA) DURING A FURTHER PUBLIC CONSULTATION. THIS PROJECT INCLUDES IDENTIFYING AND DEVELOPING IMPLEMENTATION OF A PRICING MODEL WHERE THERE IS DIFFERENTIATED VALUE OF A MEDICINAL PRODUCT ACROSS INDICATIONS, LINE OF THERAPY OR IF USED AS A MONO/COMBINATION THERAPY. THIS PROJECT INCLUDES IDENTIFYING AND DEVELOPING IMPLEMENTATION OF A PRICING MODEL WHERE THERE IS DIFFERENTIATED VALUE OF A MEDICINAL PRODUCT ACROSS INDICATIONS, LINE OF THERAPY OR IF USED AS A MONO/COMBINATION THERAPY.
By comparison, only 7/88 (8%) of NICE-approved cancer appraisals have been subject to restrictions in addition to the label. CDOs did not have access to anti-cancer drugs under the CDF to be more restrictive than those approved by NICE. Thus, attaining NICE approval for CDF-approved drugs could broaden clinical access as well as ensure reimbursement after the fund is due to close in 2016. Nevertheless, the CDF does provide a formal mechanism under which the reimbursed list can be provided for off-label use of cancer drugs, which NICE will not consider.

PCN257
APPLICATION OF THRESHOLD VALUE FOR COST-EFFECTIVENESS IN RECOMMENDATIONS ISSUED BY AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT IN POLAND FOR CANCER DRUG TECHNOLOGIES
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OBJECTIVES: To analyse HTA recommendations for cancer drug technologies issued by the AHTAPol. In particular, to analyse if in the period from January 2012 to March 2014 were recommended drugs where the ICUR value was either above or below the official threshold.

METHODOLOGY: The review of HTA recommendations concerning cancer technologies issued by AHTAPol in the period from January 2012 to March 2014 was performed. The classification of HTA recommendations was based on the approach labeling them as positive, positive with major with defined restrictions, and negative. The classification with defined restrictions was related to the unacceptable cost-effectiveness. The same analysis on the ICUR values without implementation of RSS was conducted to compare the official threshold value for cost-effectiveness (in Poland defined as 3xGDP for each year) and defined whether the ICUR value is either above or below the official threshold.

RESULTS: The review of 259 recommendations included 66 (25.6%) recommendations with defined restrictions and 175 (67.8%) recommendations which were classified as positive. Other aspects of recommendations, such as criterion for decision, type of RSS implemented and reasons for restrictions were also analysed. RESULTS: The studied period contained more recommendations for 35 different cancer drugs (due to the multiplicity of recommendations for 4 drugs). After review, 32 recommendations with calculated ICUR (with Risk Sharing Scheme (RSS) if implemented) were included in the analysis. For 13 of these recommended medicines, IUR values were below official AHTAPol's threshold. For 7 of 11 positive recommendations ICUR values were placed below threshold. On the other hand, for 5 of 7 positive recommendations with ICUR values the results in this study were the same as previously published with the ICUR value is either above or below the official threshold. The same analysis on the ICUR values without implementation of RSS was conducted to compare the official threshold.

CONCLUSIONS: The official threshold values set in AHTAPol are respected in the majority of situations for cancer drugs. Other aspects of recommendations, such as criterion for decision, types of RSS implemented and reasons for restrictions were also analysed. RESULTS: The studied period contained more recommendations for 35 different cancer drugs (due to the multiplicity of recommendations for 4 drugs). After review, 32 recommendations with calculated ICUR (with Risk Sharing Scheme (RSS) if implemented) were included in the analysis. For 13 of these recommended medicines, IUR values were below official AHTAPol's threshold. For 7 of 11 positive recommendations ICUR values were placed below threshold. On the other hand, for 5 of 7 positive recommendations with ICUR values the results in this study were the same as previously published with the ICUR value is either above or below the official threshold. The same analysis on the ICUR values without implementation of RSS was conducted to compare the official threshold.

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be issued a “do not recommend” decision due to non- oncology reviews (56% vs. 16%, p<0.01). Over time there was a significant increase in the rates of “recommend with restrictions” decisions for oncology reviews and oncology reviews, though rates of “do not recommend” decisions have increased for oncology reviews since 2008. There were no differences in the rates of “recommend” and “recommend with restriction” decisions between oncology and non-oncology reviews (p=0.87). Over time there was a significant decrease in the rates of “recommend with restrictions” decisions for oncology reviews (p=0.07), but no statistical trend in non-oncology reviews. CONCLUSIONS: NICE was more likely to issue a “do not recommend” decision for oncology reviews compared to non-oncology reviews, but there was no difference in the overall rates of “recommend with restrictions” decisions. Over time, NICE appears to be replacing “recommend with restrictions” decisions with “do not recommend” decisions in oncology reviews, but this did not pass traditional significance levels.

PCN264
SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS IN CANCEROLOGY IN BRAZIL BETWEEN 1980 AND 2013
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Nowadays, economic evaluation has been increasingly used in health care decision-making in Brazil. The Brazilian economic evaluation literature in cancerology is unknown. OBJECTIVES: This systematic review aims to identify and characterize the economic evaluation studies in cancerology conducted in Brazil. METHODS: Ten online databases (MEDLINE (PubMed), EMBASE, Latin American and Caribbean Literature on Health Sciences Database (LILACS), Scientific Electronic Library Online (SciELO), NHS Economic Evaluation Database (NHS EED), HTA Database (Centre for Reviews and Dissemination (CRD)), Biblioteca Virtual em Saúde Economia da Saúde (BVS ECOS), SCOPUS, Web of Science, and the Sistema de Informação da Rede Brasileira de Avaliação de Tecnologias em Saúde (SISREBRATS) were systematically searched. We also performed manual search. We selected partial and full economic evaluation studies in cancerology, where at least one of the authors was affiliated to a Brazilian institution. Two authors performed study selection and data extraction independently. Disagreements were resolved through discussion or through consultation with a third reviewer. The study characteristics were summarized in figures and summary tables. RESULTS: A total of 11946 records were identified. Fifty six articles met inclusion criteria, of these, 33 (59%) were a full and 23 (41%) were partial economic evaluation. The cost-effectiveness analysis was the most used (27%). There was an increase in the number of publications over the years, especially after 2006. Researchers from the Southeast region of Brazil were responsible for the majority of the publications (82%). Cancers most frequently studied were breast cancer (37%), followed by cervical cancer (16%), lung cancer (12%) and colorectal cancer (9%). The technologies most studied were medications (34%). CONCLUSIONS: The expansion in the analyzed literature and data sets in Brazil, along with the growing demand for HTA studies by the National Policy for Health Technology Assessment in Brazil that may have stimulated the scientific production in this area.

PCN265
HEALTH TECHNOLOGY ASSESSMENTS IN ONCOLOGY: CRIZOTINIB CASE STUDY
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OBJECTIVES: Crizotinib (Xalkori®) was approved for the treatment of adults with non-small cell lung cancer (NSCLC). The objective of this study was to illustrate the diversity of Health Technology Assessments (HTA) debated by costly products like crizotinib (Xalkori®) for the National Institute for Health and Care Excellence (NICE), the Federal Joint Committee (G-BA) and French National Authority for Health (HAS). METHODS: Crizotinib’s pivotal trial (Study 1007) was analysed. NICE, G-BA and HAS used the same primary endpoints. RESULTS: Cross-over and fixed sample size comparisons considered. RESULTS: Study 1007 was a randomised open-label trial comparing crizotinib with chemotherapy in patients with ALK-advanced NSCLC and who had failed one chemotherapy regimen. The primary endpoint was progression-free survival (PFS) and overall survival (OS) was a secondary endpoint. While treatment with crizotinib increased significantly the PFS (4.7 months) no significant improvement in OS was observed versus chemotherapy group (OS interim analysis). Some quality of life (QoL) items (e.g. chest pain, dyspnea, fatigue) were improved within the crizotinib group. Even though no improvement in the OS was shown, the G-BA assessed the crizotinib benefit as considerable based on the improvement of QoL and morbidity decrease. The HAS also granted crizotinib an improvement in actual benefit of 37% based on the improvements in the PFS and QoL. However, the significant gain in FAS was not sufficient to get positive guidance from NICE. Indeed, NICE did not recommend the use of crizotinib due to the uncertainties surrounding the OS interim data and high rate of patients “crossing-over” from standard therapy to crizotinib. CONCLUSIONS: Cross-over has become a real obstacle to appreciate oncology product value. While an additional benefit can be granted based on improvement of QoL plus morbidity and QoL results in Germany and France, products supported solely by an increased FAS and no change in OS may face access barriers in England.

PCN266
IMPACT OF HEALTH CARE REFORM ON DRUG REIMBURSEMENT DECISION-MAKING IN TAIWAN
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OBJECTIVES: Taiwan is considered a challenging market to access, largely due to strict pricing and reimbursement policies. To assess the impact of health insurance reforms introduced in Taiwan in 2005 and 2008, the first part of the Second General National Health Insurance (SGNHI) Taiwan reimbursement decisions and granted prices before and after the introduction were compared with major western countries. METHODS: Publications of Taiwan NHRI from March 2011 to February 2014 were searched and reimbursement decisions identified. The largest therapy areas, oncology and cardiovascular, which accounted for 40% of decisions, were compared with those of three major HTA agencies: CADTH, NICE and PBAC. HTA reports and meeting transcripts were analysed and categorised by date, therapy area, decision, rationale, and pricing decision. Resubmissions or those not assessed by the western HTA agencies were excluded. RESULTS: A total of 65 NHRI reports were identified. Of these 26 reported decisions on oncology or cardiovascular drugs, 9 were excluded (3 resubmissions, 9 not reviewed by the other agencies). Prior to 2008, NHI, 4 out of 5 decisions were positive, or 80% approval rate, while after, only 4 out of 9 were positive, a 44% approval rate. Prior to 2008, all NHI reimbursement decisions were “recommend with restrictions” and CADTH, NICE, and PBAC. After 2008, only 6/9 or 66% matched. Clinical effectiveness and budget impact were most cited in reimbursement rejections. For example Zytiga, NICE appreciated the cost-effectiveness but stated budget impact was too high, issuing a negative recommendation, contrary to all other agencies. Interestingly, a “local” product was recommended for limited reimbursement even though budget impact was high. CONCLUSIONS: Since implementation of Taiwan’s NHRI reforms in January 2013, cardiovascular and oncology drug approvals increased by 36% and 50% respectively, agreeing with west cancer NICE and PBAC, placing an emphasis on budget impact. However, this analysis was constrained by its small sample size, and limited therapy areas.

PCN267
EXPANDED DATA SETS FOR HTA DECISION-MAKING IN ONCOLOGY: DO THEY HELP TO ACHIEVE POSITIVE APPRAISALS?
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OBJECTIVES: Phase III, randomised controlled trials remain the gold standard for health technology assessment (HTA) submissions. Data sets may be supplemented with other sources (e.g. Phase II trials, observational studies, treatment comparisons). However, the influence of expanded data sets on HTA appraisals is unclear. METHODS: We reviewed recent National Institute for Health and Care Excellence (NICE) and French National Authority for Health (HAS), to determine the frequency and type of expanded data sets. We then evaluated the influence of expanded data on agency decisions. A similar review of submissions to the Australian Federal Authority (AuSBT) was performed. RESULTS: There were 30 relevant appraisals on the NICE website covering a range of cancer types. Of these, 14/30 made use of expanded data sets featuring Phase II trials, observational studies, meta-analyses and/or mixed treatment comparisons. However, the influence of expanded data sets on HTA appraisals is unclear. CONCLUSIONS: We found that expanded data sets feature in nearly half of recent NICE oncology HTA assessments. However, expanded data sets are not sufficient to influence a positive appraisal by NICE and PBAC. Expanded data sets have a place in contributing to HTA decision making, but overall, rigorous Phase III RCT data remain essential to obtain a positive HTA appraisal.

PCN268
THE LIFE AND DEATH OF THE END OF LIFE TREATMENT APPRAISAL CRITERIA IN NICE TECHNOLOGY APPRAISALS
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OBJECTIVES: Since January 2009, NICE in the UK allows end of life (EOL) treatments to be considered for inclusion by the upper end (EOL) criteria of the threshold. We examined the frequency of end-of-life effectiveness ratios (ICERs) and the probability of EOL life-years gained. RESULTS: End of life (EOL) criteria were considered in 40 TAs covering 44 technologies. EOL weighting was considered appropriate for 36% of technologies. Most technologies fulfilled the criterion of 24 month life expectancy (rejected in 14%), extension of life by ≥ 3 months or robustness of its calculation was the most common cause of rejection (25%/25% respectively). These criteria were inconsistently applied, using different methods (e.g. medians, restricted means from extrapolation, means from trial or model). The criterion of small population favoured technologies with limited indication (rejection 25%). Earlier TAs presented weight calculations, while later TAs only presented ICERs. CONCLUSIONS: Although aiming for greater transparency, the criteria left considerable scope for interpretation, affecting the decision. It is crucial for NICE to move towards a clear basis for applying additional weights to EOL life-years shifting to a differential threshold for certain indications, the original idea of considering wider societal preferences seem to have been neglected, that the new guidance should remedy.

PCN269
APPLICATION OF EU EUNHTA RELATIVE EFFECTIVENESS ASSESSMENT OF PAZOPANIB FOR NATIONAL ASSESSMENTS
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NHI from March 2011 to February 2014 were searched and reimbursement decisions identified. The largest therapy areas, oncology and cardiovascular, which accounted...
OBJECTIVES: In many European jurisdictions relative effectiveness assessments (REAs) for pharmaceuticals are performed as part of the reimbursement decision making process. Collaboration in the production of these assessments across jurisdictions prevent duplication of information in various jurisdictions and save resources accordingly. A first pilot of a joint REA of pharmaceutical (paclitaxel for the treatment of advanced ovarian cancer) was established in 2011. The aim of this research study is to verify how informative the joint REA is for national assessments by comparing the joint REA of paclitaxel with nationally produced assessments on the same topic.

METHODOLOGY: National assessment reports were identified through a literature search and an email request to health technology assessment (HTA) organisations. Data were abstracted from the assessments using a structured data abstraction form including questions about the criteria assessed, the study population, the evidence included, the assessment of the evidence and the outcome of the assessment. The abstracted data were validated by representatives from the organisations.

RESULTS: In total five jurisdiction specific HTA reports, available in English, were included in this review. Two of the REAs were negatively focused and included extracted data, and assessed the quality of reviews. PRISMA checklist was used by the author to undertake the meta-analysis. RESULTS: 146 publications were retrieved. Final number of publications included went down to 14 [The PRISMA scoring for 71% of them (10 publications) were 21-24/27]. From which 25 cost effectiveness studies were extracted. Not every oncology drug showed high ICER (above £30 000), only 10 studies (45% of the publications), which contradicts the controversy about ICERs of oncology. More surprisingly was that eight (80%) of the 10 studies showed moderate cost per treatment. CONCLUSIONS: Cost of drug treatments is not the main driver for the high ICER (P-value: 0.982) but it is one of many that heavily impact the ICER value.

PCN270
HUMAN EPIDIDYMIS PROTEIN 4 TEST
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OBJECTIVES: Human Epididymis Protein 4 (HE4) is diagnostic test that diagnosis ovarian cancer with CA125 for pelvic mass patients or monitoring of response to treatment, prognosis and recurrence for ovarian cancer patients. So we assess the safety and efficacy of HE4 test.

METHODOLOGY: We searched eight domestic databases and other foreign databases such as Ovid-MEDLINE, Ovid-EMBASE, and Cochrane Library. The 44 articles were included in this review. The reviewers independently assessed selection of studies and quality assessment of each study. Quality assessment tool was used SIGN. The meta analysis results reported pooled sensitivity and specificity.

RESULTS: HE4 was conducted with patient’s serum sample, so safety is same as a blood sampling. Therefore, there is no safety problem. EFCICACY: 1) HE4 vs CA125: In 10studies, the pooled sensitivity and specificity were HE4 0.771, 0.931 and CA125 0.839, 0.677. In the intermediate risk group increasing CT use (HT to CT 0% (-4 to 3) in the intermediate risk; and -2% (-3 to -1) in the high risk group, in this latter case increasing CT use (HT to CT

PCN271
THIRD PARTY PARTICIPATION IN EARLY BENEFIT ASSESSMENT OF CANCER DRUGS IN GERMANY
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OBJECTIVES: In Germany, third party like manufacturers, physician associations, medical societies, or industry organisations are allowed to comment on the early benefit assessments (EBA) of drugs by submitting written statements (WS) and attending oral hearings (OH) before the Federal Joint Committee (G-BA) decides on a resolution. This review assesses the number of WS and OH participants of cancer drugs’ EBA and evaluates tends in third party participation (TPP).

METHODOLOGY: The status of cancer drugs’ EBA and associated documents from 2011 until May 2014 were retrieved from the G-BA website. All completed assessments were included if a summary documentation including the OH protocol and all WS was available. Information on number and category of third parties submitting WS or attending OH were extracted from the summary documentation, categorized and analysed.

RESULTS: Until May 2014 28 cancer drugs’ EBA were started and 25 completed. Summary documentation was available for 14 (56%) completed assessments. The number of submitted WS was 9 (range 3-9). The number of third parties in OH was 5.9 (range 3-9). In all EBA the manufacturer submitted WS and participated in the OH. Representatives of at least one competitor and pharmacy associations were usually present as WS and OH participants. In 12 (80%) of the 15 completed assessments, which no dossier was available, medical societies always tuned in WS and attended 11 (85%) OH. In the beginning of the EBA process the number of submitted WS was slightly lower than the number of WS. An overview of the data was presented in Table 1. TPP availability was therefore defined as the number of WS and OH per dossier.

CONCLUSIONS: German TPP in cancer drugs’ EBA is broadly used by both medical societies and the pharmaceutical industry. Further research is required to identify reasons why medical societies do not attend OH although a WS was handed in.

PCN272
IS THE DRUG COST THE MAIN DRIVER FOR THE HIGH INCREMENTAL COST UTILITY RATIOS IN ONCOLOGY TREATMENTS? A SYSTEMATIC REVIEW AND A META-ANALYSIS
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BACKGROUND: Cancer is one of the most prevalent diseases in the UK with over 300,000 cases every year, with breast cancer being the most common cause of death for adults aged 35-64.48% of all diagnosed with cancer die within 5 years. Cancer drugs and treatments involve the use of drugs to either slow down the proliferation of cancer cells or kill them, with variable success. The new innovative drugs are deemed to be too expensive; hence, many patients may offer as a reason for stopping. Therefore, it is of great importance to understand the cost of these drugs and treatments.

OBJECTIVES: To perform a systematic review and meta-analysis to investigate whether the drug cost is the main driver for the high Incremental Cost utility ratios. METHODOLOGY: Systematic search and meta-analysis were performed in a manner consistent with the research question. The search was concentrated to the drugs of the three most common cancers in the UK (breast, lung and prostate). Cardiff search database was used to perform the search. Two independent reviewers screened the titles and abstracts, extracted data, and assessed the quality of reviews. PRISMA checklist was used by the author to undertake the meta-analysis. RESULTS: 146 publications were retrieved. Final number of publications included went down to 14 [The PRISMA scoring for 71% of them (10 publications) were 21-24/27]. From which 25 cost effectiveness studies were extracted. Not every oncology drug showed high ICER (above £30 000), only 10 studies (45% of the publications), which contradicts the controversy about ICERs of oncology. More surprisingly was that eight (80%) of the 10 studies showed moderate cost per treatment. CONCLUSIONS: Cost of drug treatments is not the main driver for the high ICER (P-value: 0.982) but it is one of many that heavily impact the ICER value.

PCN273
META-ANALYSIS OF DECISION IMPACT AND NET DECISION CHANGE IN ADJUVANT CHEMOTHERAPY ALLOCATION IN EARLY STAGE NODE-NEGATIVE, ESTROGEN RECEPTOR-POSITIVE BREAST CANCER WITH A 21-GENE ASSAY
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OBJECTIVES: Risk stratification based on reports provided by a 21-gene assay (Oncometric IGENE) can help to identify women who may benefit from adjuvant chemotherapy (HT) and chemotherapy (CT) decisions, by stratifying women according to recurrence risk. Previous reviews addressing the issue were outdated or did not provide data on both overall and net decision impact of the CT in the HT+CT and CT decisions, which we aimed to perform a systematic review and meta-analysis on global decision impact and net change in CT use by risk category before and after assay results.

METHODOLOGY: We updated a broader systematic review (Carlson, search up to 03/12). Inclusion criteria are women who participate in HT with or without CT before receiving assay results. Global decision impact was estimated as the proportion of patients whose management was changed after assay results were available. Net change was estimated as the difference between the proportion of all patients who received chemotherapy before and after the test.

RESULTS: Ten studies (N=1218) met our inclusion criteria; 49.75, 38.18 and 12.07% of patients were low, intermediate and high risk. Due to significant heterogeneity among studies, a random effects model is presented. Treatment decision was changed in 30.83% (95% CI 26.75 to 35.07) of all patients. From all patients, 80% (95% CI 69 to 90) of the 10 studies showed moderate cost per treatment.

PCN274
FORWARDS A FRAMEWORK FOR ANALYSING SUSTAINABILITY OF ECONOMIC VALUE: THE CASE OF A SHORT STAY PROGRAMME FOR BREAST CANCER SURGERY CARE AFTER IMPLEMENTATION
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OBJECTIVES: Critical analysis of sustainability of health care innovations is a relatively new concept. The aim of this study was to provide an analytical framework for the evaluation of sustainability of economic value in health care. The application of the framework was demonstrated by using an exemplary case on a short stay programme for breast cancer surgery care (SSP) in the Netherlands.

METHODOLOGY: Sustainability of economic value was determined in terms of the incremental net monetary benefit (INMB) in the Netherlands. Associated with the SSP was the difference between the INMB earned during breast cancer surgery care between the SSP and the standard treatment (HT+CT) for the creation of economic value in our study period. INMB was converted into a monetary benefit (iNMB), in this case, five years after the end of active implementation (LATE POST) compared to early post-implementation results (POST). Economic value was evaluated as fully sustained if the INMB equalled zero or was positive. Values for the INMB were calculated for each complete five-year period in which no dossier was available, which no dossier was available, medical societies always tuned in WS and attended 11 (85%) OH. In the beginning of the EBA process the number of submitted WS was slightly lower than the number of WS. An overview of the data was presented in Table 1. TPP availability was therefore defined as the number of WS and OH per dossier.

CONCLUSIONS: The SSP programme for breast cancer surgery care (SSP) in the Netherlands.
tive and level of analysis (macro or meso level), and whether regression correction should be performed. A limitation of the illustrative case study was that costs of sustainability activities were not collected.

PCN276
CRITICAL ASSESSMENT OF COST-SHARING SCHEMES USING A SIMPLE MODELING APPROACH

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OBJECTIVES: To critically assess cost-sharing schemes between payers and marketing authorization holders (MAHs) that are in some jurisdictions used as a means to control public spending on prescription drugs. METHODS: Cost-sharing scheme can be theoretically analyzed as a two-step process where the discount equals \( p \) when \( x < n \), and 0 when \( x \geq n \), where \( n \) is the number of weeks/months with reduced price of a drug and \( x \) is the length of treatment in weeks/months. Within such a scheme, the discount has no impact until it is as it is shown to \( x \), i.e., np/m. Payers and MAHs may estimate and agree upon the expected length of treatment \( x = n \), based on, e.g., randomized clinical trials (RCTs); however, these estimates may be unreliable due to, inter alia, market power of MAHs that could disproportionately influence the selection of patients. RESULTS: Two-step cost-sharing scheme results in the effective discount that is lower than expected discount by \( \text{np/m} \times \left(1 - \frac{n}{m} \right) \). CONCLUSIONS: While the two-step cost-sharing scheme was initially thought to increase the effective discount, this finding may be of value to those jurisdictions that resort to cost-sharing as a tool in curtailing prescription drug costs.

PCN277
NEW REIMBURSEMENT SCHEMES FOR STRATIFIED MEDICINE IN ONCOLOGY – A SYSTEMATIC REVIEW

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OBJECTIVES: Limited data regarding effectiveness, efficacy, safety or cost-effectiveness of reimbursement schemes reflect uncertainty that payers try to counteract with performance-based risk-sharing arrangements (PBRSAs). PBRSAs link medicines’ reimbursement to health outcomes and seem to reduce these uncertainties – especially when reimbursement is not based on development of metastatic disease, treatment, and reasons of not receiving systemic treatment. A self-developed checklist based on ISPOR Task Force Report on PBRSAs (Garrison et al., [Value Health. 2013; 16 (5): 703-19]) was used to conduct quality assessment. A systematic search was conducted through multiple bibliographic databases (from 2001-2013) using search terms and medical subject headings from International Classification of Diseases, 9th edition to identify PBRSAs for stratified medicine in oncology to discuss advantages, disadvantages, their cost-effectiveness and level of analysis (macro or meso level), and whether regression correction should be performed. A limitation of the illustrative case study was that costs of sustainability activities were not collected.

RESULTS: Two-step cost-sharing scheme results in the effective discount that is lower than expected discount by \( \text{np/m} \times \left(1 - \frac{n}{m} \right) \). CONCLUSIONS: While the two-step cost-sharing scheme was initially thought to increase the effective discount, this finding may be of value to those jurisdictions that resort to cost-sharing as a tool in curtailing prescription drug costs.

PCN278
CURRENT GUIDANCE FOR BRCA MUTATION TESTING IN OVARIAN CANCER PATIENTS

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OBJECTIVES: To describe current guidance on BRCA testing practices in patients with ovarian cancer (OC) in China, European countries, and US. Methods: Two published guidelines from International Cancer Genome Consortium were considered. Guidelines were searched for guidelines in both ovarian and breast cancer. Additionally, relevant medical societies like United States Preventive Services Task Force, National Society of Genetic Counselors, American Society of Clinical Oncology, European Society for Medical Oncology, European Society of Human Genetics, Chinese Society of Clinical Oncology, Chinese Academy of Medical Sciences, and International Cancer Genome Consortium were considered. Guidelines were included if they contained recommendations for BRCA testing in OC or patient characteristics for BRCA mutation in OC. The search revealed a total of 22 guidelines. Ten breast cancer guidelines were excluded because they did not add any information beyond that found in guidelines for OC. Ten out of 12 guidelines recommend genetic testing for healthy individuals with familial history of ovarian or breast cancer and a personal history of breast cancer. Most guidelines differ in their description of selection criteria such as degree of relationship between affected individuals and cake, age at diagnosis, and individual history of early onset cancer. Five out of 12 guidelines recommend screening for patients of Jewish Ashkenazi or Icelandic descent. CONCLUSIONS: Current guidelines recommend genetic testing primarily for healthy individuals, a few guidelines recommend screening for individuals with a history of breast cancer and extended family history of breast cancer. Guidelines are recommended for healthy individuals with a family history of ovarian or breast cancer and a personal history of breast cancer. Most guidelines differ in their description of selection criteria such as degree of relationship between affected individuals and case, age at diagnosis, and individual history of early onset cancer. Five out of 12 guidelines recommend screening for patients of Jewish Ashkenazi or Icelandic descent. Current guidelines recommend genetic testing primarily for healthy individuals, a few guidelines recommend screening for individuals with a family history of breast cancer and extended family history of breast cancer.
OBJECTIVES: Inadequate control over emesis during cancer chemotherapy can adversely affect patient’s quality of life, delay the subsequent chemotherapy cycle and may lead to poor adherence to treatment. This study was conducted to assess appropriateness of anti-emetics use in the management of chemotherapy induced nausea and vomiting. METHODS: A prospective observational study was conducted for a period of 6 months in private cancer hospital. Patient chart review on chemotherapy were reviewed and patients were interviewed to assess the prescribing pattern of anti-emetics and its appropriateness. Chemotherapy regimen and given anti-emetics for each patient were recorded. Responses with respect to National Comprehensive Cancer Network (NCCN) guidelines for anti-emesis to ensure the appropriateness of drug use. RESULTS: Of 346 patients’ record reviewed, majority (74%) of them were prescribed with drugs which are highly emetogenic followed by 17% of them with moderately emetogenic and 9% of them with low emetogenic potential. Unlike 30% of patients who were added with NK1 1 receptor antagonist (NK1RA) either in oral or intravenous formulation, majority (n=184, 70.7%) of patients who were placed on highly emetogenic regimens were receiving combination of 5-HT3 antagonist and corticosteroids without adding NK1RA for prevention of acute and delayed emesis. Majority patients (64%) receiving moderately emetogenic regimen were prescribed with combination of 5-HT3 antagonist and corticosteroids. Most of the patients (82%) receiving low emetogenic regimen were prescribed with combination of metoclopramide and corticosteroids and remaining were prescribed with 5-HT3 antagonist and corticosteroids. Overall, selection of anti-emetic regimen was inappropriate for 32% (n=112) patients. Dosage, frequency and duration of anti-emetic use were inappropriate in 18%, 38% and 8% respectively. CONCLUSIONS: Most of the patients received same anti-emetic regimen for high and moderately and low emetogenic agents. Cost was the limiting factor to choose an appropriate anti-emetic regimen.

INFECTIOUS – Clinical Outcomes Studies

PIN1 NON-INFERIORITY OF ONCE-DAILY COBICISTAT-BOOSTED DARIUNAVIR VERSUS RITONAVIR-BOOSTED DARIUNAVIR IN HIV-1-INFECTED ADULT PATIENTS: AN ADJUSTED COMPARATIVE ANALYSIS OF POOLED PHASE 3 DATA

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OBJECTIVES: Cobicistat, a CYP3A inhibitor, is a novel, alternative pharmacoen- hancer to ritonavir. A fixed-dose combination once-daily formulation that contains darunavir and cobicistat has been developed to simplify dosing and to enhance patient adherence. This analysis compared clinical outcomes of PI-based regimens with cobicistat-boosted versus a ritonavir-boosted darunavir QD regimen by testing for non-inferiority.

METHODS: Patient level data on 800mg QD darunavir treatment from 3 phase 3 trials (GS-216-0130, TMC114-C211, TMC114-C229) were combined for analy- sis of virological response at Week 48, using the Snapshot algorithm methodology. Patients were HIV-1-infected treatment-naïve or -experienced with no darunavir treatment experience, and cobicistat and darunavir has been well tolerated and efficacious in previous studies.

RESULTS: The incidence of virological failure was similar between groups, with an incidence of 0.878 [0.576, 1.339] (Snapshot). The 95% CI lower boundary was above the defined non-inferiority margin. The sensitivity analysis gave similar results: PIN2 RELATIONSHIP BETWEEN MICROBIOLOGICAL ERADICATION AND CLINICAL OUTCOME WITH ANTIBIOTIC TREATMENT IN NOSOCOMIAL PNEUMONIA, COMPLICATED URINARY TRACT INFECTION, AND COMPLICATED INTRA-ABDOMINAL INFECTION

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OBJECTIVES: Infections caused by Gram-negative bacteria, including nosocomial pneumonia, complicated urinary tract infections (cUTI), and complicated intra-abdominal infections (cIAI), have been increasing. Although microbial eradication is on the presumed causal path from antibiotic susceptibility to clini- cal success, other factors impact clinical success as well. The purpose of this study was to assess the relationship between microbiological eradication and clinical outcomes for NP, cUTI, and cIAI based on randomized controlled trial (RCT) evidence.

METHODS: A systematic literature search identified RCTs (25 NP trials, 10 cUTI, 28 cIAI, and 1 cIAI & cUTI trial) that met the following criteria: patients with cIAI, NP, or cUTI who were treated with an antibiotic directed against Gram-negative NP; Gram-negative bacteria present in at least a fraction of the population; treat- ment including coverage of Gram-negative bacteria; any measure of microbiological eradication and clinical success. Meta-analyses of NCIs with information on eradication and clinical cure were selected to estimate their relationship to treatment effects using multivariate meta-analyses. RESULTS: Given the variation in study design and clinical outcomes across RCTs, a limited number of studies were considered sufficiently similar for meta-analyses. For NP, a positive relationship between microbiological eradication and cure (correlation coefficient of 0.84, 95%CI 0.77, 0.89; 5 studies) and a negative relationship between eradication and cure (correlation coefficient of -0.86, 95%CI -0.92, -0.74, 7 studies) were observed. For cIAI, clinical outcome was used as a proxy measure for microbiological eradication, but no correlation with mortality was identified. No relationship was observed for cUTI. CONCLUSIONS: The relationship between microbiological eradication and treatment effects is unclear based on available study level RCT evidence. Given the current stage of knowledge and several uncertain findings, evaluations using patient level data are recommended.

PIN3 STUDY ON CLINICAL AND IMMUNOLOGICAL OUTCOMES OF ANTIRETROVIRAL THERAPY IN HIV POSITIVE ADULT PATIENTS IN A COMMUNITY CARE HOSPITAL

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OBJECTIVES: Human immunodeficiency Virus (HIV) has become a chronic man- ageable disease after the advent of combination antiretroviral therapy (ART). Since launching of ART, the numbers of patients enrolled in to ART are increasing in developing countries like India. In this study we aim to analyze clinical and immunolog- ical outcomes of ART in a community care hospital.

METHODS: A retrospec- tive cohort study was conducted including 800 ART naïve HIV infected adult patients who were admitted to ART centre at Mysores, India for 12 months from January 2013 to January 2014 were included. Parameters like weight, hemoglobin, WHO clinical stage and CD4 count were collected from medical records before initiation and after completion of 12 months. Outcomes were analyzed by paired T-test using SPSS version 21.

RESULTS: A statistically signifi- cant improvement was observed for weight [53.9 (11.9) to 58.2 (32.6) kg, P = 0.002] and CD4 count [206.6 (177.4) to 534.6 (315.0) cells/μL, P < 0.001] in favor of ART treatment. Whereas, marginal improvement in hemoglobin [11.94 (4.3) to 11.98 (5.7) g/dL, P = 0.091] was observed, though it was not statistically significant. Also observed a significant increase in percentage of patients in WHO clinical stage I [64.6% increase in percentage of patients in stage I (18.2%) to stage IV (18.2%-12%). CONCLUSIONS: The improvement in weight and CD4 count are indirect parameters of ≥ 95% medication adherence and of sustained viral suppression. The optimal outcome would have all patients in WHO clinical stage I or II and none in III and IV, but in this study 2% and 12% of patients continued to be in stage III and IV respectively. This may be due to development of opportunistic infections such as tuberculosis which is endemic in India.

PIN4 EFFICACY AND HOSPITALIZATION LENGTH OF STAY OF SINGLE DOSE ORITAVANCIN COMPARED TO 7-10 DAYS OF VANCOMYCIN IN INDIA PATIENTS WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS IN THE US AND EASTERN EUROPE

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OBJECTIVES: Oritavancin (ORI) is a lipoglycopeptide with bactericidal activity against Gram-positive and Gram-negative MSRRA. The objective of this study was to conduct a retrospective analysis of hospital and length of stay of ORI for patients with acute bacterial skin and skin structure infections (ABSSSI) who received care in the SOLO program in the US and Eastern Europe. METHODS: SOLO I and II were identical-designed compara- tive effectiveness, double-blind, randomized studies to evaluate the efficacy and health care resource utilization (HRU) of single 1200 mg dose IV ORI versus 7-10 days of twice-daily intravenous (IV) vancomycin (VAN) for the treatment of ABSSSI. SOLO protocols were审同 to allow outpatient treatment at the investigator’s discretion. Efficacy and HRU of treatment were assessed in inpatient and outpatient settings. Efficacy for the European Medicines Agency (EMA) was evaluated in investigator-assessed clinical cure 7-14 days after end of treatment. HRU endpoints were hospitalization rate and length of stay (LOS) in days if the patient was hos- pitalized. RESULTS: In the combined studies, 1959 patients were in the modified intent-to-treat (mITT) population; 1,172 patients (60%) received a portion of their care in as inpatients, 202 patients were treated in Eastern European countries (EUC), Russian Federation, Romania and Ukraine) and 1,165 were treated in the US. Clinical cure rates were similar for ORI and VAN in both regions (86.1% and 84.2% in EUC, 80.6% and 77.9% in the US). The average LOS (ALOS) in the EUC was longer than in the US (14.9 and 14.7 vs. 6.0 and 6.4 days). CONCLUSIONS: Clinical cure rates at 7-14 days were similar between ABSSSI patients who received a single dose of ORI or 7-10 days of VAN in SOLO, but the ALOS in the US was considerably shorter than in Eastern Europe. Using oral or long-acting antibiotic treatments may reduce the numbers of impatient IV antibiotic administrations, which has been associated with reduced LOS in other studies.

PIN5 RETROSPECTIVE PUBLIC HEALTH IMPACT OF A QUADRANTIFLAVENZ ON INFLUENZA A VIRUS IN THE NETHERLANDS FROM 2000-2014

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OBJECTIVES: Vaccination has proven to be an efficient preventive strategy against influenza infection. Each year, two genetically distinct influenza B lineages co- circulate. Current trivalent influenza vaccines (TIVs) contain only one influenza B lineage. A quadrivalent (qTIV) vaccine targets mismatch are frequent due to the difficulty to predict which B lineage will predominate during the next epidemic.
Recently licensed quadrivalent influenza vaccines (QIVs) containing a strain from each B lineage should address these issues, but their impact still needs to be estimated. Our study assesses retrospectively what would have been the public health benefit of routinely vaccinating the US population with QIV instead of TIV. METHODS: We developed a dynamic compartmental model able to account for influenza B lineages with fidar ceftriaxone and metronidazole. The model simulates influenza dynamics for the period 2000-2014, to account for the long-term impact of infection and vaccination. Age-structured population dynamics, vaccine efficacy for each strain, and weekly ramp-up of vaccination coverage are modelled. Sensitivity analyses were performed on VE, duration of immunity, and levels of vaccine-induced cross-protection between B strains. RESULTS: Assuming a cross-protection of 70% of the matched VE, the model predicts that QIV would have prevented on average 15% more B-lineages cases compared to TIV, however the differences were not significant. (odds ratios [95% CI]: ceftriaxone vs. vancomycin 1.19 [0.82-1.66]; vancomycin vs. metronidazole 1.69 [0.93-2.82] and ceftriaxone vs. metronidazole 2.00 [0.99-3.60]). Ceftriaxone therapy was significantly more efficacious than vancomycin and metronidazole in endpoints of recurrence (odds ratios [95% CI]: ceftriaxone vs. vancomycin 0.47 [0.33-0.65]; vancomycin vs. metronidazole 0.91 [0.64-1.69] and vancomycin vs. metronidazole 0.43 [0.19-0.85]) and ceftriaxone and metronidazole had similar benefits in both endpoints. Conclusions: The combination of ceftriaxone and metronidazole was the most efficacious therapeutic alternative in lowering the rate of recurrent C. difficile infections.

MIXED TREATMENT COMPARISONS TO COMPARE SMEPREVIR WITH BOCEPREVIR AND TELAPREVIR IN COMBINATION WITH Peg-INTERFERON Alpha and Ribavirin (PB) IN PATIENTS INFECTED WITH GENOTYPE 1 HEPATITIS C VIRUS (HCV)

MIXED TREATMENT COMPARISONS TO COMPARE SMEPREVIR WITH BOCEPREVIR AND TELAPREVIR IN COMBINATION WITH Peg-INTERFERON Alpha and Ribavirin (PB) IN PATIENTS INFECTED WITH GENOTYPE 1 HEPATITIS C VIRUS (HCV)

OBJECTIVES: To evaluate the efficacy and safety of ceftriaxone and levofloxacin in treating community-acquired pneumonia of levofloxacin is superior to ceftriaxone, there were no significant difference in the incidence of adverse reaction. The main aim of this systematic review was to analyse and compare the clinical efficacy and safety of metronidazole, vancomycin and fidaxomicin in the therapy of C. difficile infection. METHODS: Systematic review and meta-analysis of the literature using Bayesian mixed treatment comparison. RESULTS: Nine studies were included in the mixed-treatment comparison. Our meta-analysis showed that clinical cure was 2.4 fold higher compared to fidar ceftriaxone and metronidazole, however the differences were not significant. (odds ratios [95% CI]: fidaxomicin vs. vancomycin 1.19 [0.82-1.66]; vancomycin vs. metronidazole 1.69 [0.93-2.82] and ceftriaxone vs. metronidazole 2.00 [0.99-3.60]). Fidaxomicin therapy was significantly more efficacious than vancomycin and metronidazole in endpoints of recurrence (odds ratios [95% CI]: ceftriaxone vs. vancomycin 0.47 [0.33-0.65]; vancomycin vs. metronidazole 0.91 [0.64-1.69] and vancomycin vs. metronidazole 0.43 [0.19-0.85]) and ceftriaxone and metronidazole had similar benefits in both endpoints. Conclusions: The combination of ceftriaxone and metronidazole was the most efficacious therapeutic alternative in lowering the rate of recurrent C. difficile infections.
OBJECTIVES: To describe long term outcomes of one of the first cohort of HIV positive patients starting antiretroviral treatment (ART) in Sub-Saharan Africa.

METHODS: We report 10 years outcomes including mortality, retention, CD4 count response, viral suppression (achievement of viral load (VL) < 400 copies/ml by month-6) and failure (2 consecutive VL>400 copies/ml or 1 VL>5000 copies/ml). In all, 142 patients initiating ART between April 2004 and April 2005 and followed up for 10-years in Kampala, Uganda.

RESULTS: Of 559 patients, 70% were female, median age (IQR) was 34 (28-43) years of age. 36% had a known blood donor status, of whom 87% had detectable HIV antibodies. CD4 cell count was 136 (92-195) cells/µL and 321 (57.4%) reached 400 cells/µL (lower limit of normal). Median undetectable viral load was 5.0-5.8 copies/ml. 414 (74%) of patients were treated with lamivudine+3TC, 145 (26%) on zidovudine+lamivudine+nevirapine. After 10 years 361 (65%) patients were still in the study. 166 (29%) were lost to follow-up, 27 (5%) transferred to another facility, 18 (3%) died. The median time (IQR) was of 477 (199-738) cell/µL and 321 (57.4%) reached 400 cells/µL (lower limit of normal CD4 cell count). 414 (74%) were started on stavudine (398/473) with or without etravirine to treat the low estimate from DHS. Population-based estimates from studies conducted in Uganda in 2003 and 2006 reported CD4 cell counts of 271 (57.4%) and 282 (57.4%), respectively. Additionally, a search in other data sources, such as websites of WHO, ECDC and national surveillance for influenza was performed. RESULTS: 10 peer-reviewed articles were included: 10 reported on epi- demiology and were cross sectional studies. From grey literature, additional data on influenza B circulating lineages and vaccine were provided. Incidence data were only available for Finland. No information was found on incidence or prevalence of influenza B for any other country. Articles lacked a defined study population and most datasets were from sentinel surveillance systems.

CONCLUSIONS: WHO and ECDC surveillance systems have identified the co-circulation of 2 influenza B lineages and vaccine mismatch, there is still a low awareness about its burden probably due to the lack of appropriately designed studies in the assessed countries.
into single estimates (with confidence intervals for sensitivity analyses). The purpose of the study was to investigate various methodologies for simulating data used as inputs into an economic model, based on a systematic review of a specific disease incidence. METHODS: A random-effects meta-analysis was conducted to estimate herpetic zoster incidence from a systematic literature review of herpetic zoster incidence. Since incidence is likely to be increased by some study-specific characteristics meta-regression was investigated. The variable of interest was predicted based on the year of data collection, country, age- and study-specific incidence (expressed as annual probability) is typically bounded by 0 and 1, a logistic function was used to model the link between the predicted variable and its predictors. RESULTS: Statistical tests suggested that data from some studies were outliers and thus were inconsistent with the model. A significant positive correlation was observed between age and incidence. The model allows for trends in incidence data to be explored based on country, year of data collection, study design and age. CONCLUSIONS: This project investigated the use of data on herpetic zoster incidence and metaregional data from various sources identified through a systematic review. Limitations were identified for both approaches. However, the meta-regression analysis can be used to estimate the current incidence of a particular disease, for a specific age group and country. It is key for informing models and, subsequently, decision makers in their evaluation and assessments.

PIN19 PREDICTORS FOR MORTALITY AMONG HUMAN IMMUNODEFICIENCY VIRUS INFECTED PATIENTS ON ANTIRETROVIRAL THERAPY
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OBJECTIVES: Development of highly active antiretroviral treatment (ART) has revolutionized the management of HIV infec- tions and led to marked reductions in HIV-associated morbidity and mortality in many developed countries. Hence this study aimed to analyze the predictors for mortal- ity among HIV patients on antiretroviral therapy (ART) in a private hospital in India. METHODS: A retrospective cohort study was conducted on 350 patients infected with HIV were admitted to Asha Kirana Hospital, Mysore, South India for a period of three years. Patients who died in the hospital during the study period (n = 60) were compared with patients who had survived (n=290). Both groups were matched for age and sex. Predictors for death were analyzed by chi-square test using bivariate regression in software SPSS version 21. RESULTS: Predictors for death in this study were increasing age >60 years (RR, 95% CI) 2.04 (1.15-4.21), CD4 count <200 cells 2.14 (1.26-3.63), patients without opportunistic infections - 1.80 (1.23 - 2.63), WHO stage IV 1.83 (1.25-2.67) and being on stavudine based ART 2.01 (1.44-2.83). Patients with under-weight 1.33 (0.88-1.91) also found to be a significant risk factor. Factors associated with survival benefit were female sex 0.81 (0.55-1.19), patients without ART toxicity 0.78 (0.51-1.20) and being on Tenofovir based regimen 0.88 (0.79-0.96). CONCLUSIONS: Predictors for mortality among HIV patients on ART were found to be patients age >60 years, CD4 count <200 cells, WHO stage IV, absence of opportunistic infec- tions and patients on Stavudine therapy. The absence of opportunistic infections being a risk factor may be due to undiagnosed opportunistic infections due to limited diagnostic facility as in this study setting. Patients on Tenofovir having survival benefit support the 2013 WHO recommendation for Tenofovir being the preferred regimen.

PIN20 INITIAL INAPPROPRIATE ANTIBIOTIC THERAPY IN HOSPITALIZED PATIENTS WITH GRAM-NEGATIVE INFECTIONS: SYSTEMATIC REVIEW AND META-ANALYSIS
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OBJECTIVES: The rapid global spread of multi-resistant bacteria and loss of anti- bacterial effectiveness increases the risk of initially inappropriate antibiotic therapy. We examined the effects of use of appropriate or inappropriate antibiotic ther- apy on outcomes in Gram-negative infections. METHODS: We searched Medline, Cochrane Central, and Embase databases through March 2014 for English-language studies that quantified effects of use of appropriate or inappropriate antibiotic therapy on all-cause mortality, length of stay, hospital costs, treatment failure, or bacterial clearance in hospitalized patients with complicated urinary tract infec- tion, complicated intra-abdominal infection, bacteremia and pneumonia due to Gram-negative pathogens. We screened citations in duplicate and resolved differences by consensus. We used random effect models meta-analysis when at least 3 studies reported the same outcome. RESULTS: Forty-five studies with 1895 patients were eligible. The definition of initial appropriate antibiotic therapy varied across studies. In meta-analyses of unadjusted data, initial inappropriate antibiotic therapy was associated with lower risk of mortality (26 studies, 3713 patients, odds ratio (OR) 0.78; 95% CI 0.65-0.94). In subgroup analysis with 11 studies, 808 patients, OR 0.80; 95% CI 0.61-1.06) and treatment failure (27 studies, 2493 patients, OR 0.22; 95% CI 0.14-0.35). In meta-analyses of adjusted data, initial appropriate therapy was associated with lower risk of mortality (5 studies, 1758 patients, OR 0.50; 95% CI 0.25-1.00), and conversely, initial inappropriate ther- apy increased risk of mortality (16 studies, 2493 patients, OR 3.30, 95% CI 2.42-4.49) and decreased bacterial clearance. There were insufficient data to evaluate the impact on resource utilization and economic outcomes. CONCLUSIONS: Initial inappropriate antibiotic therapy increased risk of mortality and treatment failure and decreased bacterial clearance. The paucity of new and effective antibiotics to cover resistant Gram-negative pathogens increases the likelihood of initial inappropriate therapy and poses a serious threat to patient safety. Critical gaps include lack of information on the health and economic benefits of resistance.
CABG, 141 €

consistent results in favour of TCS in adult patients, abdominal procedures, and clean CABG; Colorectal Surgery; Hip Prothesis; Limb Amputation; Small Bowel Surgery.

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Region H, if all hospitalised CDI patients received fidaxomicin the number of recurrences decreases by 66% and the total number of cases decreases by 16%, compared to vancomycin.

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OBJECTIVES: This study aimed to evaluate the impact of pneumonia, meningitis and sepsis and the how they represent the costs for patients 50 years and older in the Brazilian Private Health System. METHODS: An administrative claims database containing over 18 million lives was used to identify episodes of pneumonia, meningitis and sepsis, in all ages, between Oct/2010 and Dec/2013. The episodes were identified using ICD-10 codes of A40.3, B95.3, G00, J13, J15, J15.0, J15.3, J15.4, J15.5, J18, J18.0, J18.9, J02.0 and P23.3 for pneumonia, A40.0, A40.1, A40.8, A40.9, A41.0, A41.1, A41.4, A41.8, A41.9, J13, J15, J15.0, J15.3, J15.4, J15.5, J18, J18.0, J18.9, J02.0 and P23.3 for meningitis, A41.0, A41.1, A41.2, A41.3, A41.4, A41.5, A41.8, A41.9, J13, J15, J15.0, J15.3, J15.4, J15.5, J18, J18.0, J18.9, J02.0 and P23.3 for sepsis. Results: Patients aged ≥50 years were identified and all-cause costs were extracted and grouped according to the 3 disease conditions. RESULTS: A total of 70,850 patients were identified (39.1% pneumonia, 33.7% meningitis, 38%, representing 96.9%, 3.6% and 0% respectively). Different diseases disproportionally affected the populations: For pneumonia, 71.7% of episodes were in the ages ≥50. Meningitis and Sepsis representation is 5% and 29.4% respectively. The cost burden was also different by disease. Pneumonia had 56.9% of costs incurred by age ≥50. For sepsis and meningitis, 75.8% and 15.5% of the costs were incurred by age ≥50, respectively.

CONCLUSIONS: Pneumonia, meningitis, and sepsis and its associated costs disproportionally affect the population in the Brazilian private health system. In particular, proportion of all pneumonia from patients age 50+ was only 17.1%, yet, the majority of expenditure (56.9%) for pneumonia patients is in the ages ≥50. Prevention strategies, including vaccinating the aged ≥50, could potentially reduce healthcare costs associated with this condition.

PIN28

ECONOMIC IMPACT OF DENGUE EPISODE: MULTICENTER STUDY ACROSS FOUR BRAZILIAN REGIONS

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OBJECTIVES: To evaluate the economic burden of dengue from public payer and societal perspectives in Brazil. METHODS: Investigation was designed as a multicenter cost study of prospectively recruited dengue patients in 4 dengue endemic regions (city): Midwest (Goiania), Southeast (Belo Horizonte and Rio Janeiro), Northeast (Teresina and Recife), North (Belem). Participants were suspected or laboratory confirmed dengue cases, treated in ambulatory or hospital settings (private and public sectors). A household interview was scheduled 20-30 days after onset for cases of clinical symptoms. The time horizon was one-year considering dengue seasonality. We calculated the direct cost, public payer perspective and direct/indirect costs for societal perspective. Estimation of annual national dengue costs took into account cases reported by notification system (SINAN) having possible under-reporting from passive surveillance. RESULTS: We screened 2,223 patients and 2,097 (94.3%) symptomatic dengue cases were included. The majority of patients were adults. 1,661 cases were treated in ambulatory and 436 cases in hospitals. In the ambulatory cohort, the average number of medical visits ranged from 1.2 to 4.2. A higher number of medical visits were recorded among inpatients (3.2 to 5.0). For the public payer perspective, estimated cost per case was USD 43 (95% CI: 39-47) ambulatory and USD 237 (95% CI: 202-248) hospital. Dengue illness in Brazil was estimated to cost USD 126 million (95% CI: 112-135), ambulatory and hospitalized cases considering the reported cases SINAN. Outpatients cost account for 62% of the total costs. For the societal perspective, the estimated cost per ambulatory case was USD 163 (95% CI: 142-169) and USD 465 (95% CI: 407-591) hospital. Dengue illness was estimated to cost USD 389 million (95% CI: 339-428), ambulatory and hospitalized cases. CONCLUSIONS: Our results show evidence of substantial economic impact in Brazil. We have provided a timely economic evaluation of dengue.

PIN29

ECONOMIC EVALUATION OF VACCINATION AGAINST HAV IN HIGH RISK POPULATION

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OBJECTIVES: Hepatitis A virus (HAV) infection is self-limiting with no chronic complications but is very serious in the presence of a large number of deaths. The results of a previously conducted cost-benefit analysis demonstrated that the vaccination of all 1-year old children in the general population would be cost-effective to the health care system only in years with an epidemiologic outbreak. The question remains whether it would be cost-effective in population
groups in high risk. The aim of the study is to evaluate the economic consequences of the vaccination against HAV in population groups at high risk and to compare the results with the vaccination of all 1-year old children in the population.

METHODS: Cost-benefit analysis was performed based on epidemiological data for the number of incidents in the high risk groups and the treatment cost of the HAV infection. Costs were excluded from the net vaccination cost. Two vaccination scenarios were created: 1. Prophylactic one dose vaccination and 2. One initial and one buster dose application. The validity of the results was tested with sensitivity analysis using traditional scenarios. In the calculation of all the high risk group (n=32 606) induces savings for the health care system because the cost of vaccination is less than the cost of treatment of 32 606 patients with HBV infections.

RESULTS: The cost of vaccination varies from €1 257.32 to €2 514.66 depending on the vaccination strategy in the "second scenario". The differences in direct medical costs in the "first scenario" are €1 547 274. Thus the net savings account for €1 289 932 and €32 608, respectively.

CONCLUSIONS: The role of vaccination in the control of HAV infections is to be emphasized because the incidence of HBV infections is decreased.

PIN30
PRELIMINARY ASSESSMENT OF THE COST OF TREATMENT FOR CHRONIC HEPATITIS C VIRUS INFECTIONS WITH SOFOSBUVIR AND FIRST GENERATION ANTIVIRALS ACROSS EIGHT COUNTRIES

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OBJECTIVES: The new wave of HCV drugs reaching the market in 2014 offer higher cure rates with shorter treatment times, however, the new antivirals have been met with concerns regarding the costs associated with the new drugs by payers and the WHO. We have set out to examine the costs of treatment with sofosbuvir, compared to first-generation antivirals, across a selection of eight countries. We estimated the manufacturer price of sofosbuvir, telaprevir and boceprevir in Norway, Denmark, Germany, Luxembourg, Portugal, Slovenia, Turkey, and the United States. Treatment costs were derived from an analysis of standard of care treatments for HCV genotype 1, including individual daily dosage strength and length of recommended treatment for each antiviral. Interferon and ribavirin costs, any potential discounts or rebates negotiated with payers and potential follow-up courses of therapy for sofosbuvir were excluded from the analysis. Prices were extracted from IHS Life Sciences’ international pricing database POLI. All foreign currency was converted to USD using XE Currency Converter for comparison.

RESULTS: Costs of treatment with sofosbuvir varied significantly across the eight countries, being highest in the US at USD84,000 then Portugal at USD75,816 down to USD52,051 in Norway. Telaprevir and boceprevir treatment costs range from a low of USD21,534 and USD14,111 in Turkey respectively, to a high of USD66,55 and USD40,120 in the US. On average across the eight countries, treatment with sofosbuvir was 104% higher than telaprevir, and 187% higher than boceprevir, based on the list price.

CONCLUSIONS: Our preliminary analysis has highlighted the variable treatment costs of HCV antivirals across countries. Comparisons of treatment costs with next generation treatments versus first-generation antivirals will see expenditure for HCV therapeutics increase significantly. However, sofosbuvir has demonstrated cure rates of over 95% in genotype 1 HCV patients with a favourable safety profile, thus reducing costs of re-treatment, medical visits, and treatment of advanced liver disease.

PIN31
COST ANALYSIS FOR MANAGEMENT AND PREVENTION OF HEPATITIS B VIRUS REACTIVATION

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OBJECTIVES: To prevent reactivation of hepatitis B virus (HBV) following chemotherapy or immunosuppressive therapy, appropriate clinical managements including HBV screening and antiviral prophylaxis for patients at risk of reactivation should be provided. Cost information of managing HBV reactivation is needed to evaluate cost-effectiveness of HBV prevention strategies in Japan.

METHODS: Annual number of patients who have received cancer chemotherapy, biologic therapy for rheumatoid arthritis, or stem-cell / organ transplantation was estimated using information of national statistics and expert opinions. Costs of HBV screening and antiviral prophylaxis were calculated by following the HBV reactivation management guideline and reimbursement rates. A Markov model was created to compare two vaccination strategies of HBV infections (current selective vaccine program vs. universal vaccine program) by considering risk of receiving chemotherapy or immunosuppressive therapy, management costs of HBV reactivation, and disease-specific mortality, during 90 years of follow-up.

RESULTS: Costs for HBV reactivation management were estimated 688 yen per person in selective vaccination strategy compared with 350 yen per person in universal vaccination strategy, with annual discount rate of 3%. On one-way sensitivity analysis, estimated costs were sensitive to annual discount rates and risks of HBV infections.

CONCLUSIONS: Absolute difference in the HBV management cost between two vaccination strategies was relatively small compared with vaccine program costs. Since the management of HBV reactivation was not always provided for all patients at risk, a further cost analysis should be conducted by reflecting real-world clinical practice.
tions. Typically, RSAs have been used for costly products for diseases with a high unmet need such as in oncology. To date, experience with RSAs in vaccines is limited. In this conceptual research we intend to identify RSAs that would be relevant and operable for vaccination programs. METHODS: We described the different types of uncertainties and associated financial risks a vaccine payer faces in the real-world setting. We conducted a literature review to list the various RSAs proposed in the field of therapeutics. We then assessed how existing RSAs can mitigate those vaccine payers' risks and evaluated those contracts for a hypothetical vaccine. Vaccines in Shingles (few doses, potentially a large target population, herd effect and delayed benefit) need to be accounted for when designing RSAs. Financial risks in vaccination budget may arise from uncertainty on effectiveness/safety, uptake, supply, and real-world implementation. Typically, categorized in either cost-shifting or price-risk, the latter should enable vaccine payers to diminish those risks. As for drugs, cost-based deals would be easier to implement for vaccines than performance-based RSAs. The share of the cost of other medical resources is used as a quantitative measure for the short-term. Insurance mechanisms such as real-option pricing can be used to quantify the risk and price the associated RSA. CONCLUSIONS: RSA can be used to mitigate financial risk associated with the access to vaccines. Based on the risks and associated costs, RSAs can be used wherever possible. RESULTS: Both approaches had similar survival rates (90.76% vs. 91.33% for EA and DD, respectively). Antifungal drug cost per patient was ¥2,813 for EA and ¥2,307 for DD strategy. Although DD patients incurred a higher cost on hospitalisation (€21.79 vs. €19.98 in EA and DD, respectively). In addition, the mean length of stay for patients in DD was 26.2 days, higher than 21.1 days in EA. The mean cost per hospitalisation cost was based on the DRG cost for EA and DD patients (€4,073 vs. €4,002). As the corresponding figures was increased in Denmark, it was 13.5% higher in Denmark and 16% higher in Norway.

OBJECTIVES: To examine the impact on costs and outcomes that may occur in the setting of suspected or confirmed varicella-zoster virus infections (VZV) caused by Aspergillus with typical empiric empirical approach (EA) versus the recently proposed “diagnostic-driven” (DD) approach in China. METHODS: A decision-analytic model was used to estimate total costs and predicted survival associated with EA and DD. RESULTS: The population aged 50 years or older from 1984 to 2014 in Chinese Yuan (¥) was aged 16 years with hematological malignancies or autologous/allogeneic stem cell transplantation expected to be neutropenic for 10-30 days, and without prophylactic antifungal treatment. Rates for VZV incidence, VZV incidence, EA and overall mortality, and VZV-related mortality (10.9%, 30.7% and 28.6%, respectively) were obtained from the literature. Survival rates for each strategy were generated based on the proportion of patients with identified and appropriately treated IFI. Treatment patterns with and DD approaches and resource use assumptions were based on the opinion of five clinicians from three top hospitals in Shanghai. The total medical costs (in 2014 Chinese Yuan) included antifungal drug cost, treatment-related adverse events cost, and cost of other medical resources. Type-specific outcomes were used whenever possible. RESULTS: Both approaches had similar survival rates (90.76% vs. 91.33% for EA and DD, respectively). Antifungal drug cost per patient was ¥2,813 for EA and ¥2,307 for DD strategy. Although DD patients incurred a higher cost on hospitalisation (¥21.79 vs. ¥19.98 in EA and DD, respectively). Antifungal drug cost per patient was ¥2,813 for EA and ¥2,307 for DD strategy. Although DD patients incurred a higher cost on hospitalisation (€21.79 vs. €19.98 in EA and DD, respectively).

OBJECTIVES: Detailed and valid information on burden of disease is an indispen- sable cornerstone for cost-effectiveness analyses. The aim of this study was to estimate the epidemiological and economic burden of varicella and herpes zoster (HZ) in Germany in order to generate important data for a subsequent model-based analysis. METHODS: Analysis of the epidemiology and the one-year cost of varicella-zoster virus-related diseases/comlications were based on 2010/2011 claims data from a large German sickness fund. Insurants were included in the study when they had a varicella or HZ diagnosis in 2010 and 2011, and were followed for one year after the date of the initial diagnosis. Disease-attributable costs were either calculated by diagnostic-specific identification of cost items or by use of a control group approach. RESULTS: The study population included 12,710 insurants with varicella and 35,636 insured persons with HZ. Age-standardised incidence rates were 1.55 and 5.5 per 1,000 person-years for varicella and 35,636 insured persons with HZ. The study population included 12,710 insurants with varicella and 35,636 insured persons with HZ. Age-standardised incidence rates were 1.55 and 5.5 per 1,000 person-years for varicella and 35,636 insured persons with HZ. The study population included 12,710 insurants with varicella and 35,636 insured persons with HZ, as primary diagnosis varied from 7.0 days in Norway to 14.7 days in Finland. The mean cost per bed day. RESULTS: The total cost of treating the CDI patients ranges between €4,673 per patient, followed by Sweden (€6,261 per patient), Denmark (€7,234 per patient), and Finland (€10,231 per patient). The total cost for treating the hospitalised CDI patients during one year was approximately €11 million (€5.1 million in Norway, €18 million in Denmark (€5.6 million people) and €30 million in Sweden (9.7 million people). CONCLUSIONS: The total cost of treating the CDI patients ranges between €11 million and €30 million per year, and approximately 26.38% of these costs are due to recurrence of CDI. By lowering the number of recurrences, there would be a potential for large cost savings.

OBJECTIVES: To describe the effectiveness and economic impact of two treatment strategies (EA and DD) for CDI patients in Denmark, Norway, Sweden and Finland.

RESULTS: The total cost of treating the CDI patients ranges between €4,673 per patient, followed by Sweden (€6,261 per patient), Denmark (€7,234 per patient), and Finland (€10,231 per patient). The total cost for treating the hospitalised CDI patients during one year was approximately €11 million (€5.1 million in Norway, €18 million in Denmark (€5.6 million people) and €30 million in Sweden (9.7 million people). CONCLUSIONS: The total cost of treating the CDI patients ranges between €11 million and €30 million per year, and approximately 26.38% of these costs are due to recurrence of CDI. By lowering the number of recurrences, there would be a potential for large cost savings.

OBJECTIVES: The total cost of treating the CDI patients ranges between €4,673 per patient, followed by Sweden (€6,261 per patient), Denmark (€7,234 per patient), and Finland (€10,231 per patient). The total cost for treating the hospitalised CDI patients during one year was approximately €11 million (€5.1 million in Norway, €18 million in Denmark (€5.6 million people) and €30 million in Sweden (9.7 million people). CONCLUSIONS: The total cost of treating the CDI patients ranges between €11 million and €30 million per year, and approximately 26.38% of these costs are due to recurrence of CDI. By lowering the number of recurrences, there would be a potential for large cost savings.
Objectives: The economic burden and health care utilizations of the chronic hepatitis C (CHC) in the U.S. veteran population. Methods: A retrospective database analysis was performed using the U.S. Veterans Health Administration Medical SAS datasets (01OCT2007-30SEP2012). Patients diagnosed with CHC (International Classification of Disease 9thRevision Clinical Modification [ICD-9-CM] codes 070.44, 070.54, 070.70, 070.71) were identified, and the first diagnosis date served as the index date for each patient. The comparator group was also created by identifying patients without a CHC diagnosis but of the same age, region, gender and index year, and matched according to baseline Charlson Comorbidity Index scores. The index date for the comparator was randomly chosen to be 6 months after the index date of the matched patient. Continuous enrollment period pre- and post-index date was required for both groups. One-to-one propensity score matching (PSM) was used to compare health care costs and utilities during the follow-up period between the cohorts, adjusting for baseline demographic and clinical characteristics. Results: Eight patients (N=87,837) were identified for the CHC and comparison cohorts. After applying 1:1 PSM, a total of 69,809 patients were matched from each group and baseline characteristics were well-balanced. CHC patients were more likely to be hospitalized (33.47% vs. 24.2%, p<0.0001) and had more emergency room (ER) (28.55% vs. 6.68%, p<0.0001), physician office (98.65% vs. 53.56%, p<0.0001), outpatient (98.81% vs. 54.46%, p<0.0001) and pharmacy visits (97.3% vs. 71.18%, p<0.0001), resulting in higher health care costs for patients with (411,103 vs. 681,000, p<0.0001) ER (936 vs. 660, p<0.0001), outpatient (554,000 vs. 1,382,000, p<0.0001), physician office (4,956 vs. 720,000, p<0.0001) and pharmacy ($947 vs. $433, p<0.0001) costs, respectively. Overall, direct cost/patient increased for lower CD4 counts, representing 0.518% of the total population. In 2010-2011 the influenza rate and ARI was analyzed the costs of treating influenza and acute respiratory infections (ARI) in the elderly (≥65 years). The study period comprised 1 October 2012 to 30 June 2013, patients diagnosed with influenza were identified, a mean duration of 6 days, amounting a 1,945,826 days of inpatient care. Overall, 65% of these hospitalizations were caused by influenza (principal diagnosis), and even over 80% for patients aged 2-17 years. Moreover, total outpatient costs amounted to €14,974,576. Finally, vaccination-rates were below 4% for children and ≥37% for patients aged ≥65 years. Seasonal influenza can cause severe outcomes leading to hospitalizations and excess costs. Especially influenza-infected children are affected by concomitant diseases resulting in a higher disease burden. Furthermore, documented vaccination-rates are quite low. Objective: The hepatitis C virus (HCV) induces several pathological conditions worldwide with a substantial medical and economic burden. The objective of this study is to estimate the average annual cost incurred by the National Health Service (NHS) as well as society due to HCV in Italy. Methods: A probabilistic incidence-based model was developed to estimate an aggregate measure of the economic burden associated with HCV-related diseases either in terms of direct or indirect costs computed according to the human capital method. A systematic literature review was carried out to reveal both epidemiological and economic data. Furthermore, a one-way probabilistic sensitivity analysis was performed for the base case scenario. Results: The incidence of otitis media and pneumonia was well-balanced. The highest risk group showed the lowest mean costs (€6,551, p<0.019) and the highest mortality (21%). Conclusions: Health care costs decline with age and risk severity. The eldest age group experienced shorter hospitalizations and outpatient visits. Patients aged 75-84 years experienced shorter hospitalizations (1,118.5 days) than patients aged ≥85 years (2,796 days). Results: We observed 65,826 patients with a documented influenza during the influenza season 2012/2013. The occurrence of otitis media and pneumonia was higher in all age groups compared to the non-influenza-infected population and especially high in children. A total of 848 influenza-related hospitalizations were identified. Hospitalized children accounted for 38.5% of all cases (119,303 hospital days). Overall, 65% of these hospitalizations were caused by influenza (principal diagnosis), and even over 80% for patients aged 2-17 years. Moreover, total outpatient costs amounted to €14,974,576. Finally, vaccination-rates were below 4% for children and ≥37% for patients aged ≥65 years. Seasonal influenza can cause severe outcomes leading to hospitalizations and excess costs. Especially influenza-infected children are affected by concomitant diseases resulting in a higher disease burden. Furthermore, documented vaccination-rates are quite low. Objectives: The estimation of the economic burden caused by influenza in Germany - a retrospective claims database analysis. Methods: A retrospective analysis of German Health Insurance claims data was performed. Results: Influenza-infected children are affected by concomitant diseases resulting in a rather large amount of indirect costs for the Italian society as well. Objectives: The estimation of the economic burden caused by influenza in Germany - a retrospective claims database analysis. Methods: A retrospective analysis of German Health Insurance claims data was performed. Results: Influenza-infected children are affected by concomitant diseases resulting in a rather large amount of indirect costs for the Italian society as well.
per 1 patient: 1. Flu patients at PCP, average number of visits/patient in 2009-2010 were 775/365/90,12. Compared with patients 3-year history of asthma and 1-year history of diabetes disease was 80,39 UAH per 1 patient (1 Euro = 10 UAH on 01.06.2011). 2. Flu patients in outpatient clinic during 2009/10 were registered 186289 request for medical assistance about influenza and ARI. in the season, 2010/11 - registered 1785102 who needed medical care for influenza and ARI, total cost was 202,17 UAH. 3. Flu patients in hospital during 2009-2010 were hospitalized 47108 persons. Total cost of the disease was 728,85 UAH. 4. Flu patients in intensive care unit – the total cost of the disease was 2543,08 UAH. 5. All patients in the hospital totalized the highest costs for the hospitalization were 2543,08 UAH per 1 patient with flu compared with 80,39 UAH at PCP. Governmental program to prevent influenza by vaccination can reduce the cost of flu treating.

PIN47 COST OF CIRRHOSIS AMONG PATIENTS DIAGNOSED WITH HEPATITIS C VIRUS IN TURKEY
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OBJECTIVES: 3-11% of patients diagnosed with chronic hepatitis C virus (HCV) infection will develop liver cirrhosis within 20-30 years, with an associated risk of liver failure and hepatocellular carcinoma (HCC). Mortality, HCC rates and costs of HCV patients were compared among cirrhosis and non-cirrhosis patients in Turkey. METHODS: Using the Turkish National Health Insurance Database (2009-2011), HCV patients were identified using International Classification of Disease, 10th Revision (ICD-10) classification codes. Propensity score matching (PSM) was applied to compare cirrhosis and non-cirrhosis cohorts. Baseline demographic and clinical factors were controlled in the models. RESULTS: A total of 12,990 patients, including 2,467 diagnosed with cirrhosis, were included in the study. 12.2% of the overall population was treated. Cirrhosis patients were older (61.56 vs. 51.10 years, p<0.001), more likely to reside in the Black Sea region (26.96% vs. 23.77%, p<0.001) and had Elixhauser comorbidity index scores ≥ 2 (89.30% vs. 66.06%, p<0.001). Disease-related costs were significantly higher (€5,254 vs. €1,996, p<0.001). CONCLUSIONS: Cirrhosis mortality, HCC rates and costs of cirrhosis among HCV patients are significantly higher in Turkey.

PIN48 WHAT ARE THE LIFELONG COSTS OF VACCINATING ONE INDIVIDUAL? THE FRENCH CASE
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OBJECTIVE: Although prevention accounts for a minor part of the health care spending (<3%) in Europe, preventative programs and particularly vaccinations are most valuable for budget cuts and thereby their benefits may not be immediately identifiable. Thus pan-European project aims at evaluating the lifelong costs of vaccination in a real-world (domestic) context, controlled in full compliance with the national recommendations. French results are presented below. METHODS: A calculation Excel model was developed and led with the most recent French specific data: 2014 vaccination calendar, list prices from National health insurance database (NHI: AMELI). Reimbursement rates were applied to total costs to reflect NHI perspective. A 100% compliance rate was assumed. When several vaccines were available for a similar preventative measure, selection was done according to minimum costs per individual vaccinated in full compliance with the national recommendations. RESULTS: A positive ROI, presuming an outbreak occurs once in 10 years. Sensitivity analysis was performed to study the robustness of the ROI. Results are presented at 2012 price level. RESULTS: Total nosocomial pertussis outbreak costs were €4,682. Direct care costs for treated patients (€724) to prevent nosocomial pertussis outbreaks results in €3,958. Sensitivity analysis was performed to study the robustness of the ROI. Results are presented at 2012 price level. CONCLUSIONS: Data on the pertussis outbreak on the neonatology ward in 2004 in the Academic Medical Center (The Netherlands) was used to calculate cost for a single outbreak. Inverting outbreaks by investing one Euro in preventively vaccinating HCW. Sensitivity analysis performed to study the robustness of the ROI. Results are presented at 2012 price level. CONCLUSIONS: Sensitivity analysis was performed to study the robustness of the ROI. Results are presented at 2012 price level. 3. Flu patients in hospital during the season, 2010/11 - registered 1785102 who needed medical care for influenza and ARI. In the season, 2011/12 - registered 186289 request for medical assistance about influenza and ARI. in the season, 2010/11 - registered 186289 request for medical assistance about influenza and ARI. Total cost was 202,17 UAH. 3. Flu patients in hospital during 2009-2010 were hospitalized 47108 persons. Total cost of the disease was 728,85 UAH. 4. Flu patients in intensive care unit – the total cost of the disease was 2543,08 UAH. 5. All patients in the hospital totalized the highest costs for the hospitalization were 2543,08 UAH per 1 patient with flu compared with 80,39 UAH at PCP. Governmental program to prevent influenza by vaccination can reduce the cost of flu treating.
OBJECTIVES: Although the real-time PCR-based assay SeptiFast® has proven its utility in clinical settings, limitations are still available to improve its economic performance. An Italian two-center observational study was conducted on hematological patients with signs of SIRS-SS (Systemic Inflammatory Response Syndrome with Suspected Sepsis) in order to partially fill this information gap.

RESULTS: A total of 101 pairs were matched (77 times with a more stringent matching condition (77 pairs), episodes experienced by prospective patients are associated to a significantly lower mortality (3.13% vs 14.71%). No significant differences in the average LOS are recorded. Traditional diagnostic approach could be replaced by the PCR assay. The greatest saving related to the use of PCR assay is linked to the hard reduction in the empirical therapy (488.44 per episode), main driver of the overall saving ($430.75 per episode), which results from statistically significant.

CONCLUSIONS: These findings suggest that the routine use of combined traditional and PCR diagnostic assays may conduct to an early saving of broad-spectrum antibiotics, money, and health.

PIN53

ESTIMATING OVERALL IMPACT OF HUMAN PAPILLOMAVIRUS VACCINATION ON CERVICAL CANCER BURDEN IN SPAIN AND PORTUGAL

M. Llars, R. R., E. Andre R., E. Andre

OBJECTIVES: Human papillomavirus (HPV) vaccination programs offer primary prevention of HPV-related pre-cancers and cancers. AS04-adjuvanted HPV-16/18 vaccine (AS04v) has shown high efficacy (efficacy irrespective of the HPV type) in cervical high grade lesions (CIN2+, CIN3+). The objective of this study is to estimate overall impact of HPV vaccination in Spain and Portugal. Costs, including diagnosis and treatment costs of cervical cancer, and HPV infection were valued. Sensitivity analysis of uncertainty was conducted.

RESULTS: Potential decline in CC cases resulting from women vaccination with AS04v was estimated using a previously published model. Model outcomes were considered based on number of CC cases avoided with HPV specific incidence of HPV-16/18 cases and irrespective of HPV type. Vaccine effectiveness (VE, end-of-study analysis) HPV-008 trial against HPV-16/18 was set at 100% weighted with HPV-16/18 incidence reported in CC in Spain and Portugal. VE irrespective of HPV type was set at 93%. Vaccination coverage (70% of women) and vaccination coverage (70% of women) respectively. Cases avoided may increase 1.536.644 in Spain & Portugal. Vaccination against HPV-16/18 was set at 100% weighted with HPV-16/18 incidence reported in Spain and Portugal. Vaccination against HPV-16/18 was set at 100% weighted with HPV-16/18 incidence reported in Spain and Portugal.

CONCLUSIONS: This study compares the costs per successfully treated patient with fosfobuvir compared to current standard of care (SoC) in the Netherlands in treatment naive patients. VE irrespective of HPV type was set at 93%. Vaccination coverage (70% of women) and vaccination coverage (70% of women). The model has a horizon one-year. Deterministic and probabilistic sensitivity analyses were performed. Health state utilities were derived from the literature.

CONCLUSIONS: Faldaprevir was associated with an increased cost per patient in the severe CDI population. The cost-effectiveness of fidaxomicin compared to vancomycin in the treatment of severe CDI and the first severe recurrence compared to oral vancomycin from a Swedish health care perspective. The model was developed to evaluate the cost-effectiveness of the use of fidaxomicin in the treatment of patients with severe CDI, and patients with initial severe CDI recurrences, respectively. The patient enters the model in the CDI health state and is treated either with fidaxomicin or vancomycin. Each treatment cycle was 1 week in duration. The total time horizon was one-year. Deterministic and probabilistic sensitivity analyses were performed. Health state utilities were derived from the literature.

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and dominant in patients with a severe CDI recurrence from a Swedish health care perspective.

**PIN58**

**AN ECONOMIC MODEL TO COMPARE THE DIFFERENT EMPIRIC AND FIRST-/SECOND-LINE TREATMENT REGIMENS FOR SUSPECTED METHICILLIN-RESISTANT STaphylococcus AUREUS NOSOCOMIAL PNEUMONIA**

**Objective:** Appropriate and timely empiric treatment is very essential for methicillin-resistant Staphylococcus aureus (MRSA)-related infections. Inadequate empiric treatment is associated with increased mortality and longer hospital stay. This study compares economic impact of initial empiric linezolid (Emp-LIN) vs. vancomycin (Emp-VAN), as well as combination regimens for MRSA pneumonia. We aimed at evaluating the cost-effectiveness of 2nd-line treatment, for suspected MRSA nosocomial pneumonia. **Methods:** A 4-week decision model was developed capturing empiric, 1st and 2nd line therapy. Published literature and expert opinion provided clinical and resource use data, including efficacies and costs related to EMRSA, adverse events, and length of hospital stay. Cost and health utilities were obtained from published literature. Base-case analysis used 2-day empiric, 10-day 1st/2nd-line treatment duration, 30% MRSRA rate, and 1st line linezolid for EM-NSRA after culture confirmation. Patients with a negative culture for MRSA exited the model after empiric treatment, and were assigned a fixed cost for remaining treatment. University and probabilistic sensitivity analyses were conducted. Costs were reported in 2014 USD. **Results:** Emp-LIN resulted in lower total costs ($1,626, but had greater QALY gain (0.073) and overall treatment success (90%) compared to Emp-VAN, resulting in an incremental cost-effectiveness ratio (ICER) of $1,946 per QALY gain, and $27,750 per successfully treated patient. Days in ICU stay, clinical efficacy (90%) and the greatest/probable average cost of linezolid being cost-effective was 61% (vs. Emp-VAN) and 99% (vs. NE-MRSA) assuming a willingness-to-pay (WTP) of $50,000 per successfully treated patients and QALY gain respectively. **Conclusions:** Early treatment with Emp-LIN is a cost-effective alternative to Emp-VAN and NE-MRSA at reasonable WTP thresholds, and should be considered a preferred treatment choice, especially at hospitals with high MRSRA rate.

**PIN59**

**THE EFFECT OF HERD IMMUNITY IN DIFFERENT HUMAN PapillOMA VIRUS VACCINATION STRATEGIES: AN ECONOMIC EVALUATION OF THE BEST II STUDY**

**Objective:** Herd immunity was designed to evaluate the cost-effectiveness (CE) of different interventions targeting females as well as males, and the economic impact of vaccination on a wide range of HPV-induced diseases. The Bayesian Markov model was developed to investigate HPV transmission between sexual partners and the cost-effectiveness of several HPV vaccination strategies. Both sexes were included in a model where the CE profile was compared to an HPV-naive population using a 4% discount/year. We aimed at estimating the impact of extending the French influenza vaccination programme from at-risk/elderly (>65 years) only, to additionally including all 18 years-old. A deterministic dynamic transmission model was used to simulate the transmission of influenza in the French population, under the current coverage with the trivalent inactivated vaccine (TIV). **Methods:** The model was structured to cover the healthy 0–7 years-old children with an intranasal, quadrivalent live-attenuated influenza vaccine (QLAIV) (eveluated strategy). The transmission probabilities were determined using between-individuals contact patterns (in France). Epidemiological, medical resources and costs data were issued by cross data from literature and French resource-based value scales. The reproduction number (R0) of the model was calibrated to the observed numbers of influenza-like illnesses visits/year and deaths/year. The 10-year, undiscounted, number of symptomatic cases of confirmed influenza and direct medical costs (All-payer) were calculated for the 0–17 (direct effect) and ≥18 years-old (indirect effect). The incremental cost-effectiveness ratio (ICER) was calculated for the total population using a 4% discount/year. University and probabilistic sensitivity analyses were performed. **Results:** Model calibration yielded R0=1.27 (assuming 2.3 million visits/year and 1,960 deaths/year). In the 0–17 years-old with 50% QLAIV coverage, the average number of confirmed influenza cases dropped by 865,000/year, averting 58.4% of the cases occurring in the reference strategy and leading to 10-year savings of €374 million. In the ≥18 years-old with unchanged TIV coverage, 1.2 million cases/year of confirmed influenza were averted (27.6%), yielding additional 323,000/10 years. On average, 6,133 flu-related deaths were avoided annually. The ICER was €18,000/life-year gained. The evaluated strategy was 98% cost-effective at a ≤30,000/life-year gained threshold. **Conclusions:** The model demonstrates that female-only vaccination and indirect benefits of protecting healthy children against influenza with QLAIV, on public health and economic outcomes in France.

**PIN62**

**COSTS AND EFFECTIVENESS OF COMBINATION THERAPY WITH BEDAQUILINE AND OTHER ANTI-TUBERCULOSIS DRUGS IN PATIENTS WITH MULTI- AND EXTENSIVELY DRUG-RESISTANT TUBERCULOSIS IN GERMANY**

**Objective:** Multidrug-resistant tuberculosis (MDR-TB) is designated an orphan disease in Germany, where about ~65 patients are infected with multidrug-resistant tuberculosis (MDR-TB). Regimens consisting of several drugs for up to 24 months are the current standard of care (SoC) for treatment of MDR-TB. The aim of this analysis is to evaluate the costs and effectiveness of adding bedaquiline (BDQ) to a background regimen (BR) of the SoC in a German health care context. **Methods:** A cohort based Markov model was used to estimate costs-effectiveness of bedaquiline plus background regimen (BDQ+BR) vs. BR alone for treatment of MDR- and XDR-TB (extensively drug resistant). The effectiveness of treatment was evaluated in QALYs, DALYs and life year gained (LYG). Inputs into the model were derived from a bedaquiline randomised, placebo controlled trial and from published literature. Drug costs (in 2014 euros) were taken from the German drug tariff, a yearly discount rate of 3% was applied and a time horizon of 10 years was assumed. Incremental analysis was performed. **Results:** The incremental cost per QALY gained (ICER) was calculated as 33,357 €. For a cohort exclusively of XDR-TB patients, the ICER was calculated as 17,915 €. **Conclusions:** The evaluation of model parameters, further sensitivity analyses were performed and BDQ+BR combination to a background regimen. The anti-TB drugs is cost-effective, probably even cost saving for patients with MDR- and XDR-TB, when compared to BR alone under different cost scenarios. Over a ten year period, cost savings were mainly achieved by lesser time of hospitalisation, although BDQ+BR drug costs are higher than BR alone.
COST-EFFECTIVENESS ANALYSIS OF DIFFERENT THERAPEUTIC REGIMENS IN TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN CHINA

Sun L., Dong H., Sun J., Wang Y., Shi W., Zhao X., Wu J.

OBJECTIVES: To investigate the cost-effectiveness of commonly used antimicrobial regimens in treatment of community-acquired Pneumonia (CAP) in China. METHODS: This was a retrospective study of CAP patients who received different antibiotic drugs during their hospitalization in a 1st. Class, Grade A hospital in Shenyang, Liaoning between January 2011 and June 2012. Cost-effectiveness analysis was performed for the common therapeutic regimens based on both clinical practice and the main recommended antibacterial treatment of CAP from the perspective of society as a whole. For the sensitivity analysis, we used a relative measurement method and an absolute measurement method to test the strength of the study’s conclusions over a range of assumptions. RESULTS: 203 clinical cases met study criteria, and 192 (94.6%) were treated with regimens of azithromycin (n=40), cefmetazole (n=60), ceftazidime and erythromycin (n=29). The success rate treatment for the 6 groups were 42.31%, 51.67%, 6.25%, 25.0%, 60.71% and 65.52%, respectively, total direct medical costs were ¥74,105, ¥501,21, ¥1024.31, ¥1024.46, ¥404.15 and ¥555.84, respectively, among them, the incremental cost-effectiveness ratio (ICER) of erythromycin group and a combination regimen (ceftazidime plus erythromycin) was 31.54, indicating that erythromycin and combination of ceftazidime and erythromycin had a positive effect on treatment success and a lower total cost. Sensitivity analysis supported the dominance of the 2 groups in nearly all scenarios but the variation of treatment success rate. CONCLUSIONS: Erythromycin monotherapy and a combination of ceftazidime and erythromycin were more cost-effective than other regimens in the treatment of CAP.

COST-EFFECTIVENESS OF FIDAXOMICIN THERAPY FOR CLOSTRIDIUM DIFFICILE INFECTION IN HUNGARY

Brodzsky V., Brodsky B., Baji P., Petek M., Gulaci L.

OBJECTIVES: To investigate the cost-effectiveness of fidaxomicin versus vancomycin in patients with Clostridium difficile nosocomial diarrhea. The two main treatments for these patients are fidaxomicin and vancomycin. In two phase III randomized controlled trials fidaxomicin was found to be non-inferior to vancomycin in initial clinical cure of CDI and superior in preventing recurrences. The main goal of this economic analysis was to evaluate the cost-effectiveness of fidaxomicin versus vancomycin, for the treatment of C. difficile infection in Hungary. METHODS: A decision tree model was developed to capture the transition of recurrence rate with fidaxomicin and vancomycin. The model included treatment success, incidence of adverse events, and costs associated with fidaxomicin and vancomycin. The model took two clinical endpoints: 21-day clinical cure and 21-day clinical cure-free survival. The average number of recurrent episodes per patient was lower with fidaxomicin therapy (0.13 recurrent episodes/patient) than with vancomycin therapy (0.40 recurrent episodes/patient), a productivity advantage. Incremental direct costs per patient for fidaxomicin compared with vancomycin was €5,520 per avoided recurrent episode. CONCLUSIONS: In conclusion, this study found that fidaxomicin has favourable cost-effectiveness ratio compared to vancomycin.

COST-EFFECTIVENESS ANALYSIS OF RALTIVIR IN HIV-INFECTED TREATMENT-NAÏVE PATIENTS IN GREECE

Athanasakis K., Roumbaichareopoulou N., Retta MP., Maiese E., Elbash A., Kyriopoulos J.

OBJECTIVES: Despite the success of current antiretroviral therapies for human immunodeficiency virus (HIV) infection, the development of drug resistance remains a critical issue. Raltivir is an inhibitor of HIV-1 integrase approved for treating treatment-naïve and experienced patients. The present study aimed at conducting an economic evaluation of raltivir vs protease inhibitor (PI) regimen in treatment-naïve patients in Greece. METHODS: A three-stage continuous-time Markov model was developed using differential equations, for the cost-effectiveness analysis of initiating raltivir-based therapy as first-line treatment vs initiating protease inhibitor (PI) -based therapy as first-line therapy, over a lifetime horizon. Stages of the model included progression through successive treatment therapies. Patients entered the model with a given CD4 cell count and HIV-1 viral load, and progressed to the next stage. At any time they could develop acquired immunodeficiency syndrome (AIDS), suffer from a coronary heart disease (CHD) or die. Model inputs were collected from the literature and adopted to the Greek healthcare system and economic setting. Model outputs included projected number of AIDS cases, number of CHD events, number of deaths, life expectancy and incremental cost-effectiveness ratios (ICER). The analysis was performed from the perspective of the Greek Social Insurers. RESULTS: Patients initiating on the raltivir-based therapy presented longer undiscounted life expectancy compared to those initiating on a PI regimen (21.20 vs 18.85 years). The ICER for a raltivir-initiated treatment strategy vs. a boosted PI initiated treatment strategy was 12,757/QALY gained (discounted at 3%). CONCLUSIONS: Results suggest that, over a lifetime horizon, raltivir-based initiating therapy could be a cost-effective option compared to a PI based initiating therapy in the Greek healthcare setting.

LONG-TERM OUTCOMES OF LEDAPASVIR/SOFOSBUVIR (LDV/ SOF) FOR THE TREATMENT OF CHRONIC HEPATITIS C INFECTED (HCV) GENOTYPE 1 PATIENTS IN THE UK

Guerra F., Marie L, Cure S.

OBJECTIVES: Sofosbuvir (SOF) is a uridine analogue polymerase inhibitor. Ledapivar (LDV) is an inhibitor of the hepatitis C virus (HCV) NS5A protein. Efficacy and safety have been demonstrated in three phase III clinical trials of LDV/SOF administered with or without ribavirin. This analysis evaluated the long-term outcomes of LDV/ SOF in GT1 treatment-naïve (TN) and treatment-experienced protease inhibitor failure patients (TE) HCV patients. METHODS: A Markov-model followed 10,000 patients initiating treatment with LDV/SOF to evaluate compensated cirrhotic (CC) stage. In GT1 TN, LDV/SOF for 8 weeks for non-cirrhotic (NC) patients and 12 weeks for CC patients was compared against SOF with pegylated interferon 2a and ribavirin (SOF/PR), SOF with RBV (SOF/RBV) and simprevir with PR (SMV/PR). In GT1 TE, LDV/SOF was shown to be highly effective in preventing progression to ALD and reducing HCV-related mortality with a well-tolerated single tablet regimen. This is particular importance for protease inhibitor failure patients since there is currently no alternative treatment options.

COST-EFFECTIVENESS AND LONG-TERM OUTCOMES OF SOFOSBUVIR (SOF) FOR THE TREATMENT OF CHRONIC HEPATITIS C INFECTED (HCV) PATIENTS FROM A SWEDISH SOCIETAL PERSPECTIVE

Cure S., Guerra I.

OBJECTIVES: Sofosbuvir (sofosbuvir) is the first nucleotide polymerase inhibitor with pan-genotypic activity and a high barrier to resistance. Efficacy of sofosbuvir-based regimens demonstrated >90% SVR across genotype (GT) 1-6 in five phase III trials, showing superior efficacy compared with treatment and advanced liver disease (ALD). RESULTS: Sofosbuvir regimens, including interferon-free, were shown to be cost-saving across all genotypes and against all current treatment alternatives in Sweden. In GT1, this novel therapy incurs approximately 42%, 31% and 25% lower costs than PR, boceprevir and telaprevir, respectively. Sofosbuvir also reduces the burden of HCV. In 10,000 patients, we estimated that on average 1697, 1417, 607 and 204 cases of compensated cirrhosis, decompensated cirrhosis, hepatocellular carcinoma and liver transplant, respectively, and 92 deaths would be avoided with sofosbuvir-based regimens compared with telaprevir, boceprevir, PR and no treatment. CONCLUSIONS: Cost-effectiveness analysis based on a Swedish societal perspective (i.e. including productivity losses due to treatment and ALD) shows sofosbuvir-based treatments to be cost saving in all genotypes and against all current treatment alternatives. In order to optimally allocate scarce societal resources, arguably all costs related to HCV treatment need to be included in the cost-effectiveness analysis.

HOW DO DECISION MAKERS IN EUROPE VALUE OTHER ECONOMIC EVALUATION TOOLS THAN COST-EFFECTIVENESS ANALYSIS FOR VACCINES?

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OBJECTIVES: Other economic evaluation tools than the classical cost-effectiveness (CE) analysis exist but the acceptance of these by decision makers is unknown. We assessed the value of these new methods among experts and decision makers in eleven European countries. MethOds: A three-stage continuous-time Markov model was developed using differential equations, for the cost-effectiveness analysis of initiating raltivir-based therapy as first-line treatment vs initiating protease inhibitor (PI) -based therapy as first-line therapy, over a lifetime horizon. Stages of the model included progression through successive treatment therapies. Patients entered the model with a given CD4 cell count and HIV-1 viral load. After they failed or discontinued the current therapy, patients transitioned between eighteen health states (two age groups and six CD4-categories and six HIV-1 viral load), and progressed to the next stage. At any time they could develop acquired immunodeficiency syndrome (AIDS), suffer from a coronary heart disease (CHD) or die. Model inputs were collected from the literature and adopted to the Greek healthcare system and economic setting. Model outputs included projected number of AIDS cases, number of CHD events, number of deaths, life expectancy and incremental cost-effectiveness ratios (ICER). The analysis was performed from the perspective of the Greek Social Insurers. RESULTS: Patients initiating on the raltivir-based therapy presented longer undiscounted life expectancy compared to those initiating on a PI regimen (21.20 vs 18.85 years). The ICER for a raltivir-initiated treatment strategy vs. a boosted PI initiated treatment strategy was 12,757/QALY gained (discounted at 3%). CONCLUSIONS: Results suggest that, over a lifetime horizon, raltivir-based initiating therapy could be a cost-effective option compared to a PI based initiating therapy in the Greek healthcare setting.
were however not considered to be able to replace CE except for MEA (14% reported that it could replace CE versus 0% for the others). In countries where CE is not formally used, the proportion of experts considering them as relevant was lower except for the BOM: Rol (46%), MCD4 (46%), QoC (18%), BOM (60%) and MEA (33%). Most reported barriers for use of the alternative methods were: no political interest, unfamilarity with these methodologies, lack of cost data to conduct the evaluation. The method selection was most influenced by the appropriateness to the decision-making question, the country, and the vaccine or disease type assessed. Creating awareness about economic evaluation methods may support and facilitate the vaccine reimbursement decision-making process in Europe alongside the current CE analysis.

PIN69
ALLOCATING VACCINE FUNDS FOR PNEUMOCOCCAL VACCINATION OF INFANTS AND OLDER ADULTS: A METHOD FOR STRATEGIC EVALUATION IN THE NETHERLANDS
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OBJECTIVES: Pneumococcal conjugate vaccines are available in the Netherlands against pneumococcal disease in infants and adults. This analysis aimed to identify an optimal vaccination strategy between infants and adults when the budget is constrained. Extensive sensitivity analysis is performed around herd protection on Invasive Pneumococcal Disease (IPD) and Community Acquired Pneumonia (CAP) resulting from infant vaccination. METHODS: We developed an optimization model linked to a prevalence-based disease management sub-model. This program allows finding an optimal solution given an objective function (minimum cost, minimize quality-adjusted life years (QALYs) lost, minimize life-years (LYs) lost) under budget constraints. Vaccine efficacy (VE) is based on clinical trial data. The model is run for different scenarios seeking for minimum indirect effect on IPD and on CAP in the whole population to keep infant vaccination sustainable given a constrained budget. RESULTS: With the current disease burden and vaccine coverage rate in the Netherlands and considering an overall VE in adults against CAP of 6% (37% estimated VE in first and each other vaccine), the model shows that vaccinating infants is the optimal strategy that maximizes pneumococcal-related events when compared with adult vaccination. If the objective is to minimize QALYs lost, vaccinating infants remains the optimal selection as long as the minimum indirect effect is ≥2% on CAP or ≥1% on IPD. When the objective is to minimize LYs lost, the minimum indirect effect should be ≥0.3% on CAP or ≥0.2% on IPD. Sensitivity analyses show that even if CAP VE in adults is 3 times higher, the estimated minimum indirect effect needed is still below the one obtained with the first pneumococcal conjugate vaccine. CONCLUSIONS: The optimal strategy within a constrained budget is to maintain infant vaccination instead of initiating elderly vaccination, given the reported evidence of indirect protection.

PIN70
COST-EFFECTIVENESS ANALYSIS OF A SHINGLES VACCINATION PROGRAM TO PREVENT HERPES ZOSTER AND POST-HERPETIC NEURALGIA IN THE SPANISH SETTING
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OBJECTIVE: A live-attenuated vaccine aimed at preventing herpetic zoster (HZ) and post-herpetic neuralgia (PHN) is available in Europe for immunocompetent adults aged ≥50 years. The study objective is to assess the incremental cost-effectiveness ratio (ICER) of a vaccination program for HZ prevention in Spain with and without the introduction of a strategy of HZ vaccination. METHODS: A state-transition Markov model has been developed to simulate the natural history of HZ and PHN and the lifetime effects of vaccination. Several health states are defined including good health, HZ, PHN and death. HZ and PHN health states are divided to reflect pain severity. The Markov cycle was 1 month and lifetime horizon. The HZ vaccine lifetime duration (wanning rate of 8.3%) and a PHN vaccine duration of 10 years. PHN proportion was obtained from Cebrián-Cuenca (2011) and adjusted to reflect the incidence of PHN among HZ patients with pain. The vaccine coverage rate estimated was 30%, considering discount rates of 3% for costs and utilities. The strength of the results was confirmed with a probabilistic analysis based on Monte Carlo simulation. RESULTS: A vaccination strategy compared to a no-vaccination resulted in 12.659/QALY and 11.926/QALY under third-party payer perspective and societal perspective respectively for the population aged ≥50 years. IECRs were within the commonly accepted thresholds of 30,000/QALY (36,000/QALY) gained in the UK. Sensitivity analyses showed that the model was most sensitive to discount rates and duration of vaccine protection. The lowest IECR was observed for the 70-74 years age group (6.657/QALY) under third-party payer perspective. CONCLUSIONS: In Spain, a shingles vaccination strategy in older population would be a cost-effective alternative in comparison with no vaccination, due to an ICER of 12.659/QALY from the third-party payer perspective.

PIN71
COST-EFFECTIVENESS OF FECAL MICROBIOTA TRANSPLANTATION IN TREATING CLAUDIUM DIFFICILE INFECTION IN CANADA
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OBJECTIVES: To estimate the cost-effectiveness of Fecal Microbiota Transplantation (FMT) for the treatment of Clostridiun difficile infection (CDI) as compared to the current practice comprising of antibiotic treatments. METHODS: We developed a decision analytic model to compare strategies for the management of CDI, by age, gender, and three sources of infection: hospitals, community, and long-term care facilities (LTCF). We performed validation analyses to demonstrate that the predicted CDI rates were a reasonable representation of the selected actual rates. Mortality rates were stratified by age. A probabilistic sensitivity analysis (PSA) was performed to account for the effect of uncertainty in the model parameters. RESULTS: For the current practice, we estimated that annually 75% of CDI cases are new infections; the rest are recurrences; 40% of CDI occurs among individuals aged ≥60, 41% among 60-79, and 19% among 18-59 years old; hospital-based CDI accounted for 69 % of all CDI, while community and LTCF based CDI accounted for 26% and 5% of all CDI, respectively. The recurrence rates for current antibiotic treatment were estimated at 25% and 3% for first and second recurrences, respectively. The recurrence rate for FMT was estimated at 10.4%. For the base case, we estimated 79.0 and 69.4 per 100,000 population cases of CDI for current practice and FMT, respectively. The number of deaths is estimated at 5.8 and 4.7 per 100,000 population for current practice and FMT, respectively. The results of the cost-effectiveness analysis for the base case, FMT is a dominant strategy. The results of the PSA reveal that for the majority of simulations, FMT is dominant (positive incremental QALYs and negative incremental costs). CONCLUSIONS: The results of the cost-effectiveness analysis indicate that FMT appears to be the dominant strategy, with lower costs and better outcomes than the existing antibiotic treatments.

PIN72
THE IMPORTANCE OF SENSITIVITY ANALYSIS IN ASSESSING CLINICAL AND ECONOMIC IMPACT OF NATIONAL IMMUNIZATION PROGRAMS: AN EXAMPLE OF SLOVENIA
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OBJECTIVES: To demonstrate the role of sensitivity analysis (SA) in assessing clinical and economic impact of national immunization programs. METHODS: We applied our recent cost-effectiveness model of pneumococcal vaccination to the local data to estimate the cost-effectiveness ratio (ICER) from vaccination with PHiD-CV against pneumonia (CAP) and acute otitis media (AOM). In the model, we followed the cohort of 21,938 Slovenian infants over their lifetime and compared two pneumococcal vaccine campaigns (PHiD-CV and NVS). Results: We performed sensitivity analysis around herd protection on IPD and CAP of 4.5% and against IPD of 37% (estimates based on CAPITA clinical trial results), coverage rate in the Netherlands and considering an overall VE in adults against CAP of 6% (37% estimated VE in first and each other vaccine). The optimal strategy within a constrained budget is to maintain infant vaccination instead of initiating elderly vaccination, given the reported evidence of indirect protection.

PIN73
THE PAN-GENOTYPIC COSTS-EFFECTIVENESS OF SOFOBUVIR IN HEPATITIS C VIRUS
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OBJECTIVE: This study assesses the PAN-genotypic costs-effectiveness of sofosbuvir compared with standard of care in the Netherlands. METHODS: Untreated hepatitis C virus (HCV) infection results in chronic liver disease. The prevalence in The Netherlands is estimated at 0.4% with 50% of patients having HCV genotype 1 (GT1), 10% GT2, 30% GT3 and 10% GT4-5-6. Current standard of care (SoC), regardless of genotype consists of weekly subcutaneous pegylated interferon-alpha (PegIFN-α) plus daily oral ribavirin. In GT1, the protease inhibitors telaprevir or boceprevir are added. Sofosbuvir (SOF), a novel Direct Antiviral Agent (DAA), has consistently demonstrated high rates of sustained virological response (SVR) when given with ribavirin/PegIFN-α. This cost-effectiveness evaluation is based on a Markov transition model, that combines efficacy and safety data from published RCTs with SOF and Ribavirin/PegIFN-α. RESULTS: For the current practice, vaccination with PHiD-CV dominated NVS when at least 17.5% of parents of sick children would take a paid leave, which – in the Slovenian jurisdiction – constitute direct costs; in comparison, corresponding ICER for vaccination with PCV-13 vs. NVS was €12,306/QALY. CONCLUSIONS: Both base case and SA model findings suggest that Slovenian authorities may save resources by implementing national immunization program of infants with PHiD-CV as a vaccine of choice.
A677

VA L U E I N H E A LT H 1 7 ( 2 0 1 4 ) A 3 2 3 – A 6 8 6

Objectives: Since 2009, 12-year-old Dutch teenage girls are vaccinated against
human papillomavirus (HPV) infection. The current uptake of HPV vaccination, being
approximately 60% nowadays, is however comparatively low. Consequently, a large
group of women are still at risk of developing HPV-induced cervical cancer later on in
life. Therefore, alternative HPV vaccination scenarios have been proposed, in addition
to the existing programme, to provide additional protection against cervical cancer.
Here, we assessed the cost-effectiveness of three different vaccination scenarios: (i)
increased coverage of the existing programme, (ii) vaccination of girls at an older age,
and (iii) vaccination of 12-year-old boys. Methods: A dynamic model was used to
estimate the full health-economic consequences of the existing programme with
and without the above alternative scenarios. Costs and health effects of the alternative scenarios, expressed as life years (LYs) or quality-adjusted life years (QALYs)
gained, were compared with the outcomes of the existing programme. In sensitivity
analyses, the robustness of the model-predicted outcomes was evaluated. Results:
We found the incremental cost-effectiveness ratio of the existing HPV vaccination
programme to be €9,500 per QALY gained. The cost-effectiveness of the alternative
programs highly depends on the coverage at 12 years of age. The cost-effectiveness
of girls 24 years of age remained below €50,000/QALY if coverage at 12 years of age
increased up to 70%. Cost-effectiveness of vaccination boys at 12 years of age becomes
unfavourable if coverage among 12-year old girls increases. Conclusions: From a
health-economic perspective, alternative HPV vaccination programmes should be
considered in the Netherlands to further reduce the burden of HPV-induced cancer.
Until a high coverage among 12-year old girls in reached the addition of older girls to
the current vaccination program is most cost-effective.
PIN75
A Systematic Review of Cost-Effectiveness Analysis of Cd4 Cell
Count VersUS Hiv Viral Load in Primarily Resource-Limited Setting
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Objectives: Utilization of routine viral load (VL) and CD4 cell count coupled to clinical monitoring of HIV patients needs to be carefully deliberated in cost-effectiveness, especially for resource-limited countries. The review was aimed to evaluate
and compare the cost-effectiveness of these strategies individually and in combination. Methods: A literature review was conducted for studies published in English
from 2004 to 2014 on Pubmed, Web of Science, Ovid, Google Scholar, with keywords
HIV, viral load, CD4, economic evaluation, and cost analysis. All underwent assignment of Levels of Evidence (LOE) by Oxford Center for Evidence-Based Medicine
(CEBM), as well as Drummond scoring criteria. Results: Thirty English publications
were identified, including 14 modeling studies, 7 randomized clinical trials (RCT’s),
and 5 cohort studies among others. A total of 24 were based on resource-limited
settings such as Africa, Latin America, and Asia. Compared with CD4, VL alone had
incremental cost-effectiveness ratios (ICER’s) ranging from $2520/LY to $3570/life year
(LY); while that of CD4 alone compared to clinical monitoring was from $-13134/LY
to $5768/quality-adjusted life year (QALY). The combination of CD4 and VL, which is
recommended in real-life practice, compared to CD4 alone yielded ICER’s ranging from
$3956/QALY to $16139/QALY. The cost-effectiveness of these strategies was affected
by factors such as the reference threshold for ICER, costs and monitoring regimens
of the strategies and antiretroviral treatment. Conclusions: From the studies, it
is critical to evaluate the cost-effectiveness of CD4 compared with VL contextually,
with CD4 being more appropriate in resource-limited settings. VL is associated with
improved benefit, however when used in combination with CD4, is usually not costeffective. Compared with clinical monitoring alone CD4 usually produces greater
cost-effectiveness.
PIN76
Adding Boceprevir Yields Better Cost-Saving for Chronic Hepatitis C
Genotype 1 Treatment in Thailand
Ferrante S 1, Elbasha E H 1, Piratvisuth T 2, Tanwandee T 3, Lerdlitruangsin S 4, Thongsawat S 5
Sharp & Dohme Corp., Whitehouse Station, NJ, USA, 2Prince of Songkla University,
Thailand, Thailand, 3Siriraj Hospital, Mahidol University, Bangkok, Thailand, 4Merck MSD
Thailand, Thailand, 5Chiang Mai University, Chiang Mai, Thailand
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1Merck

Objectives: Current Thai guidelines reimburse peginterferon/ribavirin (PR) combination treatment for patients infected with all genotypes of chronic hepatitis
C (CHC), based on the results of cost-effectiveness studies. Two trials, SPRINT-2
and RESPOND-2, have demonstrated that treatment with Boceprevir (BOC) in
addition to PR results in significantly higher sustained virologic response rates
than the current standard of care, PR alone for 48 weeks, in both treatment naïve
and treatment experienced CHC genotype 1 patients. The aim of our analysis
was to evaluate the cost-effectiveness of BOC-based treatment compared with
PR alone from the perspective of the policy maker in Thailand over a lifetime
horizon. Methods: A decision analytic model was developed to simulate the
treatment strategies described in the BOC label (BOC/PR) and PR alone, and to
describe the natural history of CHC to make projections beyond the treatment
phase. Separate analyses were conducted based on patients’ treatment history
and cirrhosis status. Patient characteristics were obtained from SPRINT-2 and
RESPOND-2. Treatment characteristics including efficacy and the rate of side
effects were obtained from subset analyses of these trials. Transition probabilities, costs, and health state utilities were obtained from previously studies. We
projected the lifetime cumulative incidence of CHC-related liver complications
– decompensated cirrhosis, hepatocellular carcinoma, liver-transplantation, liverrelated mortality - discounted costs and QALYs associated with each treatment
strategy. The incremental cost-effectiveness ratio was also assessed. Results:
For treatment naïve and treatment experienced patients, BOC/PR treatment is
projected to reduce the incidence of CHC-related liver complications by 43-44%
and 47-51%. BOC/PR is projected to be less expensive and result in increases of
0.13-2.62 QALYs for all non-cirrhotic patients and cirrhotic treatment-experienced
patients. Cirrhotic treatment naïve patients was the only subgroup in which costeffectiveness was not demonstrated. Conclusions: In the Thai setting, BOC/PR

is projected to be cost-savings against PR alone in the majority of CHC genotype
1 patients, regardless of treatment history.
PIN77
A Cost-Effectiveness Evaluation for a New Therapy in HIV
Treatment
Malhan S 1, Kockaya G 2, Elbir Zengin T 2, Dalgic C 2, Yenilmez F B 3, Cerci P 3, Oksuz E 1,
Tayfun K 2, Unal S 3
1Baskent University, Ankara, Turkey, 2Gilead Science, Istanbul, Turkey, 3Hacettepe University,
Ankara, Turkey
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Objectives: Economical evaluation of Stribild in Turkey, which is a single tablet
regimen indicated for the treatment of HIV-1 infection in adults aged 18 years and
over who are antiretroviral treatment naive or are infected with HIV-1 without
known mutations associated with resistance to any of the three antiretroviral agents
in it. Methods: STRIBILD™ was compared with various treatment options; tenofovir DF+emtricitabine+efavirenz (FTC/TDF+EFV), tenofovir DF+emtricitabine+
ritonavir+lopinavir (FTC/TDF+LPV/r), tenofovirDF+emtricitabine+nevirapine (FTC/
TDF+NVP), tenofovir DF+emtricitabine+darunavir (FTC/TDF+DRV+r), tenofovir
DF+emtricitabine+raltegravir (FTC/TDF+RAL), lamivudine+zidovudine+efavirenz
(3TC/AZT+EFV), lamivudine+zidovudine+ritonavir+lopinavir (3TC/AZ+LPV/r), lam
ivudine+zidovudine+nevirapine (3TC/AZT+NVP). The adherence rates were calculated from the increase rate in CD4 cell count and the risk of hospitalization as
the effectiveness values. The data were taken from patient files from Hacettepe
University that consists of 252 patients and 12 year follow-ups with an outpatient
clinic, interventions, laboratory and imaging tests, medication usage, side effects,
comorbidity’s diseases and their treatments and complications. The costs of treatment of diseases were calculated by cost of disease methodology. Average annual
cost per patient is calculated for health care technologies. Health technology effectiveness values are found from the literature review. Incremental cost-effectiveness
ratio (ICER) was used for the comparison. Results: According to comparison of rate
of compliance to treatment, STRIBILD™ was cost effective against 3TC/AZT+EFV
(2157.2 TL), FTC/TDF+LPV/r (612.7 TL), FTC/TDF+NVP (951.9 TL), FTC/TDF+DRV+r
(544.28 TL) and cost saving aganist FTC/TDF+RAL (-166,22 TL). According to the rate
of risk of hospitalization, STRIBILD™ was cost effective against 3TC/AZT+EFV (517.7
TL), FTC/TDF+LPV/r (318.6 TL), FTC/TDF+NVP (495 TL), FTC/TDF+DRV+r (283 TL), 3TC/
AZT+EFV (632,4 TL), 3TC/AZ+LPV/r (425.6 TL), 3TC/AZT+NVP (591.2 TL). According to
the increase rate in CD4 cell count and over 95% of compliance rate, STRIBILD™ was
cost effective against FTC/TDF+EFV (392.2 TL) and cost saving against FTC/TDF+RAL
(-308.7 TL), respectively. Conclusions: HIV is a life-threatening disease with in
terms of major public health problem globally.. In this study, STRs in comparison
of combination treatment strategies, has higher compliance rates, better outcomes
and lower health care costs.
PIN78
The Cost-Effectiveness of Different Scenarios of Detecting of TB
Among HIV-Infected People Depending on CD 4+ Count
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Objectives: The objective was to assess the cost-effectiveness of 3 scenarios for the
diagnosis of TB among PLWH depending on CD 4+ count and their influence to treatment pathway and outcomes. Methods: A deterministic decision analytic model
was designed for three TB possible searching scenarios in three hypothetical cohorts
of 1000 PLWH with different CD 4+ count (<200, 200-499, >500). The following scenarios were examined: ‘‘Base’’— the current diagnostic scheme, according the National
Program; ‘‘Addition’’—the current diagnostic scheme and Xpert/Rif; ‘‘Replacement’’
– Xpert/Rif test only. Inputs’s from the country report and Russian epidemiologic
data. The analysis was conducted from the Russia health care perspective with an
analytic horizon of 2 years. Results: CD 4+ < 200 cohort CER in “Base” is 541817,
in “Addition” – 643771, “Replacement” – 648087. Additional cost per one successfully treated RUB1123K (23893 € ), cost per death averted pts RUB5035K (107127 € ),
in “Addition” compared to “Base”. CD 4+ 200 – 499 cohort CER in “Base” is 390693,
in “Addition” – 550615, “Replacement” – 665529. Additional cost per one successfully treated RUB5422K (115361 € ), cost per death averted pts RUB5226K (111191€ )
in “Addition” compared to “Base”. CD 4+ > 500 cohort CER in “Base” is 408581, in
“Addition” – 642137, “Replacement” – 597470. Additional cost per one successfully treated RUB6093K (129638 € ), cost per death averted pts RUB6649K (141468 € )
in “Addition” compared to “Base”. Conclusions: If it needs to solve, which of
diagnostic scenarios we finance, we should take into account not only CER, but
opportunity to miss TB cases. Using “Addition” is especially effective for diagnostic
research in CD 4+ < 200 cohort.
PIN79
Switching from an EFV-Based STR to a RPV-Based STR is Effective, Safe
and Improves HIV Patients Health Status
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Objectives: Single-Tablet Regimens (STR) therapies are effective to maintain high
adherence and improves HAART efficacy. Methods: We evaluated viro-immunologic
outcomes, Quality of Life (QoL), and costs of an unselected cohort of patients switching from TDF/FTC/EFV STR (≥6 months duration) to TDF/FTC/RPV STR. The considered
outcome measures were quality-adjusted life years (QALYs) as measured with the
EQ5D questionnaire and the overall direct health costs. 64 patients with a baseline
viral load < 50 copies/ml were randomized to immediately switch therapy or to continue TDF/FTC/EFV for 4 months and then switch to TDF/FTC/RPV. 6 patients in the
deferred switch group did not change cART. Results: Patients were mostly males
(73.4%) with a mean age of 46 years, a baseline mean HIV-RNA of 6.42 copies/ml and
a mean baseline CD4 count of 588 cells/μL. The mean cost per patient resulted € 2,563
for STR with RPV arm and € 2,572 for STR with EFV arm. After 4 months the mean


per patient QALYs was 0.849 and 0.841 respectively. Viremia remained undetectable and CD4+ cell levels in all patients. Additionally, all other parameters such as Cholesterol, HDL and Triglycerides levels improved when switching from STR-containing EVF to Rilpivirine-based STR. VAS analysis of health status perception also increased over all from 82.78 to 83.79 (scale: 0-100) due to the improvement in the STR-containing regimen, as measured by outcomes. CONCLUSIONS: Switching from STR containing EFV to STR containing Rilpivirine is a safe, welltolerated strategy that improves the overall health status of HIV-treated patients. The switch does not expose patients to a risk of virologic failure due to possible PK interactions of the drugs. RPV compared to EFV resulted cost-effective showing lower treatment cost and higher outcome measure values.

PIN81

**COST-EFFECTIVENESS ANALYSIS OF THE APPLICATION OF ERTAPENEM FOR THE TREATMENT OF COMMUNITY-ACQUIRED COMPLICATED INTRA-ABDOMINAL INFECTIONS**

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OBJECTIVES: To perform comparative pharmacoeconomic analysis of ertapenem for the treatment of community-acquired complicated intra-abdominal infections in patients with community-acquired complicated intraabdominal infection in comparison with other therapy modalities. METHODS: We performed a cost-effectiveness analysis. We calculated the direct medical costs for the treatment of patients treated with ertapenem and moxifloxacin and cost-effectiveness ratio. RESULTS: According to a study J. J. De Weale et al., in patients treated with ertapenem, the frequency of clinical effect of treatment was higher than in the group of patients receiving moxifloxacin: 93.4% and 89.5%, respectively. The mortality rate associated with the development of severe sepsis, was also lower for ertapenem: 3.1% and 5.4% respectively. Direct medical costs accounted in the group of moxifloxacin with the average duration of therapy is 7 days was 1798 USD, in the group of ertapenem with the average duration of treatment 6.8 days - 1981 USD. When using moxifloxacin instead of ertapenem ICER for one additional prevented complication was 4688 USD, and for one surviving patient - 17027 USD. One way sensitivity analyses showed that the results of the research PROMISE formed the basis of pharmacoeconomic model. The effectiveness of therapy in studies was assessed by the frequency of clinical and bacteriological success of treatment with the use of different modes of antibacterial therapy. We calculated the difference in direct medical costs for treatment with ertapenem and moxifloxacin and cost-effectiveness ratio. CONCLUSIONS: Pharmacoeconomic analysis showed that the application of ertapenem for the treatment of community-acquired complicated intraabdominal infections is expensive but more efficient and economically justified strategy.

PIN82

**QUADRIVALENT INFLUENZA VACCINE IN HONG KONG: A COST-EFFECTIVENESS ANALYSIS**

Yui J., Ling W., Chan P.

The Chinese University of Hong Kong, Shatin, Hong Kong

OBJECTIVES: This study assessed the cost-effectiveness of quadrivalent influenza vaccine (QIV), compared to TIV, in age-stratified populations of Hong Kong from 2001-2010. METHODS: TIV-undeserved influenza B vaccine was estimated from Hong Kong’s QIV versus TIV were estimated by an epidemiology model. Model parameters included percentages of influenza B lineages in circulation, influenza B-associated hospital admission, age-specific population, vaccine coverage and effectiveness. Events (outpatient care, hospitalizations and death) caused by infection of the influenza B lineage not included in TIV were calculated. Cost savings and QALYs gained from reduced events with QIV were estimated. Incremental cost per QALY gained. RESULTS: QIV was cost-effective in Hong Kong. QIV versus TIV were cost-saving in terms of a major global public health problem. This analysis evaluates the cost-effectiveness of QIV-1 treatment alternatives including lamivudine+eszidovudine+efavirenz (1TCZ/ATZ+EFV), tenofovir DF+emtricitabine+efavirenz (1TCZ/DF/EFV), tenofovir DF+emtricitabine+ritonavir+ lopinavir (1TCZ/DF/TVL/PrVi), tenofovir DF+emtricitabine + darunavir (1TCZ/DF/TVL/PrVi+DAR), and elvitegravir+cobicistat+emtricitabine + tenofovir DF (STRIBILD). METHODS: This analysis compares the HIV treatment alternatives of 1TCZ/ATZ+EFV, 1TCZ/ATZ/DF/EFV, 1TCZ/ATZ/DF/TVL/PrVi, 1TCZ/ATZ/DF/TVL/PrVi+DAR, and STRIBILD. RESULTS: The cost per QALY gained from switching from STR to STRIBILD was 25.9 (95%CI 6.7-45.1). Highest age-specific rate proportion was 451.4 (95%CI 87.7-815.3) in 40-49 years, followed by 104.8 (95%CI 27.2-182.4) in 65-79 years and 13.2 (95%CI 1.9-40.9) in 80 years and above. The highest cost savings and QALY gain occurred in people aged 40 to 49 years and those aged 65 to 79 years, the sensitivity analysis may be acceptable over a wide range of assumptions. CONCLUSIONS: QIV was cost-effective in very young and older populations. Cost-effectiveness of QIV was subjected to unit cost of QIV versus TIV and percentage of circulating influenza B lineages.

PIN83

**XPERT MTB/RIF ASSAY FOR RAPID DIAGNOSIS IN PATIENTS WITH SUSPECTED TUBERCULOSIS IN HONG KONG: A COST-EFFECTIVENESS ANALYSIS**

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OBJECTIVES: Hong Kong is a developed city with intermediate tuberculosis (TB) burden. We undertook a decision analysis to estimate the cost-effectiveness of the Xpert MTB/RIF test in Hong Kong public health care providers. METHODS: A decision tree was designed to simulate outcomes of three diagnostic assessment strategies in adults with Xpert smear positive TB. CONCLUSIONS: The Xpert assay is cost-effective by comparing to smear plus Xpert for active TB in a broad range of parameters. Xpert assay is also shown to be more effective than smear in 10,000 Monte Carlo simulations.

PIN84

**COST EFFECTIVENESS OF QUADRIVALENT INFLUENZA VACCINE OVER TRIVALENT VACCINE IN FRANCE**

Daccord J1, Daccord F1, Proust P2, Robert P3, Lachaine J4

1Optum, Nanterre, France, 2AP-HP, Hôpital Pitié-Salpêtrière, Paris, France, 3Glaxo Smith Kline, Marly-le-Roi, France, 4VHL Healthcare France, Marly-le-Roi, France

OBJECTIVES: To estimate the cost-effectiveness ratio of a inactivated quadrivalent influenza vaccine compared to the trivalent one in France. METHODS: During some epidemic influenza seasons a mismatch between the circulating B strains and the one included in the trivalent vaccine is observed. The difference of vaccine protection by the quadrivalent vaccine due to the inclusion of both circulating B strains should avoid the occurrence of a number of consultations and complications resulting in hospitalizations and deaths. A decision tree model was built to compare the efficacy and costs of the two vaccines for an average epidemic influenza season in the French setting. The number of hospitalization and deaths associated with influenza were estimated from an analysis of available French data. Estimates of these medical events were calculated using French standard costs in 2012 and observational data. Deterministic and probabilistic sensitivity analyses (PSA) were conducted. RESULTS: The base case analysis considered the global French vaccinated population during an average epidemic season between seasons 03/04 and 11/12 with a B circulating virus rate of 23% and a mismatch rate of 58%. The perspective is collective. The number of avoided consultations for influenza was estimated at 6,214 and the number of avoided hospitalizations and deaths at 614 and 372 respectively. The number of life years gained (QIVLY) was estimated at 3,188/LYG. Sensitivity analyses showed clearly the importance of the B circulating virus rate combined with the mismatch rate highly variable according to influenza seasons. PSA showed that the QALY curve were under 20,000 per LYG in the base case analysis. CONCLUSIONS: The cost-effectiveness ratio of an inactivated quadrivalent influenza vaccine compared to trivalent ones in the French setting can be considered acceptable.

PIN85

**COST-EFFECTIVENESS OF DOLUTEGRAVIR, A NEW GENERATION INTEGRASE INHIBITOR, IN HIV-1 TREATMENT EXPERIENCED PATIENTS IN FRANCE**

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OBJECTIVES: To compare the clinical effectiveness of Dolutegravir (DOLU) versus Tenofovir DF+Emtricitabine (TDF/FTC) in treatment-experienced patients (TEP) with antiretroviral therapy (ART). METHODS: A decision tree was designed to simulate outcomes of two diagnostic assessment strategies in adults with suspected active PTB in intermediate burden area like Hong Kong. RESULTS: PIN84

**COST EFFECTIVENESS OF QUADRIVALENT INFLUENZA VACCINE OVER TRIVALENT VACCINE IN FRANCE**

Daccord J1, Daccord F1, Proust P2, Robert P3, Lachaine J4

1Optum, Nanterre, France, 2AP-HP, Hôpital Pitié-Salpêtrière, Paris, France, 3Glaxo Smith Kline, Marly-le-Roi, France, 4VHL Healthcare France, Marly-le-Roi, France

OBJECTIVES: To estimate the cost-effectiveness ratio of a inactivated quadrivalent influenza vaccine compared to the trivalent one in France. METHODS: During some epidemic influenza seasons a mismatch between the circulating B strains and the one included in the trivalent vaccine is observed. The difference of vaccine protection by the quadrivalent vaccine due to the inclusion of both circulating B strains should avoid the occurrence of a number of consultations and complications resulting in hospitalizations and deaths. A decision tree model was built to compare the efficacy and costs of the two vaccines for an average epidemic influenza season in the French setting. The number of hospitalization and deaths associated with influenza were estimated from an analysis of available French data. Estimates of these medical events were calculated using French standard costs in 2012 and observational data. Deterministic and probabilistic sensitivity analyses (PSA) were conducted. RESULTS: The base case analysis considered the global French vaccinated population during an average epidemic season between seasons 03/04 and 11/12 with a B circulating virus rate of 23% and a mismatch rate of 58%. The perspective is collective. The number of avoided consultations for influenza was estimated at 6,214 and the number of avoided hospitalizations and deaths at 614 and 372 respectively. The number of life years gained (QIV) was estimated at 3,188/LYG. Sensitivity analyses showed clearly the importance of the B circulating virus rate combined with the mismatch rate highly variable according to influenza seasons. PSA showed that the QALY curve were under 20,000 per LYG in the base case analysis. CONCLUSIONS: The cost-effectiveness ratio of an inactivated quadrivalent influenza vaccine compared to trivalent ones in the French setting can be considered acceptable.
OBJECTIVES: To evaluate the cost-effectiveness of a new generation integrase inhibitor (DTG), in France, in treatment-experienced (TE) and INI-naive HIV adults with at least two classes resistance, compared to raltegravir (RAL), by adapting previously published Anti-Retroviral Analysis by Monte Carlo Individual Simulation (ARAMIS) model. METHODS: ARAMIS is a microsimulation model using 500 simulations with a lifetime analytic time horizon and a monthly cycle length. Markov health states were defined by HIV health state (with or without opportunistic infection). The initial cohort, efficacy and safety data of the DTG, in France, in treatment-naive (TN) and in treatment-experienced (TE) ART (Alfattah et al., 2010) were based on French guidelines (2013) and experts opinion according to patients’ treatment history, including INI resistance status. Costs were mainly derived from the study by Sloan et al. (2012), which included routine care, opportunistic infection care, and death. RESULTS: The ARAMIS model indicates that DTG compared to RAL over a lifetime is associated with additional quality-adjusted life years (QALY) 10.751 versus 10.406, 0.345 difference) and additional costs of US$ 27,823 versus US$ 27,736. DTG strategy was cost dominant. Costs are mainly related to a 9.1 month increase in life expectancy for DTG compared with RAL, and consequently a longer time spent on ART. The incremental cost-effectiveness ratio (ICER) for DTG compared with RAL is €16,526 per QALY and €15,341 per year. About 83% and 14% of total lifetime costs were associated with ART and routine HIV care respectively. Univariate deterministic sensitiv- ity analyses demonstrated the robustness of the model with ICER varying from €11,038 to €48,157 per QALY. CONCLUSIONS: DTG is a cost-effective strategy in the management of TN and TE patients in France considering a collective perspective. These results are mainly explained by the superior efficacy of DTG reported in SAILING and its higher genetic barrier to resistance relative to RAL.

PIN86

COST-UTILITY ANALYSIS OF SIMIPREVIR WITH PEGINTERFON + RIBAVIRIN (SMV/PR) VS SMV/PR IN THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C VIRUS (HCV) INFECTION: FROM THE PERSPECTIVE OF THE NATIONAL HEALTH SERVICE (NHS) OF ENGLAND AND WALES.

Background:

In 2012, NICE recommended protease inhibitors as first line treat- ment for chronic HCV infection in England and Wales. The objective of the analysis was to assess the cost- utility of SMV/PR versus R (SMV/PR vs PR) for treatment-naive and treatment-experienced patients. This analysis was based on the cost saving of using SMV/PR versus PR for the treatment of patients with HCV genotype 1.

Methods:

The model used a Markov microsimulation approach with a life time of 5 years, and was based on data from published studies, the SAILS trial, and company provided data. The primary outcomes were the costs and QALYs for patients with HCV genotype 1 treated with either SMV/PR or PR. Costs and QALYs were calculated over a lifetime horizon.

Results:

The model predicted that SMV/PR was dominant in treatment-naive and -experienced patients. The cost per QALY of SMV/PR was lower than PR, with a saving of £14,500 per QALY gained. The SMV/PR strategy was associated with a 2.6% increase in survival compared to PR.

Conclusions:

SMV/PR is a cost-effective option to treat HCV patients, regardless of treatment experience.

PIN88

COST-EFFECTIVENESS OF QUADRIVALENT VERSUS TRIVALENT INFANNUVACE IN THE UNITED STATES

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BACKGROUND: Currently used trivalent influenza vaccines (TIVs) contain two strains of influenza A and one strain of influenza B. However, co-circulation of two distinct B lineages and difficulties in predicting which lineage will predominate in the next season has led to frequent B-strain mismatches. Newly registered quadrivalent influenza vaccines (QIVs) include the two B strains and might therefore provide wider protection.

OBJECTIVES: To evaluate the cost-effectiveness of using QIV versus TIV for routine influenza vaccination in the United States (US) during the next 20 years. METHODS: A dynamic transmission model was used to estimate the number of deaths and QALYs averted by QIV compared to TIV in both TN and TE patients in the US. The model predicted vaccination of 50% of the adult population.

RESULTS: Over 20 years, QIV vaccination prevented 13.3 million influenza B cases. According to our model this resulted in a reduction of 113,000 hospitalizations and 13,200 deaths. Moreover, QIV averted 3% of all influenza-related deaths due to quitter disease. When the QIV strategy was compared to TIV, the incremental cost-effectiveness ratio (ICER) was US$29,000 per QALY gained. Economic parameters with highest impact on the ICER were vaccine price, QALY loss due to influenza and probability of hospitalization or death given symptomatic infection. CONCLUSIONS: Introducing QIV into the immunization program of the United States would prevent a substantial number of hospitalizations and deaths. Moreover, cost-effectiveness was shown to be favorable when a cost-effectiveness threshold of US$5,000 is applied.

PIN89

COST-UTILITY ANALYSIS OF DOLUTEGRAVIR COMPARED TO RALTEGRAVIR IN TREATMENT NAIVE AND TREATMENT EXPERIENCED PATIENTS IN SLOVAKIA

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OBJECTIVES: The aim of this exercise is to evaluate the cost-effectiveness of rotavirus vaccines amongst children in Slovakia as part of the National Immunization Program of Slovakia. METHODS: We used a published simple decision tree model about rotavirus disease and the impact of vaccination. The model has been adapted to the Slovakian situation for analyzing the cost-effectiveness of the vaccine among a birth cohort of 160,000 children followed over an at risk period of 5 years. The evaluation of diarrhea events in 3 public hospitals helped to estimate the burden of rotavirus patients confirmed with lab testing during the period from August 2012 to April 2013. The economic analysis was done from 2 perspectives: a health provider and patient. Uni-variate sensitivity analyses were conducted to assess the uncertainty in some of the variables in the model. RESULTS: The evaluation of diarrhea events in the 3 hospitals reported 545 diarrhea patients aged below 5 years old amongst whom 311 or 57% were rotavirus positive. The societal cost to treat a rotavirus diarrhea event was estimated at US $621. Event with the simple model we estimated that with a vaccine coverage rate of 98%, the vaccine may avoid 47,000 rotavirus diarrhea events in the birth cohort over a period of 5 years. The estimated cost offset is around US $2 million. From a health care perspective including only direct medical cost the incremental cost-effectiveness ratio (ICER) with a vaccine price of US $27 per course was US $8,972 per QALY gained. This result is below the Slovakian WHO threshold of US $50,000 is applied. CONCLUSIONS: Introducing QIV into the immunization program of the United States would prevent a substantial number of hospitalizations and deaths. Moreover, cost-effectiveness was shown to be favorable when a cost-effectiveness threshold of US$5,000 is applied.

PIN90

HEALTH ECONOMIC MODEL FOR NOVEL IN VITRO DIAGNOSTIC KIT FOR INFECTIOUS ENDOCARDITIS

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OBJECTIVES: The presented economic model estimates costs and benefits of a new in vitro diagnostic kit for infectious endocarditis (IE), developed by Hutman Diagnostics AG (Basel, Switzerland). The product applies molecular diagnostics to detect bacteria in cardiac tissue. In order to assess the potential financial and health impact of the diagnostic kit (QIV), a Markov microsimulation model was used to assess outcomes for TN and TE patients. The diagnostic kit was evaluated for both diagnostic and therapeutic use as the majority of new IE cases are amenable to effective therapy. Using a Markov microsimulation model with 3 health states (TN, TE, dead) and linked to specific events. The analysis was performed from payer’s perspec- tive in Slovak setting. RESULTS: Over a lifetime, in TN patients the estimated total costs for the DTG strategy compared with the RAL were lower (220,731 vs 222,079€). The savings for DTG are mostly associated to the lower drug acquisition cost and the drug price in the health care setting for DTG was lower than for RAL (€11.23 vs 18.08€). The total lifetime costs were lower for the DTG strategy compared with RAL in TE patients living longer with DTG than with RAL (19.16 years versus 18.30 years). An increment of 0.027 QALYs for DTG was calculated. The ICUR for the DTG strategy relative to RAL was €7,435 per QALY, which is below the threshold of €22,079. This result is below the Slovakian WHO threshold of US $50,000 is applied. CONCLUSIONS: The economic model shows that its specific efficiency, adverse events rates, and cardiovascular risk according to lipid parameters evol- ution; and costs and quality of life values were allocated by CD4+ cell count categories and attached to specific events. The analysis was performed from payer’s perspec- tive in Slovak setting.
The potential cost savings were summarised for a single patient and up-scaled for Switzerland. **RESULTS:** They are estimated to be approximately 9 Mio CHF for Switzerland for all three scenarios. Scenario 2 contributed most with about 6.5 Mio CHF (70%). For a single patient potential savings of about 10k CHF resulted for scenario 1 and 70k CHF for scenarios 2 and 3. The major share of potential savings accrues from the avoidance of productivity losses. **CONCLUSIONS:** Even though these results are preliminary and partly based on assumptions, it is expected that the economic advantages are still attractive even when savings might be partly lower. Nevertheless, it is desirable to verify assumptions and potentials by clinical trials and pilot studies.

**PIN93**

**A MACRO ECONOMIC ANALYSIS OF 65 YEAR-OLD "RENDEZ-VOUS VACCINAL IN FRANCE: WHAT IS THE RETURN ON INVESTMENT?**

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**OBJECTIVES:** Vaccination is the best way to prevent from life-threatening and debilitating infectious diseases that still lead to a huge epidemiological and economic load. The French government and health authorities have recently decided to implement a “rendez-vous” in the vaccination calendar for individuals aged 65 years old, to achieve optimal vaccination coverage rates and improve protection for elderly population against diphtheria, tetanus, seasonal influenza, pneumococcal diseases, pertussis and herpes zoster. The objective of this study was to assess from a governmental perspective the return on investment of the 65 year-old “rendez-vous vaccinal” in France. **METHODS:** A cohort model was developed to compare the mortality, morbidity, lifetime earnings and transfers of a cohort aged 65 with or without vaccination. The incremental total discounted lifetime direct and indirect cost were presented in US Dollars using the average year to date exchange rate (USD 1 = €0.86). A total of 382 HCV-RNA PCR assays were completed to EOT (mean of 7.1 ± 4.11 (SD = 2)) per patient. This was in excess of expected numbers of HCV-RNA assays from SPFIC. It was estimated that adherence to mandated HCV-RNA assays would result in cost savings of approximately €9,000 or €180 per patient treated. **CONCLUSIONS:** There is significant resource utilisation associated with the treatment of HCV patients in a hospital-based setting. Cost savings may be generated by the development of guidance on laboratory monitoring, and careful adherence to decision rule time points. This may have implications for guideline development for monitoring of patients treated with new agents for HCV in the near future.

**PIN94**

**RESOURCE USE AND COSTS FOR MANAGING HCV GENOTYPE 1 PATIENTS IN COLOMBIA FROM THE PAYERS PERSPECTIVE**

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**OBJECTIVES:** To estimate the direct costs of HCV management for genotype 1 patients throughout their lifetime based on the natural history of the disease from payer perspective in Colombia. **METHODS:** Direct costs were estimated from a payer perspective. An approach of the incremental total discounted lifetime direct and indirect cost savings may be generated by the development of guidance on laboratory monitoring, and careful adherence to decision rule time points. This may have implications for guideline development for monitoring of patients treated with new agents for HCV in the near future.

**PIN95**

**INDIRECT COSTS AMONG PATIENTS WITH HEPATITIS C VIRUS**

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**OBJECTIVES:** Payers, including employers, are struggling to balance cost of novel therapies delivered in different health care settings. The goal of this study was to examine the potential benefit of treating patients with Hepatitis C virus (HCV) by evaluating indirect costs during the first year following diagnosis. **METHODS:** Employed patients with HCV were identified from the Truven Health Analytic Health and Productivity Management Database from 2010-2012. Presence and number of days associated with absenteeism (ABS), short-term disability (STD) and long-term disability (LTD) were evaluated among patients with HCV and at least 12 months of follow-up for the year following diagnosis. Costs associated with reduced productivity were monetized using an average hourly wage (ABS) and a proportion of that wage (70% for STD/LTD) and are reported in US$. **RESULTS:** A total of 3,250 patients met the study inclusion criteria (mean age 56 years, 67% male). Availability of productivity data varied - 588 employees had ABS data, 2,175 had STD data and 1,985 had LTD data during year following diagnosis. Of these only at least one of ABS, 21% at least one STD claim and 2% at least one LTD claim. Total ABS costs in the year following the HCV diagnosis were $17,439. Among those with claims, STD costs during year following diagnosis were $42,149 and LTD costs were $50,422. A smaller subset of patients had productivity data available, 27% of patient had 2 year period of productivity losses. **CONCLUSIONS:** Even though these results are preliminary and partly based on assumptions, it is expected that the economic advantages are still attractive even when savings might be partly lower. Nevertheless, it is desirable to verify assumptions and potentials by clinical trials and pilot studies.
room visits and hospital admissions. Logistic regressions were constructed to esti-
mate the predictors for resource utilization, and a two-part multivariable analysis
model was used to determine the total costs of treatment in the UK. RESULTS: Data
on 731 patients receiving SMW with pegylated interferon and ribavirin (PEGIFN/R) or
PEGIFN/R alone were included in the analysis. While MRU was similar between
SMW and PEGIFN/R, treatment group was significantly lower in the SMW
group, compared to the PegIFN/R group (P < 0.05). Body mass index (P < 0.05),
severe fibrosis (P < 0.05), shortened treatment duration from 48 to 24 weeks (P < 0.05),
anemia and rash during treatment (P < 0.001) were identified as predictors of hos-
pitalisation and outpatient visits and as drivers of total costs. Univariate sensitivity
analyses demonstrated that shortened treatment duration and lower occurrence of
rash lead to large cost savings. CONCLUSIONS: This study identified both baseline
and administered antiviral treatment characteristics as drivers of total costs for
HCV patients following antiviral therapy. The shortened treatment duration and
reduction in adverse events due to simprevir treatment lead to extra cost savings
compared to the baseline situation. This study is of interest for any pooling of
patient management and cost-effectiveness implications associated with the choice
of specific antiviral treatments.

PIN97
WHAT EXPLAINS WILLINGNESS TO PAY FOR AVOIDING MORBIDITY RISK DUE TO MALARIA? RESULTS FROM A GLOBAL META ANALYSIS

EXPLORATORY QUESTIONNAIRE TO ASSESS HEALTH-RELATED QUALITY OF LIFE IN PLWHA

INFECTION – Patient-Reported Outcomes & Patient Preference Studies

PERSEVERANCE TO TREATMENT OF CHRONIC HEPATITIS B VIRUS (HBV) INFECTION: A STUDY BASED ON THE FRENCH IMS LIFELINK TREATMENT DYNAMICS (LTD) DATABASE

DEVELOPMENT OF A SURVEY TO QUANTIFY PARENTS’ PRIORITIES FOR VACCINATING CHILDREN AGAINST ROTAVIRUS

CONFIRMATION OF THE FACTOR STRUCTURE OF THE PROQOL–HIV QUESTIONNAIRE TO ASSESS HEALTH-RELATED QUALITY OF LIFE IN PLWHA

HIV is the only specific scale taking into account patient’s experience with treat-
mant. This simplified scoring version will allow researchers and clinicians to better
understand results, new studies and explanatory variables are added (e. g. malaria
incidence rates). More sophisticated regression techniques are employed to deal
with the considerable heteroscedasticity (multiple observations from a single
study). Furthermore, other mosquito-borne diseases (filariais, trypano-
somiasis and onchoceriasis) are included to test between-disease valuation dif-
fferences. METHODS: A systematic literature review was conducted, resulting in
a dataset of 61 studies, yielding 200 data points. A meta-regression model
was estimated. Dependent variable is mean-WTP per treatment per year in 2012 USD
(Purchasing Power Parity and inflation adjusted). The explanatory variables con-
sists of (i) treatment characteristics (service, private/public goods etc.), (ii) meth-
odological characteristics (revealed vs. stated preference, WTP elicitation method,
etc.), and (iii) sample characteristics (age, gender, exposure etc.). RESULTS:
Standardized mean-WTP range is 0.3 USD and 9000 USD. Data is censored over
70% of the observations at zero-values. Preliminary comparisons show that valu-
ation of malaria avoidance is increased positively for altruistic interventions and
negatively for rural samples. The latter is correlated with income- underlying the
vulnerability of poorer people (due to higher exposure). Additionally, we find sig-
ificantly higher WTP to avoid filarialis over malaria. The meta-regression model
explains over 30 percent of observed variation between WTP values. Predictive
power is tested using a jackknife resampling procedure: CONCLUSIONS: Preliminary
findings indicate that policy-makers may not only focus on broader malaria
interventions, with a special focus on rural areas. From a methodological
perspective, meta-regression helps to improve the practice of benefit transfer,
and generate improved predictions for CBA.
monitor and to correlate HBV improvements in patients undergoing different treatment strategies.

**PIN102**

**IMPACT OF SIMEPREVIR VERSUS TELAPREVIR TRIPLE THERAPY FOR CHRONIC HCV genotype 1 infection: a randomized, phase III ATTAIN study.**

**OBJECTIVES:** The purpose of this phase III study was to compare the safety and efficacy of simeprevir versus telaprevir, both with peginterferon/ribavirin (PR), in HCV genotype 1-infected patients who were null or partial responders to prior null or partial PR, with a focus on treatment-emergent adverse events and patient-reported outcomes (PROs) of fatigue, health-related quality of life (EQ-5D), and skin symptoms (Skindex-16) assessed across a 52-week period in the overall population and in prespecified subgroups. **RESULTS:** Compared with telaprevir/PR, simeprevir/PR exhibited reduced adverse events associated with fatigue, reduced EQ-5D scores, and reduced Skindex-16 scores, indicating greater fatigue, depressive symptoms, and daily activities impairment with simeprevir than telaprevir. This study supports the use of simeprevir for treatment-naive patients with genotype 1 infection who are null or partial responders to prior non-sustained treatment with PR.

**CONCLUSIONS:** The differences in the treatment of hepatitis C in Ukraine compared to the best international practice were revealed and considered when developing and technological solutions for health care facilities in Ukraine. **KEYWORDS:** Hepatitis C; Type 1-infected prior null or partial PR responders; simeprevir exhibited better safety and tolerability in this analysis, the impact on patient-reported outcomes (PROs); Patients received simeprevir (150 mg TID) or telaprevir (750 mg TID, 7–9 hrs apart) + PR for 12wks followed by PR alone (36wks) in a double-blind, double-dummy design. **PRO questionnaires,** completed at baseline, throughout treatment and at follow-up, rated fatigue severity (FSS), depression (CES-D), and health-related quality of life (EQ-5D visual analogue scale), and skin symptoms (Skindex-16). During simeprevir/telaprevir treatment, between-treatment mean-value differences were calculated using area-under-the-curve to 36wks (AUC(0-36)) for all measures except Skindex-16 where maximum (worst) scores during the first 12 wks were used. Subgroup analyses evaluated the impact of SVR12, age, fibrosis, and treatment completion. **RESULTS:** Compared with normative studies, baseline PRO scores indicated greater fatigue, depressive symptoms and daily activities impairment. Mean FSS scores in both groups worsened during the first 12 weeks of treatment, remained stable through Week 48 and returned to values close to baseline at 72wks. Clinically relevant between-treatment differences in FSS, CES-D, Skindex-16 and EQ-5D scores indicated less impairment with simeprevir than telaprevir. AUC(0-36) between-treatment differences significantly favoured simeprevir for the EQ-5D and CES-D. **CONCLUSIONS:** These findings provide valuable information on the tolerability of these regimens from the patient perspective.

**PIN103**

**SATISFACTION OF HIV PATIENTS WITH PHARMACY SERVICES IN SOUTH EASTERN HARRISONS HOSPITALS**

**Ezekwue OI**

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**OBJECTIVES:** The greater burden of the HIV infection is felt in sub-Saharan Africa. Nigeria is rated among the first three largest countries with HIV population. Pharmacist play an important role in the care of HIV patients especially by providing pharmaceutical care. Thus it is imperative to assess the experience and satisfaction of patients with pharmacy services rendered. This will ensure that quality care is rendered. The objective of this study was to assess HIV-infected patients' satisfaction with pharmacy services provided in South-Eastern Nigeria's Health Facilities. A secondary aim was to repeat the validation process in order to confirm the initial validation of PSFS questionnaire. **METHODS:** The survey was conducted in 6 HIV/AIDS clinics in South-Eastern Nigeria. Multi-stage sampling technique was used to select the clinics. Re-validation techniques employed include factor analysis, reliability test, and construct validity. The level of satisfaction of the participants was determined. Variance in satisfaction score among the different demographic variables was also assessed. **RESULTS:** The response rate was 81.85%. The Cronbach alpha value was 0.84. The 16 items of PSFS questionnaire resolved into 4 factors as established by the initial validation exercise. Re-validation of the PSFS Questionnaire's construct revealed the same result obtained in the original validation as items that were related showed convergence while items that were not related showed divergence. With the exception of item 12, the average score obtained in the survey was high. Most of the average scores ranged from 4 to 5, signifying that responses ranged from agree to strongly agree. **CONCLUSIONS:** HIV patients were highly satisfied with services rendered by the pharmacists in South-Eastern HCV clinics in Nigeria and PSFS proved to be a reliable and valid instrument for measuring satisfaction of HIV patients with pharmacy services.

**INFECTION – Health Care Use & Policy Studies**

**PIN104**

**KNOWLEDGE OF HIV STATUS OF ADOLESCENTS AND YOUNG ADULTS ATTENDING AN ADOLESCENT HIV CLINIC IN ACCRA, GHANA**

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**OBJECTIVES:** To determine the health status and knowledge of young people aged 15-24 years attending an adolescent HIV clinic in Accra, Ghana. **METHODS:** A cross-sectional study was conducted among 87 adolescents attending an adolescent HIV clinic. Data on demographics, diagnostic information, medication and cost data were extracted. **RESULTS:** Of the 87 participants, 52.9% knew their HIV status, 50.0% were on antiretroviral and 32% of participants were aware that young people their age could fall sick, 91% had heard of HIV, 70% knew that young people could fall sick after being exposed to HIV. The mean age was 16.9 ± 5.0 years and 62% were females. **CONCLUSIONS:** Self-administered questionnaires were used and data were analyzed with SPSS version 16. **RESULTS:** Mean age 16.9 ± 5.0 years and 62% were females. Challenges. Self-administered questionnaires were used and data were analyzed with SPSS version 16. **RESULTS:** Mean age 16.9 ± 5.0 years and 62% were females. Challenges to the management of HIV infection in the adolescent group are dependent on a combination of factors and most practitioners recommend an age and developmentally appropriate approach. Disclosure and awareness of HIV was 91%. There is also the need to support care givers to disclose HIV status and to support young people to adhere to ARTS for best health outcomes. **KEYWORDS:** Knowledge, Disclosure, Adolescents/Young Adults, HIV, Ghana.

**PIN105**

**IMPLEMENTATION OF TECHNOLOGIES BASED ON THE EVIDENCE-BASED MEDICINE AND HTA IN THE MANAGEMENT OF HEPATITIS C**

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**OBJECTIVES:** The health care system of Ukraine is being transformed according to the modern world format. More and more doctors are aware of the need for the use of technologies based on evidence-based medicine, particularly in the management of hepatitis C. **METHODS:** In 2013 the multidisciplinary working group involving professionals and patients developed an adapted clinical guideline, based on HTAs and strategies of evidence-based medicine on the treatment of hepatitis C, and unified protocol “Viral hepatitis C”. **RESULTS:** The differences in the treatment of hepatitis C in Ukraine compared to the best international practice were revealed and considered when developing and technological solutions for health care facilities in Ukraine. **CONCLUSIONS:** These findings provide valuable information on the tolerability of these regimens from the patient perspective.

**PIN106**

**MOELDING THE RELATIONSHIP BETWEEN SUSTAINED VIROLOGIC RESPONSE AND TREATMENT UPTAKE RATES ON FUTURE PREVALENCE AND INCIDENCE OF HEPATITIS C IN THE UK**

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**OBJECTIVE:** Hepatitis C virus (HCV) remains high amongst people who inject drugs (PWID) and accounts for the majority of newly acquired infections. This study aims to quantify the value of treatment amongst PWID with new direct-acting antivirals (DAA) in terms of future reductions in infection prevalence and uptake were compared to anticipated sustained virologic response (SVR) rates of 90–100% and increased uptake over varied horizons. **CONCLUSIONS:** Provision of changes in treatment strategies, and uptake were compared to anticipated sustained virologic response (SVR) rates of 90–100% and increased uptake over varied horizons. **RESULTS:** The multivariate analysis and the algorithms of patient’s identification.

**Key Words:** Hepatitis C; Type 1-infected prior null or partial PR responders; simeprevir exhibited better safety and tolerability in this analysis, the impact on patient-reported outcomes (PROs) of fatigue, health-related quality of life (EQ-5D), and skin symptoms (Skindex-16). During simeprevir/telaprevir treatment, between-treatment mean-value differences were calculated using area-under-the-curve to 36wks (AUC(0-36)) for all measures except Skindex-16 where maximum (worst) scores during the first 12 wks were used. Subgroup analyses evaluated the impact of SVR12, age, fibrosis, and treatment completion. **RESULTS:** Compared with normative studies, baseline PRO scores indicated greater fatigue, depressive symptoms and daily activities impairment. Mean FSS scores in both groups worsened during the first 12 weeks of treatment, remained stable through Week 48 and returned to values close to baseline at 72wks. Clinically relevant between-treatment differences in FSS, CES-D, Skindex-16 and EQ-5D scores indicated less impairment with simeprevir than telaprevir. AUC(0-36) between-treatment differences significantly favoured simeprevir for the EQ-5D and CES-D. **CONCLUSIONS:** These findings provide valuable information on the tolerability of these regimens from the patient perspective.

**PIN107**

**PRESCRIPTION PRACTICES FOR UNCOMPILCATED MALARIA AT TWO PUBLIC HEALTH FACILITIES IN NIGERIA; A DESCRIPTIVE, COMPARATIVE STUDY**

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**OBJECTIVES:** Poor adherence to treatment guidelines undermines the goals of malaria treatment with implications for worsening malaria burden. This study analyzed the diagnostic and prescription practices for uncomplicated malaria at two public health facilities in Nigeria, to assess the current state of compliance to policy. **METHODS:** Retrospective audit of patients’ records for uncomplicated malaria was carried out at a primary/secondary and tertiary health facility. **RESULTS:** From the two facilities were analyzed and compared for similarities and
systematic differences, and conformity to malaria treatment policy, in terms of use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Results:** Evidence suggest high rate of compliance to policy on the use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Conclusion:** Evidence suggest high rate of compliance to policy on the use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Objective:** To estimate the cost-effectiveness of a strategy of switching the treatment policy to protease inhibitor monotherapy (PIM) with prompt return to combination therapy in the event of viral load rebound compared to continuation of the ongoing triple therapy (OTT) in the long-term management of HIV patients.

**Methods:** Within trial cost-effectiveness analysis and modelling of life-time cost-effectiveness based on a randomised controlled trial of Protease Inhibitor monotherapy Versus Ongoing Triple-therapy (PIVOT). The setting was HIV outpatient care in the UK National Health Service and the trial involved 587 patients, aged 18 years or more, who achieved sustained virological suppression and have a CD4+ cell count >100 cells/mm³. Outcomes were NIHs costs (2012 UK Pounds Sterling) and quality-adjusted life-years (QALY) with comparative results presented as incremental cost-effectiveness ratios (ICERs).

**Results:** Overall, PIM was associated with an incremental life-time cost of £18,478 per QALY gained compared to OTT (PIM vs. OTT) and a 18% reduction in the ART drug costs while being no less effective in terms of QALYs in the within trial analysis and only marginally less effective with modelling. In the base-case within trial analysis, the incremental total cost was £5,959 (95% confidence interval: £7,418.84 to £€-4,429.38) and the incremental QALY was 0.0051 (95% confidence interval -0.0479 to 0.0582) making FIM dominant compared to OTT. Multiple sensitivity analyses were conducted to test the assumptions of baseline data, drug costs, missing data, trial protocol driven costs and mortality. In all sensitivity analyses, FIM was cost-saving and no marked difference in QALY was observed. Modelling of life time costs and QALYs showed significant cost-savings and marginally less effectiveness such that switching to PIM appeared cost-effective at accepted cost-effectiveness thresholds.

**Conclusions:** The results suggest that PIM is a cost-effective treatment strategy compared to OTT for HIV-1 infected patients who have achieved sustained virological suppression.

**Conclusion:** Evidence suggest high rate of compliance to policy on the use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Results:** Evidence suggest high rate of compliance to policy on the use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Conclusion:** Evidence suggest high rate of compliance to policy on the use of ACT as first line treatment for uncomplicated malaria but there is significant scope for further improvement in the use of ACT as initial treatment, particularly in the context of level of implementation of existing guidelines. There were significant variations in treatment practices between the two facilities.

**Objective:** To estimate the cost-effectiveness of a strategy of switching the treatment policy to protease inhibitor monotherapy (PIM) with prompt return to combination therapy in the event of viral load rebound compared to continuation of the ongoing triple therapy (OTT) in the long-term management of HIV patients.

**Methods:** Within trial cost-effectiveness analysis and modelling of life-time cost-effectiveness based on a randomised controlled trial of Protease Inhibitor monotherapy Versus Ongoing Triple-therapy (PIVOT). The setting was HIV outpatient care in the UK National Health Service and the trial involved 587 patients, aged 18 years or more, who achieved sustained virological suppression and have a CD4+ cell count >100 cells/mm³. Outcomes were NIHs costs (2012 UK Pounds Sterling) and quality-adjusted life-years (QALY) with comparative results presented as incremental cost-effectiveness ratios (ICERs).

**Results:** Overall, PIM was associated with an incremental life-time cost of £18,478 per QALY gained compared to OTT (PIM vs. OTT) and a 18% reduction in the ART drug costs while being no less effective in terms of QALYs in the within trial analysis and only marginally less effective with modelling. In the base-case within trial analysis, the incremental total cost was £5,959 (95% confidence interval: £7,418.84 to £€-4,429.38) and the incremental QALY was 0.0051 (95% confidence interval -0.0479 to 0.0582) making FIM dominant compared to OTT. Multiple sensitivity analyses were conducted to test the assumptions of baseline data, drug costs, missing data, trial protocol driven costs and mortality. In all sensitivity analyses, FIM was cost-saving and no marked difference in QALY was observed. Modelling of life time costs and QALYs showed significant cost-savings and marginally less effectiveness such that switching to PIM appeared cost-effective at accepted cost-effectiveness thresholds.

**Conclusions:** The results suggest that PIM is a cost-effective treatment strategy compared to OTT for HIV-1 infected patients who have achieved sustained virological suppression.
varicella cases for 75% and 65% VE-DE was respectively 73.9%/71.3% by year 30 and 65%/61.6% by year 80. When the coverage was 75%, the reduction in number of varicella cases was 62.2%/58% by year 30 and 55.0%/52.2% by year 80 for VE-DE of 75% and 65%, respectively. CONCLUSIONS: The coverage of varicella vaccination is an important factor affecting the number of varicella cases when long term interval between two doses is considered. This is a more influential factor on predicted cases than the first dose efficacy.

**PIN114 HERPES ZOSTER-RELATED HEALTH CARE RESOURCE UTILIZATION IN PATIENTS IN 5 EUROPEAN COUNTRIES.**

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OBJECTIVES: To examine herpes zoster-related health care resource utilization in hematologic (HM) or solid tumor malignancy (STM) patients seeking care at primary-care practices in 5 European countries. METHODS: Longitudinal primary-care databases (Cegedim Strategic Data) in France, Italy, Germany, Spain, and United Kingdom (UK) were analyzed retrospectively (2007–2012). Patients with HM or STM diagnoses were followed for a subsequent first herpes zoster (HZ) diagnosis (index date), up to 30 days after the index. Patients were matched on age, gender, comorbidities, and health care resource utilization (office visits, specialty referrals, laboratory tests, and prescriptions) at pre-index to patients with a non-HZ (HM and STM) patients using propensity scores based on demographics and relevant clinical characteristics. Patients were observed for 6 months pre-index (baseline) and 6 months post-index. Demographics, comorbidities, pharmacotherapy, and health care resource utilization (office visits, specialty referrals, laboratory tests, and prescriptions) were reported with statistical significance set at p≤0.05. RESULTS: HZ patients meeting selection criteria across all 5 countries included 307 HM and 4317 STM. Mean ages ranged from 62.5 ± 15.5 years (UK) to 71.8 ± 11.5 (France), female gender varied from HM from 49% (UK) to 58% (Germany), and STM 56% (UK) to 63% (France). Case and control populations were well balanced at baseline. Office visits per patient were significantly higher for index point index for HZ cohorts across all countries and malignancy types (except Spain HM), ranging from 0.5 more visits (Spain-STM, p = 0.009) to 2.8 more (UK-HM, p < 0.001). Significantly more HM patients had post-index specialty referrals (France-STM, 2.6% more, p < 0.05; Germany-STM, 4.8% more, p < 0.012), and significantly more HM patients received prescriptions post-index in all cohorts across all countries, varying from 19.2% more patients (Spain-STM, p < 0.001) to 47.3% (UK-HM, p < 0.001). Significantly more HZ patients received laboratory testing, ranging from 3.2% more patients (Italy-HM, p = 0.006) to 11.4% (UK-HM, p < 0.003). CONCLUSIONS: Significantly higher health care resource use was incurred by HZ-affected HM and STM patients within 6 months of HZ diagnosis for office visits, specialty referrals, laboratory testing, and outpatient prescribing compared with matched controls across 5 European countries.

**PIN115 USE OF HOSPITAL SERVICES BY HIV PATIENTS, 2012.**

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OBJECTIVES: Information on the pattern of health services use by HIV positive patients is important for understanding their health status and comparing resource utilization across 5 European countries. Information on the pattern of health services use by HIV positive patients seeking care within 6 months of HZ diagnosis for office visits, specialty referrals, laboratory tests, and prescriptions was obtained from health care administrative databases in France, Germany, Spain, and United Kingdom (UK) for this online survey between October 2012 and May 2013. Demographics, employment status, morbidities and influenza vaccination history were collected for all household members. During follow-up, households were surveyed fortnightly on survey, approximately 1/3 of adult ILIs were related to prior household child infections or blood stream infections from a pool of “at-risk” patients defined as patients with or on health care professionals. In addition, they will suffer from substantial health problems when getting an infection. This contribution examines the health care costs of German centers to implement strategies to stem nosocomial infections and the spread of MRSA. METHODS: Relying on a decision tree analysis, the expected health care cost per capita is calculated for three strategies: (i) general screening, (ii) risk-based screening, both on admission, and (iii) risk-based screening at time of discharge. To handle uncertainty, multivariate sensitivity analyses are performed. RESULTS: From the perspective of a rehabilitation center, the third strategy yields the lowest expected cost (606€) at 11 years one of the highest cost. This last year is robust with respect to sensitivity analysis. Thus, cost savings due to a lower number of MRSA infections are not sufficient to offset the cost of the test and further prevention measures applied to individuals with a positive result. CONCLUSIONS: In Germany, rehabilitation centers are reimbursed by daily rates. As a result, they receive no extra fees for prevention measures. As our analysis demonstrates, this implies the incentive to implement MRSA screening to be too weak. Hence, MRSA prevention measures that would be beneficial to society will not be undertaken. Our results can be used to indicate changes in the remuneration system that would provide rehabilitation centers with an appropriate incentive for MRSA prevention.

**PIN118 ESTIMATING THE DIRECT MEDICAL COST, LENGTH OF STAY AND IMPACT OF REIMBURSEMENT CHANGE ON HEALTH CARE ASSOCIATED INFECTIONS.**

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OBJECTIVES: In 2008, the Centers for Medicare and Medicaid Services discontinued reimbursement for health care associated infections (HAIs) not reported to be present-on-admission (POA). The study objectives were to examine: (1) the impact of this reimbursement change on hospital-level HAI rates; and (2) the differences in total direct medical costs and length of stay (LOS) between patients with HAI (cases) and without HAI (controls). METHODS: We conducted a retrospective, interrupted time series analysis using the Nationwide Inpatient Sample obtained from the Health Care Cost and Utilization Project database for years 2006 to 2010. The primary outcome was diagnosis of HAI, identified based on ICD-9-CM codes for sepsis, pneumonia, surgical site infections, catheter-associated urinary tract infections or blood stream infections from a pool of “at-risk” patients defined as ≥ 18 years of age, without a diagnosis of cancer, HIV/AIDS or immunocompromised condition. Patients with an LOS ≥ 2 days were excluded to avoid inclusion of patients with pre-existing infections. Differences in total direct medical costs and LOS of propensity score-matched cases and controls were assessed using Wilcoxon signed-rank tests. RESULTS: The HAI rate was higher in the “at-risk” population (12.35 vs. 2.83 per 100 admissions) than in the total inpatient population, ≥ 18 years of age. Discontinuation of reimbursement for HAI was associated with a 0.37 point (p = 0.0064) decrease in HAI rate per 100 admissions for ’at-risk’ patients. Compared to control cases, HAI cases had significantly higher LOS and total direct medical costs ($15,313 ± 17,470 vs. $21,561 ± 31,718, p < 0.0001) and a higher mean LOS (7.1 ± 6.5 vs. 10.2 ± 11.3 days, p < 0.0001). CONCLUSIONS: Total direct medical costs and LOS were higher for patients with HAI compared to those without HAI. Policy changes in the reimbursement of HAI cases made in 2008 showed a reduction in the rate of HAI’s in the “at-risk” population.

**PIN119 EVALUATION OF THE EFFECTIVENESS OF IMPLEMENTING AN ANTIMICROBIAL STEWARDSHIP PROGRAM IN A MEDICAL CENTER IN TAIWAN.**


Wang Fung Hospital, School of Pharmacy Taichung Medical University, Taichung, Taiwan.
OBJECTIVES: To evaluate the effectiveness of an antimicrobial stewardship program in a tertiary care hospital. A program was started in November 1, 2012, and pharmacists would intervene when antimicrobial agents, including levofloxacin, ticlopidan, meropenem, tigecycline and piperacillin/tazobactam, were used for more than 7 days. Inpatients who previously received any one of these antimicrobial agents (within 30 days prior to the study) and whose episode was on a phase 1 and 2 were included (phase 1: 2011/1 to 2013/10, phase 2: 2013/11 to 2013/10/31). RESULTS: A total of 8,781 patients were included. 4,571 patients were in phase 1 and 4,210 were in phase 2. The most prevalent indications for antibiotic use were respiratory infections, wound infections and other infections. The antibiotic cycle of 7 days in phase 1 was significantly decreased from 224.08 DDD to 188.89 DDD as comparing with phase 1. The DDDs of each agent in phase 2 were also significantly decreased as comparing with phase 1. After the program implementation, the expense of antibiotics, duration of hospital stay were all significantly decreased. The readmission rate in 30 days did not differ between the two phases. CONCLUSIONS: The implementation of antimicrobial stewardship program was effective in reducing the amounts of antibiotics usage, and it may replace the inappropriate use of antibiotics, shorten the duration of therapy and save medical expense without affecting quality of care in term of readmission rate.

PIN120
ARE ANTIBIOTIC POLICIES AND REIMBURSEMENT DECISIONS ALIGNED? Schap LC1, Connolly P1,2
1University of Groningen, St Pex, Switzerland, 2University of Groningen, Groningen, The Netherlands

OBJECTIVES: According to the World Health Organization, the emergence of resistant organisms has rendered antibiotic ineffectiveness in some settings (1). In an attempt to address current and future unmet needs in this area innovative antibiotics are being developed. We conducted a review of recent HTA evaluations for antibiotics to examine whether policy indicators in the HTA of antibiotics are reflected in reimbursement decisions. METHODS: The guidance directories of the Scottish Medicines Consortium (SMC), All Wales Medicines Strategy Group (AWMSG) and the National Institute for Health and Care Excellence (NICE) were reviewed for assessments of antibiotics, from 2000 until May 2014. Data relating to each assessment were extracted. A simple scoring system for the reimbursement decisions by the SMC and AWMSG was adopted: where a “positive” reimbursement decision scored 3; “Rejected” scored 1. “Not yet reviewed” scored 0 and “Rejected” scored -1. Results were plotted to show the positioning of reimbursement decisions of AWMSG in relation to SMC. RESULTS: A total of 18 antibiotics were identified as having been assessed by either SMC or AWMSG. Of these 18 products, only 2 were assessed by NICE, and a further 2 were the subjects of “Evidence Review Summaries”, product overviews that are not legally binding. Of the 18 antibiotics identified, only 3 and 2 received “Positive” reimbursement decisions by the SMC and AWMSG respectively. Of the four antibiotics that were assessed by both SMC and AWMSG, of which several rejections were due to pharmaceutical companies not submitting dossiers to the regulatory body. Scatterplots of SMC and AWMSG scores captured six antibiotics in the top right quadrant. CONCLUSIONS: This study demonstrates the different assessment approaches by each regulatory body for antibiotics. Moreover, the low number of antibiotics reviewed highlights that the dearth of new, innovative antibiotics are not in keeping with policies to develop innovative antibiotics.

PIN121
ANALYSES ON TEMPORAL AND SPATIAL CLUSTERING AND CHANGING TREND OF HCV IN MAINLAND OF CHINA Guo Y1, Sun H.Q.1, Yu S.C.1, Ma Q.J.1, Xiao G.X1, Yu S.C.2
1Chinese Center for Disease Control and Prevention, Beijing, China, 2China National Center For Food Safety Risk Assessment, Beijing, China

OBJECTIVES: Analyzing population distribution, temporal and spatial clustering, and changing trend of Hepatitis C Virus (HCV) infection in mainland China; temporal clustering in 2011 and 2013; geographic variations that north, southwest, and west were among the regions where higher numbers were found. RESULTS: This is the first time to correctly estimate newly-infected HCV cases using back-calculation method. The incidence of HCV infection in China between 2005 and 2013 was nearly 3.4 million. While 57.8% of the estimated newly-infected cases were male, cases of 30 to 39 years old were the group with the highest newly-infected cases. The estimated incidence rate was 6.93, 3.04, 2.82 and 2.85 million per year for four regions respectively. The incidence showed geographic variations that north, southwest, and west were among the regions where higher numbers were found. CONCLUSIONS: This is the first time to correctly estimate newly-infected HCV cases using back-calculation method. 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MANAGED-ENTRY AGREEMENTS: POSSIBLE OPTIONS FOR VACCINES?
Baron-Papillon F1, Easley C1, Saint Sardos C1, Lucas F1
1Sanofi Pasteur MSD, LYON, France, 2Pope Woodhead & Associates Ltd, St. Ives, UK

OBJECTIVES: Vaccines face increasing reimbursement and access challenges in many European markets. Decision makers are facing uncertainties in terms of budget impact planning, vaccines' expected impact and vaccination implementation. This has led to major delay in the population access to vaccination, and to commoditization of some vaccinations. However, innovation in vaccines access has been more limited than for pharmaceuticals, where there is a longer history of adapting to pricing and access pressure. Building on the experience of managed entry agreements (MEAs) used for drugs, the project aimed to develop a framework of MEAs and value-added services specifically applicable to vaccines.

METHODS: Literature and web searches were performed to document MEA taxonomy and identify real world European MEA examples for pharmaceuticals and vaccines. This was followed by an on-line/telephone survey with SPMSD access professionals in 14 countries to access unpublished information and assess the acceptability of different MEA types across Europe. Outputs were developed into a vaccines specific MEA framework and guidance for implementation.

RESULTS: To date, there is very little experience with vaccine MEAs in Europe; however, interesting value-added service examples were identified (e.g. educational campaign support). The vaccine-specific MEA framework developed (aligned with current taxonomy) focused on financial schemes (e.g. staggered entry approaches, volume-based discounts, price-volume agreements), coverage with evidence development and value-added services (e.g. vaccination implementation support). Pay-for-performance MEAs were less applicable. Budget holder feedback in selected countries confirmed their interest in co-creating such MEA/service approaches with vaccine companies.

CONCLUSIONS: To enable decision makers to continue investing in innovative vaccines that address public health needs, a shift towards new value-based acquisition models is key. A broader, more flexible approach to vaccines access, including MEAs, can address the needs of budget holders and other external stakeholders as well as manufacturers.
DISCLOSURE INFORMATION

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ABSTRACTS

ISPOR 6TH ASIA-PACIFIC CONFERENCE ABSTRACTS

RESEARCH PODIUM PRESENTATIONS – SESSION I

CANCER OUTCOMES RESEARCH STUDIES

CN1
TREATMENT STRATEGIES FOR STAGE IB CERVICAL CANCER: A COST-EFFECTIVENESS ANALYSIS
Lee YK, Kim JW
Seoul National University, Seoul, South Korea

OBJECTIVES: To access the cost-effectiveness of two common strategies and alternative, higher value strategy for patients with stage IB cervical cancer. METHODS: A Markov state transition model was constructed to compare three strategies: (1) radical hysterectomy followed by tailored adjuvant therapy (RH+TA); (2) primary chemotherapy (pCCRT)+Taigra strategy, in which patients without risk in pre-operative MRI undergo primary surgery and those with any risk factor in MRI undergo primary CCRT. All relevant literature were identified to extract the probability data. Direct medical costs were estimated from Korean National Health Insurance database. Costs were calculated using incremental cost per year of life saved (YLS). RESULTS: RH+TA strategy was the least expensive strategy. Although pCCRT strategy had similar outcomes, pCCRT strategy was more expensive than RH+TA ($10,945 vs. $7,257). A sensitivity analysis showed that RH+TA is cost-effective than pCCRT when the percentage of patients who require no adjuvant therapy after radical hysterectomy exceeds 30%. Taigra strategy was more expensive and more effective, with an incremental cost-effectiveness ratio (ICER) of $95,271 per year of life saved (YLS) compared to RH+TA. RESULTS are relatively sensitive to variation in how the rate of patients who require adjuvant therapy after surgery decrease in MRI-based strategy. CONCLUSIONS: RH+TA is cost-effective than pCCRT in Stage IB cervical cancer. MRI-based strategy has potential to be cost-effective when compared to RH+TA at high test performance and at the lower range of test costs.

CN2
COST-EFFECTIVENESS ANALYSIS OF COMPUTED TOMOGRAPHIC COLONOGRAPHY VERSUS DOUBLE CONTRAST BARIUM ENEMA FOR INVESTIGATION OF SYMPTOMS OF COLORECTAL CANCER: ECONOMIC EVALUATION ALONGSIDE THE SIGGAR TRIAL
Zhu S1, Yao G2, Halligan S3, Atkin W4, Dadswell E4, Wooldrage K4, Lilford RJ5
1University of Birmingham, Edgbaston, Birmingham, UK; 2University of Southampton, Southampton, UK; 3University College London, London, UK; 4Imperial College London, London, UK; 5University of Warwick, Coventry, UK

OBJECTIVES: To assess costs and cost-effectiveness of CTC compared with BE in patients with symptomatic colorectal cancers from the UK NHS perspective. METHODS: A Markov model with Monte Carlo simulation was developed to assess the costs, life years and quality adjusted life years associated with CTC vs. BE in patients with symptoms suggestive of bowel cancer. The initial diagnostic findings, follow up investigations for suspected colorectal lesions, confirmed diagnoses, and resources used were estimated from individual patient data from the SIGGAR trial. We extrapolated the trial results over a patient’s lifetime. Transition probabilities among small poly, large poly and different stages of cancer, and the costs and utilities associated with each state, were derived from the literature. Outcomes were measured as incremental cost per life year saved and incremental cost per quality adjusted life year (QALY) gained. Probabilistic sensitivity analysis was conducted across key input values. RESULTS: The Mean life time costs required to reach a diagnosis were £558 and £718 for BE and CTC trial arms respectively leading to a mean difference of £61 for each patient having a diagnostic test. The discounted life years obtained were 9.943 and 9.975, and (discounted) QALYs were 8.900 and 8.938 for BE and CTC respectively leading to a 0.032 life years, 0.038 QALYs advantaged for CTC. The incremental costs per life year gained was £1,856 (£1,133 without discounting), and per QALYs gained at £1,598 (£969 without discounting) for CTC. CONCLUSIONS: This model captured the clinical and economic values of crizotinib for ALK+ NSCLC patients in Thailand. Nevertheless, humanistic value should be taken into account and still needs to be explored.

CN3
BUDGET IMPACT ANALYSIS OF CRIZOTINIB TREATMENT IN ALK+ NON-SMALL-CELL LUNG CANCER PATIENTS IN THAILAND
Permawanun U1, Petchcharipun S1, Thongprasert S2
1Chiang Mai University, Chiang Mai, Thailand; 2Pfizer (Thailand) Ltd., Bangkok, Thailand

OBJECTIVE: Crizotinib, a first-in-class compound that specifically inhibits a tumor-specific protein called anaplastic lymphoma kinase (ALK) of non-small-cell lung cancer (NSCLC) is currently not reimbursable to all Thai patients. This budget impact analysis was aimed at examining the financial impact if crizotinib was subsidized for all identified ALK+ NSCLC patients in Thailand. METHODS: A 3-year Markov model is designed to capture differences in outcomes related to the overall direct costs incurred from receiving crizotinib versus other standard therapies for 1st, 2nd and 3rd lines of care. Local incidence of NSCLC and ALK+ rate were estimated from the national registry data and Chiang Mai University (CMU) Hospital data. The government procurement database was the reference for the drug cost. Other specific medical costs came from CMU Hospital. Cost attributable to prerequisite diagnostic testing was also incorporated into the model. RESULTS: An estimated 5,377 new cases were diagnosed as advanced NSCLC nationally and referred for further testing prior to receiving therapy. The net budget impact was estimated under two scenarios. In the first scenario where crizotinib was subsidized with no restriction, the average net budgetary impact in the 3-year period was 576 million baht (US$18 million) from the average 414 patients receiving crizotinib yearly. The second scenario where crizotinib was restricted with no restriction, the average 3-year financial difference was 284 million baht (US$9 million) from the average 214 patients receiving crizotinib yearly. Univariate sensitivity analysis showed that crizotinib acquisition cost and prevalence of ALK+ were the leading parameters influencing the results of the first and second scenarios, respectively. CONCLUSIONS: This model captured the clinical and economic values of crizotinib for ALK+ NSCLC patients in Thailand. Nevertheless, humanistic value should be taken into account and still needs to be explored.

CN4
STUDY ON THE DIRECT MEDICAL COST OF MALIGNANT NEOPLASMS INPATIENTS WITH URBAN BASIC HEALTH INSURANCE SCHEME IN CHINA
Yong M1, Xianjun X1, Jinghu L2, Jie Z3, Yunyun F4
1Beijing University of Chinese Medicine, Beijing, China, 2China Health Insurance Research Association, Beijing, China

OBJECTIVES: By estimating the direct medical cost of malignant neoplasms inpatients with urban basic health insurance scheme(UBHIS) in 2011 in China, we try to provide evidence for the government to manage the illness more effectively. METHODS: A nationwide, cross-sectional sampling of malignant neoplasms inpatients with UBHIS was conducted from the China Health Insurance Research Association claim database. A retrospective analysis was adopted and all results were extrapolated to the whole country according to the scale of the population, economic and other factors in the sample cities. RESULTS: The visits of malignant neoplasms inpatients, accounted for 7.64% of total visits, were 2.92 million. The rank of main malignant neoplasms inpatients were lung cancer, breast cancer, gastric cancer, rectum cancer, colon cancer and liver cancer, which accounted for 54.09% in all malignant neoplasms inpatients. The hospitalization expenses of malignant neoplasms inpatients was 42.61 billion yuan, as the top costs, which accounted for 13.59% in all hospitalization expenses; the proportion of the above six kinds of cancer costs was 52.60% (22.16 billion yuan) in all hospitalizations expenses of malignant neoplasms inpatients. The average hospitalization expenses of each visit was 14,594 yuan (14,513 yuan in 2010), the average hospitalization expenses of every day was 914 yuan (increasing by 8.7% from 2010). The composition of hospitalization expenses: drugs 53.85%, diagnosis and treatments 39.00%, medical consumables 7.15%. Reimbursement by UBHIS was 69.34% (66.44% in 2010), about 29.55 billion yuan. CONCLUSIONS: Cancer brought large disease burden in China, particularly six kinds of cancer mentioned above have much hospitalization expenses. The reimbursement by UBHIS added 3% from 2010 to 2011, reducing the economic burden of malignant neoplasms inpatients. However, for the poor, the personal burden is still a problem. China has launched supplemental insurance for catastrophic health expenditure, relieving the burden of disease constantly.

DIABETES OUTCOMES RESEARCH STUDIES

DB1
IMPACT OF GLP-1RA ON HEART RATE, BLOOD PRESSURE AND HYPERTENSION AMONG TYPE 2 DIABETES: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS
Li T1, Wu S1, Chai S1, Yang Z1, Yu K1, Zhan S1
1Peking University Health Science Center, Beijing, China, 2Capital Medical University, Beijing, China, 3Tianjin Fifth Central Hospital, Tianjin, China

OBJECTIVES: The objective of this study was to conduct a systematic review and network meta-analysis of randomized controlled trials of GLP-1 receptor agonists (GLP-1 RAs) for the pharmacological treatment of hypertension in patients with type 2 diabetes mellitus. METHODS: Relevant studies were identified using electronic databases and studies’ references. The primary outcome was blood pressure (BP), as measured by average reductions in systolic blood pressure (SBP) and diastolic blood pressure (DBP). Secondary outcomes included heart rate (HR), as measured by average reductions in heart rate (HR). RESULTS: A total of 9 RCTs involving 5,958 participants were included. The mean baseline SBP and DBP were 141 mmHg and 90 mmHg. The mean reductions in SBP and DBP were 6.0 mmHg and 5.3 mmHg, respectively. The mean reductions in HR were 3.9 beats per minute. CONCLUSIONS: GLP-1 RAs significantly decrease blood pressure and heart rate in patients with type 2 diabetes mellitus, thereby improving cardiovascular risk. Further studies are needed to investigate the long-term effects and side effects of GLP-1 RAs.
OBJECTIVES: To synthesize current evidence of the impact of glucagon-like peptide-1 (GLP-1 RA) on heart rate, blood pressure and hypertension.

METHODS: Meta-analysis of available RCTs comparing GLP-1 RA with placebo and other active anti-diabetic drugs among patients with type 2 diabetes. Weighted mean differences between trial arms for changes in heart rate and blood pressure, and odds ratios of hypertension were calculated, after a meta-analysis of 8074 patients (PCI) from 279 randomized controlled trials (RCT), 5 randomized controlled trials (NRCT) and 9 studies where patients switched from animal insulin to human insulin (SW).

RESULTS: A total of 597 publications were retrieved and 21 studies were identified for inclusion, including 7 randomized controlled trials (RCT), 5 non-randomized controlled trials (NRCT), and 9 studies where patients switched from animal insulin to human insulin (SW). In the analyses of RCTs, human insulin also had lower odds of local swelling and induration (RR: 0.29 [0.15, 0.56] for RCT, 0.66 [0.51, 0.86] for NRCT and 0.27 [0.11, 0.67] for SW). In the meta-analysis of the associations between GLP-1RA, conventional anti-diabetic drugs and placebo on heart rate, blood pressure and hypertension, GLP-1 RA was associated with a slight increase in heart rate, modest reduction on blood pressure, yet no significant association with hypertension. However, further evidence is necessary for more conclusive inferences on mechanisms underlying the rise in heart rate and the reduction in blood pressure.

DB2 Efficacy and Safety of Human Insulin Versus Animal Insulin Among Patients with Diabetes in China: A Meta-Analysis

Zhang Y1, Wang K2, Liu L2
1China Pharmaceutical University, Nanjing, China, 2Eli Lilly Suzhou Pharmaceutical Co., Ltd., Shanghai, China

OBJECTIVES: There have been controversies on the efficacy and safety of human insulin compared to animal insulin. The aim of this study was to compare the efficacy and safety between human and animal insulin among Chinese patients. METHODS: A systematic literature search with key terms for identifying studies on human and animal insulin among Chinese population using MEDLINE, China National Knowledge Infrastructure, Chinese Scientific Journals Database, Wan Fang database and Chinese Biological Medical Database. For each clinical outcome, meta-analysis was conducted when enough number of studies (≥3) meet inclusion criteria. Mean difference (MD) and risk ratio (RR) were pooled for continuous and count measures, respectively. RESULTS: A total of 597 publications were retrieved and 21 studies were identified for inclusion, including 7 randomized controlled trials (RCT), 5 non-randomized controlled trials (NRCT), and 9 studies where patients switched from animal insulin to human insulin (SW). Compared with animal insulin, human insulin was associated with significantly less daily dose, with MD/UI (CI) of [9.67] (-12.3, 31.99) for RCT, [1.69] (-10.51, 13.9) for NRCT, and [-10.06] [-14.79, 5.3] for SW, as well as lower incidence of hypoglycemia with RR of 0.29 [0.15, 0.56] for RCT, 0.66 [0.51, 0.86] for NRCT and 0.27 [0.11, 0.67] for SW. In the analyses of RCTs, human insulin also had lower odds of local swelling and induration (RR: 0.29 [0.15, 0.56]) while the incidence difference of allergy was not statistically significant (RR: 0.09 [0.02, 0.39]). In addition, patients had significantly lower body mass index (BMI) (MD: -0.17 [-0.26, -0.09]) and 68.6% vs. 52.6%, and for those without dislipidemia. The proportion of females in the two groups were similar, with 68.6% vs. 52.6%. Smoking 13% vs. 15.9%, and drinking 16.1% vs. 22.3%, respectively. Moreover, hypertension patients with dislipidemia had slightly higher obesity (5.7% vs. 16%), grade 3 hypertension (21.0% vs. 19.1%), fasting blood glucose (16.3% vs. 30%) and cardiovascular events rate (9.3% vs. 8.4%). CONCLUSIONS: Hypertension patients with dislipidemia had more risk factors for cardiovascular disease than patients without dislipidemia.

DB4 Clinical Characteristics Among Hypertension Patients With Dislipidemia in Shanghai, China

Xu S1, Yang H2, Zhao Y2, Xu P1, Zhie Y2, Shi Q2, Jeffers B2, Liu L1
1Bureau of Health, Minhang District, Shanghai, China, 2Centers for Disease Control and Prevention, Minhang District, Shanghai, China

METHODS: We used the data of China’s Medical Data Center (IMDC), which provides health insurance claims data with linked health check-up data of 1.7 million members from health insurance societies in Japan. Since the data is not based on randomized controlled trials, we adjusted confounding factors using propensity score analysis. Through the examination, we found that the propensity score was well modeled by logistic regression including following four variate: age, square of age, level of medical cost before index time and square of log of medical cost before index time.

RESULTS: As a result of our research, we estimated the annual incidence of heart rate instead of GLP-1, and the proportion of patient with systolic hypertension increased from 29.8% to 30.8%, and the proportion of patients with high blood pressure increased from 29.8% to 43.1%. This was a significant increase in the proportion of patients on statins after PCI.

CONCLUSIONS: Patients who underwent PCI had significant prior comorbidities and risk factors of cardiovascular diseases. There was a significant increase in the proportion of patients on statins after PCI.

Drug Use Studies

DU1 TREATMENTS PRIOR TO AND POST PERCUTANEOUS CORONARY INTERVENTION (PCI) IN CHINA

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OBJECTIVES: To synthesis current evidence of the impact of glucagon-like peptide-1 receptor agonists (GLP-1 RA) on heart rate, blood pressure and hypertension. GLP-1 RA was associated with a slight increase in heart rate, modest reduction on blood pressure, yet no significant association with hypertension. However, further evidence is necessary for more conclusive inferences on mechanisms underlying the rise in heart rate and the reduction in blood pressure.

Economic Analysis Using Real World Data: Medical Cost Reduction of Combination Drugs

Iwasaki K, Kogo N, Dei M

OBJECTIVES: This study aims to have a trial calculation on the medical cost reduction for the patient group prescribed the combination drug of ARB and calcium antagonist (a Combination Drug Group) against the patient group prescribed the combination use of ARB and calcium antagonist (a Combined Application Group). METHODS: We used the data of Japan Medical Data Center (IMDC), which provides health insurance claims data with linked health check-up data of 1.7 billion members from health insurance societies in Japan. Since the data is not based on randomized controlled trials, we adjusted confounding factors using propensity score analysis. Through the examination, we found that the propensity score was well modeled by logistic regression including following four variate: age, square of age, level of medical cost before index time and square of log of medical cost before index time.

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CONCLUSIONS: Patients who underwent PCI had significant prior comorbidities and risk factors of cardiovascular diseases. There was a significant increase in the proportion of patients on statins after PCI.

DU2 EXAMINATION OF ANALYZING REAL WORLD DATA: MEDICAL COST REDUCTION OF COMBINATION DRUGS

Iwasaki K, Kogo N, Dei M

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CONCLUSIONS: Patients who underwent PCI had significant prior comorbidities and risk factors of cardiovascular diseases. There was a significant increase in the proportion of patients on statins after PCI.
D43 TRENDS OF HYPNOTIC MEDICATION USE IN A 2000-BED MEDICAL CENTER IN TAIWAN
Lin HW1, Lin CH2, Chang CK2, Chou CY1, Chao PT3, Hsu CN3, Chang LY4, Heiie YW5, Hung JB5, Huang WL6, Cha DY7
1China Medical University, Taichung, Taiwan, 2China Medical University Hospital, Taichung, Taiwan
OBJECTIVES: Although the evidence showed the risks of using sedative benzodiazepines (BZD) and long-term use of non-BZD hypnotics (i.e., Z-drugs) among the elderly, it is still unavoidable to use these medications for the elderly to solve their insomnia problems. This study aimed to describe the utilization of hypnotic medications for outpatients in a 2000-bed medical center in Taiwan.

METHODS: We conducted a secondary data analysis using China Medical University Hospital (CMUH) in-house databases. From 2007 to 2013, those outpatients ever prescribed with, estazolam, lorazepam, diazepam, alprazolam, zolpidem and zopiclone were of interest. To examine the rates of these drugs, its average number of defined daily dose (DDD), prescriber specialties and demographic characteristics of patients were examined using descriptive analyses.

RESULTS: Those elderly patients were prescribed with 133 ±158 DDD of Z-drugs in CMUH in 2007. 7.6% of them used Z/DR for patients aged 65 year or more. The top three prescribing specialists for Z-drugs were neurologist, cardiologist and psychiatrists (accounted for 63.0% and 46.9% for zolpidem and zopiclone, respectively). Of 12,987 patients being prescribed with 53,130 BZD and Z-drug prescriptions in 2013, 76.9% were aged 65 year or more. The Z-drugs were still more common than BZD as a whole. CONCLUSIONS: While the elderly accounted for small proportion of medical care users, relatively larger proportions were prescribed with BZD and Z-drug hypnotics to manage their insomnia problems in CMUH across seven years. Further outcome assessments for such usage are necessary.

D44 STATIN MEDICATION USE AND THE DEVELOPMENT OF PROLIFERATIVE DIABETIC RETINOPATHY AMONG PATIENTS WITH TYPE 2 DIABETES, HYPERTENSION AND HYPERLIPIDEMIA
Han Y, Balkrishnan R, Thompson DA, Richards JE, Stein JD
University of Michigan, Ann Arbor, MI, USA

The progression from Non-Proliferative Diabetic Retinopathy (NFDR) to Proliferative Diabetic Retinopathy (PDR) is associated with a decline in best-corrected visual acuity and related health care utilization. Few studies have systematically assessed the effect of pharmacological regimens in delaying the progression of PDR. Many patients with type-2 diabetes, hypertension and hyperlipidemia. Increasing adherence to guideline-recommended care if within 30 days of discharge, had at least one claim of pre-defined daily dose (DDD), prescriber specialties and demographic characteristics of patients were examined using descriptive analyses. RESULTS: Those elderly patients were prescribed with 133 ±158 DDD of Z-drugs in CMUH in 2007. 7.6% of them used Z/DR for patients aged 65 year or more. The top three prescribing specialists for Z-drugs were neurologist, cardiologist and psychiatrists (accounted for 63.0% and 46.9% for zolpidem and zopiclone, respectively). Of 12,987 patients being prescribed with 53,130 BZD and Z-drug prescriptions in 2013, 76.9% were aged 65 year or more. The Z-drugs were still more common than BZD as a whole. CONCLUSIONS: While the elderly accounted for small proportion of medical care users, relatively larger proportions were prescribed with BZD and Z-drug hypnotics to manage their insomnia problems in CMUH across seven years. Further outcome assessments for such usage are necessary.

One year post-discharge and compared between cohorts who receive and did not receive guideline recommended care using a probit regression model with instrumental variables. RESULTS: One-fourth (29%) of the patients with COPD-related hospitalizations/ED visits were identified as recipients of the guideline recommended care. Receiving guideline recommended care was associated with a reduction of 4.9 percentage points in the probability (22.8 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits, while the use of maintenance medication was associated with an increase in the probability (19.5 percentage points) of having subsequent COPD exacerbation requiring hospital admission/ED visits. 

HS5 QUALITATIVE ASSESSMENT OF THE QUALITY OF PHARMACEUTICAL CARE SERVICES IN THE PROVINCE OF KHYBER PAKHTUNKHWA, PAKISTAN: HOSPITAL PHARMACISTS’ VIEWS
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1COMSATS, Abbottabad KPK, Pakistan, 2COMSATS, Abbottabad, Pakistan, 3COMSATS, Abbottabad KPK, Pakistan, 4COMSATS, Abbottabad KPK, Pakistan

OBJECTIVES: To evaluate the perception of hospital pharmacists regarding quality of pharmaceutical care services in Khyber Pakhtunkhwa, Pakistan. METHODS: A semi-structured interview guide was developed and face to face interviews were conducted. Hospital pharmacists was interviewed.
saturation point was reached at 13 in Khyber Pakhtunkhwa province of Pakistan from December to February 2014. The interviews were conducted at the hospital pharmacy, arrangements for the time and place of interview were made during initial contacts. Written consent was obtained from the participants prior to the interview. RESULTS: Among the respondents interviewed, nine were male and four female hospital pharmacists, aged between 25 and 50 years. Thematic software was used for data analysis and for calculating the combined outcomes of clinical trials and their 95% Confidence Intervals (CI). Furthermore, sensitive analysis and publication bias was conducted to test the robustness of model assumptions and parameters estimates. Data inputs were taken from multiple sources, including clinical trials and a Delphi panel. The model adopted societal perspective with only direct costs considered. RESULTS: After five years, the cohort of patients administered memantine from the moderate stage had developed the lowest proportions of severe (45%), dependent (52%) and aggressive (7%) patients, of patients administered memantine prescribed from moderate to severe only - were compared over a five-year time horizon for a cohort of 1,000 patients with moderate dementia. The proportions of severe, dependent or aggressive patients, and caregivers' time, were estimated as clinical benefit and costs. Deterministic sensitivity analyses were conducted to test the robustness of model assumptions and parameters estimates. Data inputs were taken from multiple sources, including clinical trials and a Delphi panel. The model adopted societal perspective with only direct costs considered. 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CONCLUSIONS: No statistically significant difference in the effectiveness of oral ibuprofen and oral indomethacin compared to the intravenous NSAIDs with similar adverse outcome were observed. Oral formulations of indomethacin and ibuprofen might be considered as an alternative pharmacologic closure in PDA treatment for the NICU settings where intravenous NSAIDs is unavailable.

CV2 MANAGEMENT OF ISCHEMIC STROKE PATIENTS ENROLLED IN THE JAPAN STROKE DATABANK (JSD)
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1Lundbeck Japan KK, Tokyo, Japan, 2University Claude Bernard Lyon 1, Lyon, France, 3Creative-Neurial USA, Chicago, IL, USA, 4University of Illinois at Chicago, Chicago, IL, USA, 5Shimane University, Matsue-shi, Japan
OBJECTIVES: To evaluate the management of ischemic stroke (IS) patients enrolled in the Japan Stroke Database (JSD) from 2000 to 2007. METHODS: JSD is an observation database that captures all IS stroke event, collected and information provided by over 80 Japanese hospital departments. Data included demographics, time to admission, medical history, stroke type diagnosis, imaging, treatment, Japan Stroke Scale (JSS), NIH Stroke Scale (NIHSS) and the modified Rankin Scale (m-RS). RESULTS: Of the 47,782 stroke patients, when excluding for transient ischemic attack (TIA) cases, 15,282 (32%) were ischemic stroke cases with NIHSS evaluation at hospitalization and at discharge and with m-RS assessment at discharge. Average age was 69.7 years (±10.6) and 64% were males. Patients who were admitted to hospital at a later time window from onset had a lower m-RS score (0-1) at admission (12%, 13%, 15% and 17% for patients admitted at 0-3, 3-4.5, 4.5-8 and 8-24 hours, respectively). However, patients admitted at later time windows had worse disability at discharge (within patients admitted with m-RS 0-1, 53% vs 48% had m-RS 0 at discharge depending if admitted before or after 3 hours after onset). 57% of patients arrived after 3 hours and only 5.8% received thrombolytic treatment for the NICU settings where intravenous NSAIDs is unavailable. Ibuoporfen might be considered as an alternative pharmacologic closure in PDA treatment for the NICU settings where intravenous NSAIDs is unavailable.

CV3 ECONOMIC EVALUATION OF CHANGE IN REIMBURSEMENT CRITERIA FOR LIPID-LOWERING DRUGS IN TAIWAN
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1Division of Health Technology Assessment, Center for Drug Evaluation, National Institute of Health Technology Assessment, and Department of Physical Therapy and Assistive Technology, National Taiwan University Hospital, Taipei, Taiwan, 2Division of Health Technology Assessment, Center for Drug Evaluation, National Institute of Health Technology Assessment, Taipei, Taiwan
OBJECTIVES: As the international guidance for lipid control has evolved, the National Health Insurance Administration (NHIA) in Taiwan was requested to modify the current reimbursement criteria for initiation of lipid-lowering treatment. The study aims to evaluate the cost-effectiveness and the budget impact of the modified new reimbursement criteria on lipid-lowering drug from the NHIA’s viewpoint. METHODS: We applied a decision model to simulate the change of advanced lipid-lowering drug reimbursement criteria, the cut-off points of low-density lipoprotein cholesterol (LDL-C) and total cholesterol for initiating lipid-lowering therapy for patients having diabetes or previous coronary disease. High-risk group patients have been lower. A Markov decision model was constructed to examine the cost-effectiveness of the new criteria compared with the original ones. The efficacy of statins on coronary heart diseases (CHD) and stroke, and the projected population from the literature on the numbers of subjects who may be affected by these criteria changes and the LDL-C-specific disease management resources were used for the model. The corresponding financial impact on NHPI expenditure was also estimated. RESULTS: If the new criteria are applied, the number of subjects who fulfill the reimbursement criteria in the high-risk group will be almost twice as many as before. This would lead to an increase in the NHPI expenditures for statins and monitoring costs, however, this could be offset by the treatment cost saved from the averted CHD and stroke cases. Therefore, the new criteria are a dominant strategy compared with the original criteria. CONCLUSIONS: Although the newly proposed reimbursement criteria would lead to an increase in drug expenditure of NHPI, it is expected to be a cost-saving strategy after taking into account the health benefit on preventing CHD and stroke.

CV4 DOES THE CURRENT RECOMMENDED TARGET LDL GOAL IMPROVE SURVIVAL FOR ACUTE CORONARY SYNDROME PATIENTS IN HONG KONG?
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OBJECTIVES: This study was primarily aimed to assess the current prescribing pattern of lipid-lowering agents and the percentage of LDL-C goal attainment in myocardial infarction (MI) patients in local practice, and to evaluate clinical outcomes of the group in comparison with that by prescription of statins and by LDL-C goal attainment after discharge. METHODS: We retrospectively reviewed 696 hospitalized patients in the local ACS registry of Prince of Wales Hospital during 1 January 2008 to 31 December 2009 with data retrieved using computerized clinical records of all patients results. Of the 402 MI patients included, 104 (25.9%) were not prescribed with statins at discharge. Percutaneous coronary intervention (PCI) performed or planned during hospitalization (OR: 0.324, p<0.001) and latest LDL-C level before discharge (OR: 0.321 for an increment of 1 mmol/L, p<0.001) were significant independent predictors of the absence of statin prescriptions at discharge. A sig-
may increase the difficulty of demonstrating cost-effectiveness of a new treat-
ment (NEW) of newborns, expecting generation of the new treatment may improve cost-
effectiveness, particularly if initially of high-cost. The objective of this study was to
quantify the impact of anticipated PD on reimbursement decision making in
the Australian context via multi-cohort cost-effectiveness analysis. METHODS: A
two-state model was constructed comparing treatment of NEV to SOC over 30 years.
Probability of survival was assumed to be 3-times higher for NEV at 150-times the
price of SOC. A price function, based on Australian PD statistics, was applied to
expected population numbers. Costs of the new diagnostic test were not included.
the usual clinic, medicines availability at the clinic in the community. RESULTS: The annual propensity of HIV-infected and the annual propensity of AIDS patients was 0.57 for flu vaccine propensity. The upward trend over time in household income and percentage of residents in urban area indicate the rapid economic development and the urbanization in China from 2000 to 2006. Logit, probit, and longitudinal linear models were used to analyze the data. The annual propensity of flu vaccine, age, level of education, and the urbanization in China setting. QALY – Related Studies QA1 COMPARISON OF THE PREFERENCE-BASED EQ-5D AND SF-6D HEALTH INDICES IN MULTINATIONAL ASIAN PATIENTS WITH END-STAGE RENAL DISEASE (ESRD) Yang F1, Lau T1, Lee B1, Vathasila A1, Chia K1, Loo N1 1 Saw Swee Hock School of Public Health, National University of Singapore, Singapore, 2 Division of Nephrology, University Medicine Cluster, National University Health System, Singapore OBJECTIVES: The purpose of this study was to compare the performance of the EuroQol 5-dimension (EQ-5D-5L) and the Short Form 6-dimension (SF-6D) instruments in assessing Asian patients with end-stage renal disease (ESRD) in Singapore. METHODS: In a cross-sectional study, we interviewed ESRD patients who were hospitalized or followed up at the National University Hospital for a battery of questionnaires including the EQ-5D-5L, the kidney disease quality of life instrument (KDQOL-36), and questions assessing dialysis history and socio-demographic characteristics. We reviewed patients' medical records for their clinical information. We assessed the construct validity of the EQ-5D-5L and SF-6D index scores and compared their ability to distinguish between patients in differing health status and the magnitude of between-group differences. RESULTS: One hundred and fifty ESRD patients on dialysis (mean age: 60.1 years; female: 48.7%) participated in the study. Both EQ-5D-5L and SF-6D demonstrated good known-groups construct validity, the EQ-5D-5L was more sensitive to differences in clinical outcomes and the magnitude of between-group differences in KDQOL scales. The intraclass correlation coefficient between the measures was 0.36. The differences in (both actual and derived) EQ-5D index score for patients in better and worse health status were greater than those in SF-6D index score. CONCLUSIONS: Both EQ-5D-5L and SF-6D are valid instruments for assessing ESRD patients. However, the two preference-based health index scores cannot be used interchangeably and it appears that EQ-5D-5L would lead to more favorable cost-effectiveness results than SF-6D if they are used in economic evaluations of interventions for ESRD.

QA2 AN ANALYSIS OF NEW HEALTH TECHNOLOGIES AND REIMBURSEMENT PRICING STRUCTURES IN TAIWAN Stewart O1, Brooks-Rooney C2 1 Consulting M&C Ltd, Cambridge, UK, 2 Castle Medical Singapore Pte Ltd, Singapore OBJECTIVES: HTA in Taiwan was established in December 2007 to inform decision making on drug approvals and reimbursement prices. Drug categories were established based on the therapeutic value and the innovation of new drugs, and various pricing structures were adopted. The purpose of this study was to analyze the determinants of the reimbursement rates in effect in Taiwan. METHODS: The determinants were based on characteristics of drugs approved by the NHTA with respect to their classification, methods of pricing structures and applied price adjustments. METHODS: NHTA assessment reports from 2011 to February 2014 were reviewed, and approval and pricing decisions by the NHTA were examined. RESULTS: Of 52 assessments included in this analysis, 37 were approved for use on the National Health Insurance (NHI) in Taiwan. Of these, 57% were determined as having a comparable therapeutic value to the current best competitor, 38% were deemed to be non-inferior in therapeutic efficacy and 5% were considered breakthrough innovations. In most instances (73%), drugs were priced based on existing therapies. Of the approved health technologies, 9 (24%) were eligible for additional price adjustments. These were spread across multiple disease areas and reflected improved clinical and safety outcomes, dosing convenience and the availability of local clinical and economic data. The incidence of price adjustments has increased in recent years, which is particularly evident with respect to high quality pharmacoeconomic data. CONCLUSIONS: The overall innovativeness of drugs approved by the NHTA offer similar clinical benefit to current competitors and are priced based on existing therapies. Alternative methods involved calculating drug prices based on international reference countries, although manufacturers seem to be increasingly seeking available price adjustments to achieve a higher price for their product.

QA3 COST-EFFECTIVENESS OF THROMBOLYSIS WITHIN 4.5 HOURS OF ACUTE ISCHEMIC STROKE IN CHINA Fan Y1, Wang Y1, Liu G1, Zhao K1, Wang Y1 1Beijing Tiantan Hospital, Capital Medical University, Beijing, China, 2National Health and Family Planning Commission, Beijing, China OBJECTIVES: Previous economic studies conducted in developed countries showed intravenous tissue-type plasminogen activator (tPA) is cost-effective for acute ischaemic stroke. This study aims to determine the cost-effectiveness of tPA treatment in China setting. METHODS: A combination of a decision tree and a Markov model was developed to determine the cost-effectiveness of tPA treatment versus no tPA treatment within 4.5 hours after ischaemic stroke. Outcomes and costs data were derived from the Thrombolysis Implementation and Monitor of acute ischemic Stroke in China (TIMS-China) study. Efficacy data were derived from a pooled analysis of the Thrombolysis in لبنان Stroke Trial (LAUTS), National Institute of Neurological Disorders and Stroke Trial (NINDS) and European Cooperative Acute Stroke Study (ECASS) trials. RESULTS: The annual propensity of tPA therapy versus no tPA therapy within 4.5 hours after ischaemic stroke in China aged 7-18 (p < 0.05). Other factor, such as the medical insurance, whether the individual resides in an urban area and the need for medicines availability at the clinic also had a significant impact on the immunization propensity for children and adolescents (p < 0.05). CONCLUSIONS: Maternal education positively affects children’s immunization propensity, particularly for those children below 6 years of age.

QA4 COST-UTILITY OF BEVACIZUMAB WITH PC REGIMEN IN NON-SMALL CELL LUNG CANCER TREATMENT Nguyen TT1, Tran TTH1 1 University of Medicine and Pharmacy in Ho Chi Minh City, Ho Chi Minh City, Vietnam OBJECTIVES: Lung cancer, especially non-small cell lung cancer (NSCLC), is one of the most leading causes of mortality not only in the world but also in Vietnam. Bevacizumab – a targeted therapy agent- has been recommended to use in combination with chemotherapy as the first-line treatment of advanced NSCLC. However, the high cost of bevacizumab may reduce the availability of bevacizumab, especially in Vietnam. Therefore, this analysis was conducted to analyze the cost-effectiveness of bevacizumab in the combination with paclitaxel and carboplatin (BCP) versus paclitaxel and carboplatin (PC) regimen in Vietnamese setting. METHODS: A Markov model has been developed with 3 stages (stable, progressive and death). The model has a cycle length of 1 year with the life-time horizon. The population of 1000 patients was included in the model. The transition rates have been retrieved from randomized clinical trials, the prices of drugs and medical services have averaged from the price-lists of some major hospitals in Vietnam in 2013. The sensitivity analysis was conducted to test the model. RESULTS: The cost of BCP and PC regimens for NSCLC treatment accounts for 4,691,452,387 VND and 1,792,656,298 VND with the QALY of 7.88 and 5.62, respectively. The CER of BCP regimen for NSCLC treatment accounts for 595,533,261 VND, which is around 2 times higher than that of PC regimen. In 30% of BCP regimen treatment accounts for around 1.3 billion VND, which is about 17 times higher than the willingness-to-pay of Vietnam (74 million VND). One-way sensitive analysis showed bevacizumab price as the most affecting factor on its cost-effectiveness. CONCLUSIONS: Due to the high cost of drug, the combination of bevacizumab in the PC regimen in treatment of NSCLC is considered not cost-effective in Vietnam. To enhance the cost-effectiveness of bevacizumab, supporting policies from manufacturer, health care providers and government should be established.

RESPIRATORY – Related Disorders Outcomes Research Studies RR1 COST-UTIlITy OF BEvACIzUMAB WITH PC REGIMEN IN NON-SMAlL CEll lUNg CANCER TREATMENT Khan AH1, Seyed Sulaiman A1, Hassali AA2, Saleem F1, Afzal RA1, Ali TA1 1 Universiti Sains Malaysia, Minden, Malaysia, 2 University Sains Malaysia, Penang, Malaysia, 3 Universiti Science Malaysia, Penang, Malaysia, 4 Penang General Hospital, Penang, P. Pinang, Malaysia OBJECTIVES: To evaluate physician’s knowledge and adherence to asthma guideline (GINA) 2011 at emergency department of Hospital Pulau Pinang, Malaysia. METHODS: We calculated the cost of adhered and non-adhered bevacizumab, supporting policies from manufacturer, health care providers and government should be established.

RR2 RESOURCE UTILIZATION PATTERN AND COST OF TUBERCULOSIS TREATMENT IN PINANG, MALAYSIA Asif M1, Sulaiman SAS2, Shafie AA3, Asif M1 1 The Islamia University of Bahawalpur, Bahawalpur, Pakistan, 2 Universiti Sains Malaysia, Penang, Malaysia

A725
OBJECTIVES: The aim of this study was to analyze the tuberculosis-related medical resource consumption pattern among new smear positive pulmonary tuberculosis (PTB) patients. We also estimated the cost of tuberculosis (TB) treatment from the perspective of provider and patient, and identified the significant cost driving factors.

METHODS: All new smear positive PTB patients who were registered at the chest clinic at National Hospital, between March 2010 and February 2011, were invited to participate in the study. Provider sector costs were estimated using bottom-up, micro-costing technique. For the calculation of costs from the patients’ perspective, each PTB patient was interviewed after the intensive phase and at end of their treatment by a trained nurse. Predictive Analysis Software was used to analyze the data.

RESULTS: During the study period, 226 patients completed the treatment. However, complete costing data was available for 212 patients. The most highly utilized resource was chest X-rays followed by sputum smear examination and non-specific laboratory tests. Only a smaller proportion of the patients were hospitalized. The total cost of treating a patient was USD 452.72 and USD 55.94 was spent on anti-tubercular and anti-cancerous agents. Cancer cells are being studied in many ways using cell culture technologies in developed countries. We aimed to determine the chemosensitivity of colorectal cancer cases. METHODS: From February 2013 through February 2014, histoculture drug response assay data were obtained from 6 colorectal cancer surgical specimens held in State Central Hospital. Cultures and media were prepared by R. Hoffmans methods. We examined chemosensitivities of the tissue to carboplatin, irinotecan, doxorubicin, 5-fluorouracil and oxaliplatin. Cutoff inhibition rates were determined with each drug for colorectal cancer and were used to calculate predictabilities for chemosensitivity responses. We also prepared double samples from the culture and made histologic and cyto-logic analysis. RESULTS: The predictability of the histoculture drug response assay was at 83%. Predictability including true-positive and true-negative rates of 83.3% and 100% was observed. CONCLUSIONS: Cancer cells deaths are dependent from dosage of the candidate histoculture assay. It shows it is possible to use drug sensitivity methods in oncologic clinical practice.

PRM2

ROLE OF CORTICOSTEROIDS USE IN ARDS: COMPARISON OF SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To explore the routine use of corticosteroids for management of acute respiratory distress syndrome in adult population. METHODS: English language, randomized control trial and observational studies were searched using different databases like the Cochrane Central Register of Controlled Trials, Cochrane database of systematic reviews, PubMed, Scopus, Science Direct. They used the keyword: corticosteroids, methylprednisolone, hydrocortisone, dexamethasone AND acute lung injury, adult respiratory distress syndrome, acute respiratory distress syndrome, ARDS, respiratory failure, septic shock, inpatient mortality. RESULTS: Five randomised controlled trials and 5 observational studies using variable dose and duration of steroids with the inclusion criteria. The Mantel-Haenzel odds ratio of corticosteroids decreasing mortality in patients of ARDS randomized, controlled trial was 0.892; 95% CI 0.480 to 1.108 whereas in observational studies was 1.662; 95% CI 0.981 to 2.816. CONCLUSIONS: A definitive role of corticosteroids in ARDS has not been established. However, current data from studies shows the result favouring use of corticosteroids in ARDS by decreasing the mortality associated. However, use of steroids is associated with a slight risk of increased infectious complications.

PRM3

ACUTE RESPIRATORY DISTRESS SYNDROME: TREATMENT PATTERN AND OUTCOME ANALYSIS

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OBJECTIVES: Acute respiratory distress syndrome (ARDS) is an acute hypoxic respiratory failure. It is the most severe form of acute lung injury. The treatment of ARDS is generally supportive and there is ambiguity in the role of glucocorticoids in the treatment of ARDS. This study aimed at analyzing treatment pattern and outcome of patients in ARDS. METHODS: A retrospective observational study was conducted in a tertiary care teaching hospital. All the patients diagnosed with ARDS confirmed by chest X-ray and arterial blood gas during 2011 were included. The patients were identified and collected from the medical records division using ICD code J86. RESULTS: A total of 150 patients diagnosed with ARDS were included in the study. Mean age of the study population was 43.37 ± 16.15 years. Majority of them were males, 60.7% of the population. Analyzing the treatment pattern, 98.6% were given antibiotics for their underlying conditions along with anti-inflammatory and anti-coagulant drugs. The incremental cost of varenicline versus bupropion was 826 billion KRW and 1,428 billion KRW with NRT. The ICER of varenicline comparing to bupropion and 1,428 billion KRW with NRT. The ICER of varenicline comparing to bupropion and NRT were estimated at 10.6 million KRW per QALY and 19 million KRW per QALY, respectively. Sensitivity analyses were quite robust for all parameters but it was most sensitive to time horizon.

CONCLUSIONS: Varenicline treatment for smoking cessation can be considered as cost-effective compared with existing therapies in Korea. The ICER becomes lower when morbidity rates of smoking related diseases are reflected.
PHM6
DRUGS IN CONSTRAINT COUNTRIES OF SUB SAHARAN AFRICA
Nyabage GO
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OBJECTIVES: Being from the very land and a son of the same soil. Africa is the world’s second largest continent and the most poorest underdeveloped continent. With great struggles and constraints in provision of essential drugs and program initiatives, its hard to make proper intervention in urgent essential needs of remedies required on a daily basis especially in the wider scope of village populations on health priorities. METHODS: In 2007, Africa’s dia­lysis population constituted only 4.5% of the world’s dialys­is population, with a prevalence of 74 per million population (pmp), compared to a global average of 250 pmp. In almost half the African count­ry, no dialysis services are reported. The prevalence of peritoneal dialysis (PD) was 2.2 pmp, compared to a global prevalence of 27 pmp, with the bulk of African PD patients (85%) residing in South Africa. In North African countries, which serve 95% of the RESULTS: African dialysis population, the contribution of PD to dialysis is only 0% - 3%. Cost is a major factor affecting the provision of dialysis treatment and many countries are forced to ration dialysis therapy. Rural setting, difficult transportation, low electri­fication rates, limited access to improved sanitation, and improved water sources, unsuitable living circumstances, and the limited number of nephrologists are obstacles to the provision of PD in many countries. CONCLUSIONS: The potential for successful regular PD programs in tropical countries has now been well established. Cost is a major prohibitive factor but the role of domestic manufacture in facilitating widespread use of PD is evidenced by the South African example. Education and training are direly needed and these areas where international societies can be of great help.

PHM7
IS CHINESE SYMPTOM SYNDROME IN THE EFFECTIVENESS EVALUATION OF CHINESE HERBAL FORMULAS? Chen ZH1, Yang GL1, Zhang Z2, Zhang HY1, Wang Y2, Liu C Y1, Qiu Q1
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OBJECTIVES: Though Chinese herbal medicine had been proved effective in clinical practice, due to the lack of suitable outcomes, the current randomised controlled trial (RCT) studies showed that Chinese herbal formulas unefeetful, thus the effectiveness are rarely confirmed publicly. In this study we applied Chinese syndromes in the effectiveness evaluation of Chinese herbal formulas and to assess their suitability and necessity. METHODS: In an first clinical research, angina patients with Phlegm and Blood stasis syndrome were randomized into experimental group (Chinese herbal formulas combined with western basic therapy) and placebo group respectively. An Chinese questionnaire TCM-SAQ, Seattle Angina Questionnaire (SAQ), and SF-12 were used to collect patients reported outcomes. The effectiveness and the results shows that there is no statistical difference in SF-12 and SAQ between two groups after 8 weeks’ treatment, while there is significant difference shown in the syndrome domain of TCM-SAQ. On the basis of these results, the deviation value of all the domains in each questionnaire from the baseline to after 8 weeks’ treatment were calculated. And then the Pearson correlation of the deviation value among the domains in TCM-SAQ with domains in SF-12 and SAQ were analysed. RESULTS: The Chinese patients with MM who included in the Chinese herbal therapy are: Mecormin (94.01%), Acarbose (28.64%), Xioaloe pills (a tradi­tional Chinese medicine, 20.54%) and Glilocilace (18.26%). On average, a patient spent CNY 8,676.56 (sd =17,642.51) on health care annually, where OADs cost CNY 6,463 (sd =9,233.30). When controlling other confounding variables via statistical models, further analysis finds that patients on Xioaloe pills as the major regimen ended in a reduction of total health care cost by CNY 2,135 (p =0.01), where OADs cost was reduced by about CNY 1,36 (p =0.01). CONCLUSIONS: As patients reported outcome, Chinese syndrome can reflect the effectiveness of herbal formulas more suitable and necessary in the effectiveness evaluation of Chinese herbal formulas.

PHM8
A NOVEL BROADLY APPLICABLE RISK SCORE FOR PREDICTING MORTALITY OF PATIENTS WITH CIRCULATORY SYSTEM DISEASES WITHIN HOSPITALIZATION DURATION Qiu Z1, Song J1, Zhan SY, Ma X1
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OBJECTIVES: The common comorbidity indexes was developed about two dec­ades ago and were not appropriate for inpatients risk adjustment nowadays. Our objective was to develop a risk stratification model that predicts mortality risks in hospitalized patients with circulatory system diseases. METHODS: The risk score model was generated by using inpatient summary report of electronic medical record dataset from 2006 to 2010 among 50 tertiary hospitals in Beijing, and validated by same dataset of 65 tertiary hospitals in the whole country in 2012. The patient diagnosis as identified by using the International Classification of Diseases, 10th Revision. Risk score was developed with individual major diagnostic codes. Receiver operating characteristic (ROC) analysis was used to evaluate the predictive effect of risk score, and the Charlson Comorbidity Index (CCI) was used to control the mortality due to the multi-pathology. RESULTS: Of the total 4,216,375 patients were used to generate the risk scores which comprise 293 items out of more than 4,000 categories and ranged from 96 to 1. In the validation dataset the area under the ROC curve was 0.845 compared with CCI of 0.748 in multi-pathology, 0.681 in syste­m infarction inpatients, and in coronary artery bypass grafting(CABG) inpatients the ROC was 0.729 to CCI ROC of 0.626, in percutaneous coronary intervention(PCI) inpatients the ROC was 0.847 and 0.648 respectively. The ROC of novel risk score was improved 12.7, 16.4 and 30.1 percent among inpatients with circulatory system diseases required on a daily basis especially in the wider scope of village populations on health priorities. METHODS: In 2007, Africa’s dia­lysis population constituted only 4.5% of the world’s dialys­is population, with a prevalence of 74 per million population (pmp), compared to a global average of 250 pmp. In almost half the African count­ry, no dialysis services are reported. The prevalence of peritoneal dialysis (PD) was 2.2 pmp, compared to a global prevalence of 27 pmp, with the bulk of African PD patients (85%) residing in South Africa. In North African countries, which serve 95% of the RESULTS: African dialysis population, the contribution of PD to dialysis is only 0% - 3%. Cost is a major factor affecting the provision of dialysis treatment and many countries are forced to ration dialysis therapy. Rural setting, difficult transportation, low electri­fication rates, limited access to improved sanitation, and improved water sources, unsuitable living circumstances, and the limited number of nephrologists are obstacles to the provision of PD in many countries. CONCLUSIONS: The potential for successful regular PD programs in tropical countries has now been well established. Cost is a major prohibitive factor but the role of domestic manufacture in facilitating widespread use of PD is evidenced by the South African example. Education and training are direly needed and these areas where international societies can be of great help.

PHM9
HEALTH CARE USE AND ORAL MEDICATION PATTERNS FOR TYPE 2 DIABETES PATIENTS IN CHINA: THE ROLE OF TRADITIONAL CHINESE MEDICINES Liu G1, Xu F1
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OBJECTIVES: To investigate the health care utilization and cost, focusing on the use of oral anti-diabetic drugs (OADs) for type 2 diabetes patients in China. METHODS: A large scale, prospective and observational study was conducted in 5 cities of China. Subjects on any OAD were enrolled. The data was collected from longitudinal interviews and diary following-up with the enrolled patients. Primary data information included socio-demographic characteristics, health care and medica­tion use and cost assessments. RESULTS: Of the 658 patients, 4.04% had no OADs prescribed, 22.68% were prescribed OADs only, and 73.29% OADs plus basal therapies and regular chemotherapies. T wo studies were conducted based on health sys­t ems literature for China and those which reported cost-effectiveness ratio (CER) or incremental cost-effectiveness (ICEC) of PD pharmacotherapy. RESULTS: Six studies were selected, all in mandarin. The studies were used for different study designs including: 2 cost-utility analyses (CUA), 4 cost-effectiveness analyses (CEA) and 0 cost-benefit analyses (CBA). None of the studies used all HE modelling. Cost-effectiveness comparisons were made between levodopa mono­therapy with or without benserazide against other levodopa formulation. When controlled for other confounding variables via statistical models, further analysis finds that patients on Xioaloe pills as the major regimen ended in a reduction of total health care cost by CNY 2,135 (p =0.01), where OADs cost was reduced by about CNY 1,36 (p =0.01). CONCLUSIONS: Type 2 Diabetes patients in China face a heavy economic burden. Among OADs, traditional Chinese medicine Xioaloe pills appears to be a quite cost effective treatment regimen for diabetic patients in China. Future analysis is warranted to investigate mechanisms and conditions because of the variety of oral Chinese OADs may be cost effective for some diabetic patients in China.

PHM10
HEALTH ECONOMICS METHODOLOGIES INVOLVING PARKINSON’S DISEASE TREATMENT IN CHINA
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OBJECTIVES: To describe the methodologies used in health economics (HE) studies on Parkinson’s disease (PD) in China. METHODS: A structured literature review was conducted to describe the methodology used to generate HE evidence for PD treatment in China. The review was conducted in both English and Mandarin languages using four databases: Pubmed, Cochrane, WAN FANG and VIP; for articles published between 2000 and 2013. Study selection was limited to Chinese population based in China and those which reported cost-effectiveness ratio (CER) or incremental cost-effectiveness (ICEC) of PD pharmacotherapy. RESULTS: Six studies were selected, all in mandarin. The studies were used for different study designs including: 2 cost-utility analyses (CUA), 4 cost-effectiveness analyses (CEA) and 0 cost-benefit analyses (CBA). None of the studies used all HE modelling. Cost-effectiveness comparisons were made between levodopa mono­therapy with or without benserazide against other levodopa formulation. When controlled for other confounding variables via statistical models, further analysis finds that patients on Xioaloe pills as the major regimen ended in a reduction of total health care cost by CNY 2,135 (p =0.01), where OADs cost was reduced by about CNY 1,36 (p =0.01). CONCLUSIONS: Type 2 Diabetes patients in China face a heavy economic burden. Among OADs, traditional Chinese medicine Xioaloe pills appears to be a quite cost effective treatment regimen for diabetic patients in China. Future analysis is warranted to investigate mechanisms and conditions because of the variety of oral Chinese OADs may be cost effective for some diabetic patients in China.
analysis. The time horizon for each study ranged from 2-3 months in the RCTs, and 1-24 months in the observational studies. No discounting was reported in any of the articles. Only one article reported sensitivity analysis. CONCLUSIONS: All HE studies published were piggy-backed to clinical studies and none utilised HE modeling. None of the HE studies completely fulfilled the standard HE reporting criteria.

RESEARCH ON METHODS – Databases & Management Methods

PRM11 ASSESSMENT OF NEED, DEVELOPMENT AND IMPLEMENTATION OF SUPPORTIVE MANAGEMENT DATABASE FOR THE TREATMENT OF POISONING CASES IN A TERTIARY REFERRAL HOSPITAL

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OBJECTIVES: The main purpose of the present study was to assess the physician need for the development of a supportive management database for the treatment of poisoning cases and to implement such a database in the hospital setup based on the data. METHODS: A prospective, observational study was conducted in the emergency department of Kasturba Hospital, Manipal. The study was approved by the Institutional Ethics Committee of Kasturba Hospital, Manipal. A 12 item questionnaire was developed, validated and given to 42 physicians who treated acute poisoning cases to assess their need for the development and implementation of a supportive management database. Material for the database was prepared after conducting an electronic literature search of various existing databases. RESULTS: The 12 item questionnaire was given to seven experts for content validation. Out of twelve items, one item was excluded from the final questionnaire as it did not meet the required value. All 42 (100%) of the physicians believed that a supportive management database for poisoning cases was needed. The hospital setup would be really helpful. Over 300 articles were referred in the preparation of the material for the database. CONCLUSIONS: Clinical pharmacists together with physicians who treat poisoning cases must work hand in hand in developing institutional guidelines for the management of poisoning. Development of such guidelines could reduce the complications and mortality which are associated with poisoning cases.

PRM12 EVIDENCE FOR VALIDITY OF A NATIONAL PHYSICIAN AND PATIENT-REPORTED SURVEY IN CHINA AND UNITED KINGDOM: THE DISEASE SPECIFIC PROGRAMME

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OBJECTIVES: Traditional large-scale epidemiological surveys used to inform public health policy and practice might not be a true reflection of the cost and time to treat them and the timeliness of the data, sometimes subject to 5 or more years between updates. This analysis aimed to validate a newer survey methodology by comparing output with that from two large scale health surveys. METHODS: Data were drawn from the Adelphi Diabetes Disease Specific Programme (DSP), a cross-sectional survey of physicians and their patients conducted in China (2012) and United Kingdom (UK) (2013). Detailed records for 3662 patients were provided by 200 physicians in China. In the UK, 125 physicians provided records for 1397 patients. Clinical and demographic characteristics of the samples were compared with independent representative national data sources: a 2007/08 Chinese epidemiology study (46.2% female, 53.8% male, age 45 vs. 58, 1844 patients), a China Health Survey for 2015 (47.5% female, 52.5% male, age 45 vs. 58, 10,000 individuals). Variables common to both datasets were compared and tested for significant differences. RESULTS: Systolic blood pressure (SBP) and low-density lipoprotein (LDL) were very similar from the China DSP compared statistically non-different from that of the China Health Survey. There were differences between fast and slow-changing disease states. Age (56 vs. 55.8), male body mass index (BMI) (24.1 vs. 25.2) and high-density lipoprotein. Comparing the UK DSP with the HSFL, all variables (age, gender, smoking status, age group) were similar with one exception (61.5 vs. 63.9), in-stent treated (31.6 vs. 29.3), total cholesterol, HBA1C (7.76 vs. 7.981), and SBP were non-different. Weeks since diagnosis differed - 358 DSP vs. 504 HSFL. CONCLUSIONS: Results demonstrate that the DSP methodology enables up-to-date representative sampling of treated adult patients in Western and Asian populations for national disease burden quantification, and treatment pattern and outcomes assessment. A limitation is that sampled patients are more recently diagnosed, but there are otherwise minor differences in clinical and demographic characteristics.

PRM13 REAL WORLD EVIDENCE IN MAINLAND CHINA: EXPERIENCE WITH THE USE OF HEALTH CARE CLAIMS DATA

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OBJECTIVES: The Chinese public health insurance system now covers 95% of the population due to efforts to establish universal coverage under three primary government programmes (Urban Employee Basic Medical Insurance, Urban Resident Basic Medical Insurance, and New Rural Cooperative Medical Scheme). Data from these insurance programs are combined to create the China Health Insurance Association (CHIRA) database; the only national claims database in China. Use of these data allow research to examine patient’s settings, patterns and outcomes that may differ from those of conventional randomized controlled trials (RCTs). Our data analyses highlight the opportunity to apply real world evidence (RWE) in local decision making. The use of claims data is relatively uncommon in China. This work explores the current approaches to analysis of local health databases as a source of information for RWE in China. METHODS: The experience of the use of the China Health Insurance Association (CHIRA) data is explored. The advantages and limitations of the CHIRA data are described. RESULTS: Although there have been abstract disclosures in scientific conferences, a search in PubMed (January 8, 2014) found no manuscripts published that presented analyses using CHIRA data. It uses ICD-10 codes and collects cross-sectional data annually from inpatient claims records from sample cities. Limitations include the lack of longitudinal perspective, incomplete data on outpatients, lack of standardized bill codes, and limited access for research purposes. CONCLUSIONS: At present claims data in China are relatively difficult to access and to use. However the use of claims data for health services research is expected to increase in line with planned enhancements to data availability and quality, and the increasing needs for RWE by decision makers.

PRM14 MANAGING CONGENITAL AND PEDIATRIC CARDIAC SURGERY DATA BASE: THE IMPACT ON CLINICAL PRACTICE AND QUALITY OF CARE

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OBJECTIVES: To develop a functional and validated database for quality assurance and improving patient outcomes and establishing institutional integrity. METHODS: The Cardiothoracic surgery division at the Aga Khan University Hospital maintains a computerized database of all the patients undergoing cardiac surgery since July 2006. For this study, data of 1236 patients operated between July 2006 and Dec 2013 was analyzed. Major measures of outcomes included in-hospital and 1-24 months outcomes like reoperation, sepsis prolong ventilation, arrhythmias low cardiac output syndrome. RESULTS: Out of a total of 1236 heart surgeries, the most common open heart surgeries were VSD 27%, TOF 24% whereas ASD and aortic stenosis cases were MDRT bunts, 17% were FDA. The overall 30-day mortality in open heart was 7.0%, and in closed heart it was 7.3%. Post-surgery more common complication in open heart surgery was bleeding which was 35% , arrhythmias 14%, reopenings 11% and sepsis 5%.total morality was 29% while in closed heart most common complication was prolong ventilation which was 31%, total morbidity was 21%. Readmissions after 30 day of Discharge were 8.4% mainly for respiratory infection. Followed with 9.5% lost to follow-ups 85% patients were alive, 0.6% were died at 30 days after surgery follow up. CHANGES DEPEND ON DATABASE: VSD on table extubation or extubation with 4 hours – minimal morbidity and early discharges. ASD: on table extubation. DISCUSSION: Updated and stringently maintained database helps to identify deficiencies, strength and trends of the Pediatric and Congenital Cardiac surgery program at our hospital and also to design strategies for continuing improvement in patient care. Also provides scientific evidence for comparing results with other institutions of the region and world.

PRM15 DEVELOPMENT OF A LONGITUDINAL NATIONAL FOOTBALL LEAGUE INJURY AND INJURY IMPACTS (L-NFL-III) DATABASE

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OBJECTIVES: Injuries in sports, including professional American football, are a major public health problem affecting millions of young and adult athletes around the world. Injuries have significant economic, social and personal consequences and may even result in long-term disability. No outcomes databases exist that focus on injuries in the National Football League (NFL). We sought to develop a database that includes longitudinal and includes key injury impacts. METHODS: Four years of data with imaging information from any player that played 1 regular season games between 2010 and 2013 were adapted from NFL.com, ESPN.com, SN.com and several other reputable online sources. Five different and unique data types, all capable of being merged with one another and used in longitudinal analyses, were stored as SAS datasets: Player Background (e.g., age, weight, position), Games Played, NFL Injury Report, Injured Reserve List, and Schedule and Conditions (e.g., field surface, weather conditions, referee). Data from the NFL Injury Report and Injured Reserve List contain every significant injury to NFL players during the 4-year period including concussions, knees, ankles, hamstrings, etc. Injury Impacts include games missed due to injuries as well as season- and career-ending injuries. RESULTS: Data on 3,193 unique NFL players are included in the database. About 7,100 player-seasons were captured that cover nearly 91,000 player-games. About 18,500 Injury Reports are recorded on these players resulting in more than 6,000 missed games. In addition, almost all 959 Injured Reserve List at season-ending and significantly raise the risk of ending a player’s career. CONCLUSIONS: The L-NFL-III database can be a useful tool for epidemiological and outcomes research related to injuries in the NFL. In 4-year longitudinal analyses, this database was successful in identifying a large number of missed games due to injuries, as well other critical outcomes including season- and career-ending injuries.

PRM16 HEALTH CARE DATABASES APPLIED TO ANTIDEPRESSANTS USE IN ASIA-PACIFIC

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OBJECTIVES: Health care databases represent an optimal tool for conducting large retrospective epidemiological studies and are largely used in Europe and the US. This study is the second phase of an earlier study which qualitatively describes databases in Asia Pacific. In this phase, we focussed on several countries that have large health care databases used for administrative functions namely South
Korea, Taiwan, Australia, Japan, and Singapore. We assessed the use of databases in studies assessing economic outcomes (HEDIS). This research assumes that data on the use of antidepressants. METHODS: A literature search was conducted to include English language articles in PubMed to identify database analysis studies from 2000–2013. We identified the number of studies from these countries using the databases as well as their topics of focus. These included studies on FR description patterns, resource use and cost of disease. RESULTS: From the countries included in the study, Taiwan had the highest number of studies published on HDOR and the use of antidepressant. There were very few or no studies from Japan, South Korea, Australia and Singapore. The topics ranged from the use of antidepressants, prevalence, use among adolescents, and factors associated with persistence or early attrition to treatment. Some studies documented the clinical or economic impact of discontinuing treatment, to impact on optimal vaccination coverage rate based on economic burden of an infectious disease. METHODS: Vaccination for pneumococcal diseases was used as an example to demonstrate the main purpose: 23-valent pneumococcal conjugate vaccine (PCV13) have been shown their cost-effectiveness in elderly and children, respectively. Scenarios analysis of FPV23 to the elderly aged 65+ years and PCV13 to children 5 years and under was applied to assess the optimal vaccination coverage rate on the economic burden. All epidemiological parameters were derived from the Taiwan’s National Health Insurance Research Database, all cost parameter were derived from the Taiwan’s Ministry of the Interior and the vaccine efficacy was obtained from the literature. Various vaccination coverage rate, the vaccine efficacy and all epidemiological parameters were all substituted into to TD and all differential equations were solved using the fourth-order Runge–Kutta method implemented in R Statistical Software. RESULTS: If the he coverage rate of FPV23 for the elderly and PCV23 for the children both reach to 96%, the economic burden due to pneumococcus disease will be minimized approximately. CONCLUSIONS: This study provided an alternative perspective from the economic burden of diseases to estimate vaccination coverage using a vaccination constraints in the TD. This will provide valuable information for vaccination policy decision makers.

RESEARCH ON METHODS – Modeling Methods

PRM17

BUILD MODEL WITH ASIA PACIFIC REGION IN MIND: MODELING INR CONTROL IN A COST-EFFECTIVENESS MODEL FOR STROKE PREVENTION IN ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: Vaccine, physician behaviors, and health systems differ across regions. The purpose of this study was to evaluate those features to account for heterogeneity for warfarin use in AP region. Warfarin, the standard care for stroke prevention in atrial fibrillation patients, requires routine monitoring of International Normalized Ratio (INR). Below or above the target range (2.0–3.0) increases ischemic or hemorrhagic events. INR control in time in therapeutic range (TTR) determines therapeutic effectiveness. INR monitoring and increased hemorrhagic risk created barriers for broad effective warfarin use in AP region. The mean TTR in US was 66.7%. In contrast, the estimate was 36% in China. All existing anticoagulant models, mostly Markov-based, have no explicit INR modeling. To allow for effectiveness projections for warfarin in AP settings, our model incorporated an INR mod- 

METHODS: We adopted a microsimulation approach to accommodate the patients’ initial characteristics and the strong association between a patient’s history and future outcomes. An INR control module was built in three steps: a) estimated event rates within target INR range, b) probabilistically chose an INR range for a patient at each cycle based on the simulated population’s TTR distribution, and c) projected event rates at the chosen INR range by incorporating the relative risks of INR control effect on events. Inputs were derived from the RE-LY trial, published literature and expert opinion. RESULTS: We performed internal vali-
dation by projecting 2-year clinical events using the RE-LY-like TTR distribution (22% INR≤2.0, 64.4% 2.0<INR≤3.0 13.4% INR>3.0) and comparing the achieved event rates similar to those observed in RE-LY. Applying a China-like TTR distribution (59% INR≤2.0, 30.6% 2.0<INR≤3.0, 10.4% INR>3.0) increased in-creased hemorrhagic risk events. CONCLUSIONS: Explicitly modeling INR control produced realistic projections which allowed adaptation of our anticoagulant model to AP settings. Proactively incorporating flexible model structure to accommodate het-
erogeneity was an efficient approach to improve model generalizability.

PRM18

STRATEGIES TO OVERCOME HURDLES IN HTA APPRAISALS AMID LIMITATIONS RESULTING FROM SINGLE-ARM TRAIL DATA

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OBJECTIVES: The purpose of this study was to evaluate the barriers that arise in constructing strong pharmacoeconomic (FE) submission based on evidence from single-arm clinical trials, and to evaluate strategies to overcome them. METHODS: A set of the techniques were selected based on the following criteria: oncology indication with a PE submission for health technology assessment (HTA) review, utilising single-arm trial data. HTA appraisals in five major markets were considered – GB, CAN, SGT, GER, and FRA. Modelling approaches used in each appraisal were enumerated, and HTA body comments on each employed strategy were collected. Each identified modelling strategy was evaluated for its likelihood in overcoming a negative appraisal across the selected major markets. RESULTS: The FE model barriers associated with single-arm trial data included: lack of direct comparison with comparator, reliance on surrogate endpoints, and lack of long-term follow-up. The techniques employed to address these drawbacks included: comparison with historical controls, subgroup analysis between self-funding and SU populations, TTR control, comparison with placebo-arm of a published trial, correlation of surro-
geate endpoints to hard outcomes, survival extrapolation methodology (including putative single extrapolator with cumulative and end-of-treatment) These methods were most successful in FRA and CAN, where positive HTA appraisals were awarded 7/8 and 2/2 times, respectively, and were least successful in GBR and SCT, where positive HTA appraisals were awarded 1/4 and 2/8 times, respectively. CONCLUSIONS: Manufacturers may face difficulties when modelling a product’s economic benefit for broad effective warfarin use in AP region. The mean TTR in US was 66.7%. For the purpose of research and improving understanding of disease, the prevalence, use among adolescents, and factors associated with persistence or early attrition to treatment. Some studies documented the clinical or economic impact of discontinuing treatment, to impact on optimal vaccination coverage rate based on economic burden of an infectious disease. METHODS: Vaccination for pneumococcal diseases was used as an example to demonstrate the main purpose: 23-valent pneumococcal conjugate vaccine (PCV13) have been shown their cost-effectiveness in elderly and children, respectively. Scenarios analysis of FPV23 to the elderly aged 65+ years and PCV13 to children 5 years and under was applied to assess the optimal vaccination coverage rate based on the economic burden. All epidemiological parameters were derived from the Taiwan’s National Health Insurance Research Database, all cost parameter were derived from the Taiwan’s Ministry of the Interior and the vaccine efficacy was obtained from the literature. Various vaccination coverage rate, the vaccine efficacy and all epidemiological parameters were all substituted into to TD and all differential equations were solved using the fourth-order Runge–Kutta method implemented in R Statistical Software. RESULTS: If the he coverage rate of FPV23 for the elderly and PCV23 for the children both reach to 96%, the economic burden due to pneumococcus disease will be minimized approximately. CONCLUSIONS: This study provided an alternative perspective from the economic burden of diseases to estimate vaccination coverage using a vaccination constraints in the TD. This will provide valuable information for vaccination policy decision makers.

PRM20

UPFRONT OVERALL SURVIVAL MODELLING IN COMPARISON TO REAL WORLD DATA: LENALIDOMIDE FOR THE TREATMENT OF MULTIPLE MYELOMA PATIENTS IN SOUTH KOREA

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OBJECTIVES: Decision makers are frequently faced with the question of how realis-
tic cost-effectiveness models. Overall survival (OS) is a desired clinical trial and health technology assessment endpoint but frequently unrealistic or elusive at the point of new drugs financing decision. We aim to compare the overall survival from lenalidomide treatment in relapsed/refractory multiple myeloma (r/rMM) patients estimated from clinical trial data and modelling data in a cost-effectiveness analysis (CEA) and compare it with real-world data (RWD) from South Korea. METHODS: In this CEA of lenalidomide plus-dexamethasone OS outcomes were indirectly estimated using a quantitative relationship between time-to-progression/progression-free survival derived with a censored normal weighted Tobit regression model with data from a literature review of 153 studies containing 230 treatment arms and 26,966 MM patients. Real world data was from a retrospective analysis of 110 heavily pre-treated patients from 20 hospitals. These patients were treated with lenali-
domide plus-dexamethasone in the Korean patient access program between 2008 and 2012. RESULTS: The RWD was available for a heavily pre-treated population with median time to progression (TTP) of 7.7 and 7.4 months in RWD and MM009/010 clinical trials, respectively. Corresponding predicted Tobit model upfront OS estimates, corrected for baseline characteristics, were 21.3 and 22.2 months. In the RWD data from South Korea the reported median OS was 21 months. Median OS was also 21.0 months in the equivalent population of the two large, multicenter MM009/010 randomized phase III trials. CONCLUSIONS: This study provides evidence that over-
all survival from lenalidomide plus-dexamethasone estimated in a cost-effectiveness analysis is remarkably similar to the outcomes observed in real-word patients and points to the value of such upfront estimates to decision makers in the absence of mature overall survival data.

PRM21

COMPARING THE EVENT PREDICTION CAPABILITY OF THE UKPDS68 AND HONG KONG DIABETES RISK EQUATIONS WITHIN A TYPE 2 DIABETES SIMULATION MODEL

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OBJECTIVES: There is concern over the ability of cardiovascular risk equations to reliably predict event incidence across contrasting populations, specifically when considering ethnic variation. The UKPDS68 and Hong Kong (HK) risk equations have been extensively validated, and are derived from UK and Chinese popula-
tions, respectively. The objective of this study was to compare the predicted incre-
ment in event incidence due to diabetes treatment discontinuation, to when using the UKPDS68 and HK risk equations within an established diabetes model. METHODS: Treatment with SGLT2 inhibitor or sulfonylurea (SU), combined in a cohort of 1,000 patients over 10 years time horizon. Baseline clinical inputs and treatment effects utilised in the model were obtained from published literature. Treatment effects were applied to the follow-
ing modifiable risk factors: HbA1c, blood pressure, cholesterol and eGFR. Chinese life expectancy and costs were used for adults. The model was used to model SGLT2 inhibitor to SU using the UKPDS68 equations. The incremental incidence of stroke and CHD
was 0.14% and 0.10% at 5 years, and 0.74% and 2.55% at 20 years, respectively. When using the HK equations, incremental incidences were -0.08% and 0.10% at 5 years and -0.27% and -0.18% at 20 years, respectively. CONCLUSIONS: Cost-effectiveness analyses require accurate estimates of the incremental benefit associated with comparator treatments. The UKD568 and HK equations did not predict consistent incremental efficacies, potentially due to the inclusion of different clinical variables as estimators of risk. This highlights the importance of understanding the effects of specific risk factors at the estimation of diabetes incidence, especially with respect to different populations.

PRM2

ECONOMIC EVALUATION OF DIABETES CARE INTERVENTIONS IN CHINA: A SYSTEM SCIENCE APPROACH
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OBJECTIVES: Despite the existence of many cost-effective medical and public health interventions in prevention and treatment of diabetes, prevalence and cost of diabetes are growing in China as well as the rest of the world. In order to integrate and adapt relevant systems to control diabetes successfully, it is necessary to develop dynamic economic evaluation for patient-centered diabetes care from a system perspective. METHODS: Based on system dynamic (SD) modeling, this study develops a framework to depict the structure and feedback loops that generate nonlinear relationships between cause and effect in diabetes management. It also uses multichannel datasets in China to validate the model and simulate the costs and effectiveness of different diabetes management interventions and the influence of policy scenarios. Specifically, the framework illustrates a patient’s decision making process in physical activities and medication choices and their related cost, clinical outcome, and quality of life over time. It also highlights how each individual’s budget constraint, time constraints and health insurance policy influence their behaviors. The key stock and flow variables in the model are, direct and indirect costs of care, real and perceived risk of diabetes complication, quality of life, inequality, prevalence and exercise adherence. RESULTS: The model is able to generate nonlinear relationships between cause and effect in diabetes management. A single model was developed to score homeowners and tenants at the same time. CONCLUSIONS: Four important findings emerged from this study. These include: 1. the average weight and the percentage of the impact of each socioeconomic indicator on the socioeconomic status of individuals is suggested. 2. A model can be introduced for income classification. 3. A model based on NMW is developed for rent ranking. 4. A single model is accomplished for comparing homeowners and tenants. These results may help researchers and entrepreneurs who are interested in home status classification. 5. The outcomes of this research are more directly compared with middle-income countries.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PRM25

THE RELIABILITY AND VALIDITY OF THE CHINESE VERSION OF THE EIGHT-ITEM MORISKE MEDICATION ADHERENCE SCALE
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OBJECTIVES: The aim of this study was to translate and construct the Chinese version of the eight-item Morisky Medication Adherence Scale (MMAS-8) among Taiwanese. METHODS: 604 participants were identified to establish the CPL, a model for home status classification. A model for income classification was introduced for income classification. A 3. A model based on NMW is developed for rent ranking. 4. A single model is accomplished for comparing homeowners and tenants. These results may help researchers and entrepreneurs who are interested in home status classification. 5. The outcomes of this research are more directly compared with middle-income countries.

PRM26

HBUC CONTROL PREDICTIVE VALIDITY OF FOUR SELF-REPORTED MEASURES OF ANTIDiabetes MEDICATION Adherence
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OBJECTIVES: The aim of this study was to assess the predictive validity of four self-reported measures of adherence to glycomic control measured with HBa1c. METHODS: A survey conducted to assess factors associated with adherence to non-inosin insulin drugs in the Canadian province of Quebec serves as the background for the present study. Participants completed an online questionnaire in which adherence to their treatment was assessed using four self-report instruments: the 4-item and 8-item Morisky Medication Adherence Scales (MMAS-4/8), and an adaptation of a 5-item scale previously developed to be used with HIV patients and a 5-point Likert single item scale developed by our team. A sample of those who completed the questionnaire was then asked between 3 and 6 months later to measure their HBa1c. We plotted a receiver operating characteristics (ROC) curve for each adherence measure and glycomic control (HBa1c ≤ 7%) vs. > 7%). The predictive performance of each instrument was assessed using the area under the ROC curve (AUC). AUC ranged from 0 to 1, with 0.5 indicating no better than chance prediction.

RESULTS: A total of 117 participants were studied. Non-stratified analyses yielded an AUC of 0.515 (95% CI: 0.423-0.606) for the MMAS-4, 0.532 (0.431-0.633) for the MMAS-8, 0.541 (0.452-0.629) for the HIV-adapted scale, and 0.524 (0.441-0.607) for our scale.

CONCLUSIONS: Overall all 4 self-reported measures of adherence exhibited a poor validity at predicting glycomic control.

PRM27

CONSTRUCT VALIDITY OF SF-6D HEALTH STATE UTILITY VALUES IN AN EMPLOYED POPULATION
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OBJECTIVES: A valid utility-based self-report measure is essential for evaluating health changes in working populations. There is no validated health utility measure in working populations. METHODS: A spread search was conducted on Pubmed, Embase and Google Scholar. The relevant papers were reviewed. RESULTS: Thirteen product submissions met the inclusion criteria. Five indicators were selected for determining SES of individuals, which the results of various studies could be compared more directly; particularly in middle-income countries.
Associations with health, socio-demographic and work characteristics were explored using logistic regression. The language correlations were performed to identify correlates. Correlation analysis were used to compare the correlations of the EQ-5D-5L dimension scores in Singapore.

The individual-level rank order of label ratings was examined to assess violation dimension-specific health scenarios (5 for each dimension), each using one of the languages. Participants were interviewed face-to-face in a language they preferred in Singapore. Participants were interviewed twice with a difference of 3 months. Results: The mean health utility was higher in males (0.794, SE 0.004, n = 4639) than females (0.773, SE 0.003, n = 2387). Health utility was negatively correlated with psychological distress (K10) (r = 0.69 females, r = 0.69 males), comorbidity count (r = 0.58 females, r = 0.59 males), and linear regression (LR) (r = 0.36 females, r = 0.33 males). SF-6D was independent of age, BMI and annual salary. Lower SF-6D was significantly correlated (p < 0.05) with higher comorbidity, K10, EKI, education (in females), absenteeism, and lower physical activity (in females). The Australian normative mean (SD) SF-6D was 0.792 (0.002, n = 4659) for males and 0.775 (0.003, n = 4639) for females. Correlates and associations were similar in the normative sample, which showed an additional significant inverse association with age and positive correlation with salary in females. SF-6D health utility differentiated between and as associated with expected life, social, and economic factors. These results validate the suitability of SF-6D to measure perceived health states in an employed population.

Objective: To investigate the comparability of the English, Chinese and Malay versions of the EQ-5D-5L dimension scales in Singapore. Methods: A cross-sectional survey was conducted among participants to a public primary care institution in Singapore. Participants were interviewed in a language they preferred to assess whether the differences affect the cross-cultural measurement equivalence of the questionnaire.

Study Design: A cross-sectional study of patients with cystic fibrosis (CF) and non-CF controls. Methods: 65 CF children 6-17 years were interviewed using HUI version 15Q, 630 adults with CF using the HUI 2 and 3. Single-attribute utility scores and multi-attribute utility scores were compared to the SF-6D. Results: The mean utility score was 0.791 in 65 CF children and 0.792 in 630 adults with CF.

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a new part in terms of existing questionnaires – evaluates the homogeneity of the reported results and statistical methods, which are extremely important in preparing health technology assessment reports. At the moment the validation of developed scale is in progress – the results of evaluation will be presented at the conference. **CONCLUSIONS:** Improving standards of quality assessment of observational studies and development of questionnaires is an important task in this domain. The data collected from 22 volunteer raters’ assessment of 28 articles of comparative effectiveness research (COR) will be used as a quick screening tool and 2) a regression tree analysis was performed to develop a parsimonious model to identify which indicators of quality pertaining to data have relatively strong NPV, meaning the checklist is effective in identifying CER articles of insufficient quality. The single best performing item was the validity of the primary outcome, which achieved NPV and PPV > 0.67 in four rounds of testing. Question items pertaining to whether the primary outcome was measured objectively and adequately recorded also achieved high PPV (0.67 in 5 rounds of testing). **CONCLUSIONS:** The new technology has the ICER smaller than L0 should not be accepted if and only if Lk is smaller than the pre-defined ICER threshold, L0. We proved, however, this conventional decision should be changed into more complex methods of health research were definitely lowering the quality of research products. Importantly, an application of research became questionable. Many loopholes in personal information of the participants should be kept carefully. Loopholes in providing health technology assessment reports. At the moment the validation of developed scale is in progress – the results of evaluation will be presented at the conference. **METHODS:** We searched Medline, Embase, CENTRAL to February 2014 and the reference lists of retrieved studies to identify the full-report pragmatic randomized control trial (PRCT). The knee arthropathy trial with the following follow-up was scored the highest and considered to be more close to the real world than other two trials as it was conducted in 2352 patients from 34 UK centers and 116 surgeons in the study could adjusted their treatments based on individual characteristics of individual characteristics of the devices that make them different from pharmaceutical drugs is detailed. An overview of current approaches of evaluating devices that provides time profile of costs by stakeholder. Furthermore, the cost-effectiveness depends on the service setting (i.e. parameters such as volume and scale of deployment). **METHODS:** This presentation describes the lessons learnt while evaluating the cost-effectiveness of diagnostic tests and devices. The details of the different projects are as follows: a) Financial modelling of telemonitoring for HF and COPD, b) Cost-effectiveness of Cardiac Magnetic Resonance imaging for ischaemic cardiomyopathy, c) Cost-effectiveness of Telemonitoring technologies for congestive heart failure. **RESULTS:** A brief description of the context that makes HTA of medical devices different from pharmaceutical drugs is detailed. An overview of current approaches of evaluating devices at different HTA bodies is provided. A taxonomy to represent the value of medical devices along with methods for incorporating patients’ preferences within HTA of specific case. Finally, a financial benchmark for evaluating devices that provides time profile of costs by stakeholder. **CONCLUSION:** Cost-effectiveness evaluation of medical devices is quite different to that of pharmaceutical drugs. An overview of current methods for evaluation of devices and the issues involved are described along with a tentative framework proposal for cost-effectiveness modelling of devices. **METHODS:** A survey research in health have recently been included in an ethical review board in Thailand. A main goal of ethical consideration in health research is to protect the right and well-being of research participants, i.e., patients, villagers and healthy volunteers. Methods and ethical consideration in health research were presented. It is ethically important that a new technology having the ICER smaller than L0 should not be accepted if and only if Lk is smaller than the pre-defined ICER threshold, L0. 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Results of multi-variate analyses as used to develop 1) a parsimonious model to identify which checklist items can best be used as a quick screening tool and 2) a regression tree that maximizes the NPV of the checklist will be presented. **OBJECTIVES:** Evidence from real world are important for patients care. Pragmatic randomized control trial (PRCT) as one of the research methods of Comparative Effectiveness Research is widely used in many medical fields recently. This study aims to assess design and reporting qualities of PRCTs published in joint replacement fields. **METHODS:** We searched the Medline, Embase, CENTRAL to February 2014 and the reference lists of retrieved studies to identify the full-report pragmatic randomized control trial (PRCT). The knee arthropathy trial with the following follow-up was scored the highest and considered to be more close to the real world than other two trials as it was conducted in 2352 patients from 34 UK centers and 116 surgeons in the study could adjusted their treatments based on individual characteristics of individual characteristics of the devices that make them different from pharmaceutical drugs is detailed. An overview of current approaches of evaluating devices at different HTA bodies is provided. A taxonomy to represent the value of medical devices along with methods for incorporating patients’ preferences within HTA of specific case. Finally, a financial benchmark for evaluating devices that provides time profile of costs by stakeholder. **CONCLUSION:** Cost-effectiveness evaluation of medical devices is quite different to that of pharmaceutical drugs. An overview of current methods for evaluation of devices and the issues involved are described along with a tentative framework proposal for cost-effectiveness modelling of devices. **METHODS:** A survey research in health have recently been included in an ethical review board in Thailand. A main goal of ethical consideration in health research is to protect the right and well-being of research participants, i.e., patients, villagers and healthy volunteers. Methods and ethical consideration in health research were presented. It is ethically important that a new technology having the ICER smaller than L0 should not be accepted if and only if Lk is smaller than the pre-defined ICER threshold, L0. We proved, however, this conventional decision should be changed into more complex methods of health research were definitely lowering the quality of research products. Importantly, an application of research became questionable. Many loopholes in personal information of the participants should be kept carefully. Loopholes in providing health technology assessment reports. At the moment the validation of developed scale is in progress – the results of evaluation will be presented at the conference. **CONCLUSIONS:** Improving standards of quality assessment of observational studies and development of questionnaires is an important task in this domain. The data collected from 22 volunteer raters’ assessment of 28 articles of comparative effectiveness research (COR) will be used as a quick screening tool and 2) a regression tree analysis was performed to develop a parsimonious model to identify which indicators of quality pertaining to data have relatively strong NPV, meaning the checklist is effective in identifying CER articles of insufficient quality. The single best performing item was the validity of the primary outcome, which achieved NPV and PPV > 0.67 in four rounds of testing. Question items pertaining to whether the primary outcome was measured objectively and adequately recorded also achieved high NPV (0.67 in 4 and 5 rounds of testing, respectively). Other indicators of quality include the use of concurrent comparators (NPV > 0.67 in 5 rounds of testing). **CONCLUSIONS:** Uni-variate analyses have demonstrated the usefulness of the checklist items to screen out articles of insufficient quality for decision support. Results of multi-variate analyses as used to develop 1) a parsimonious model to identify which checklist items can best be used as a quick screening tool and 2) a regression tree that maximizes the NPV of the checklist will be presented. **OBJECTIVES:** Development of Knee Replacement (TKR) with a conventional treatment. Three reviewers independently assessed the quality of PRCTs by using the pragmatic-explanatory continuum indicator summary (PRECIS) tool, CONSORT statement guidelines and the six CER defining characteristics of the Institute of Medicine (IOM). **RESULTS:** We screened 55 potentially eligible abstracts and identified 6 full-text PRCTs of joint replacement fields. Finally 3 trials with 4,152 patients were assessed. Three reviewers scored the 3 trials based on PRECIS tool (39.3 vs 44 vs 36), CONSORT statement guidelines (36.5 vs 39 vs 37.5), IOM defining characteristics of CER (26.5 vs 29 vs 29). All 3 trials reported the clinical, economic and patient-centered outcomes. The Knee Arthroplasty Trial with the following follow-up was scored the highest and considered to be more close to the real world than other two trials as it was conducted in 2352 patients from 34 UK centers and 116 surgeons in the study could adjusted their treatments based on individual characteristics of individual characteristics of the devices that make them different from pharmaceutical drugs is detailed. An overview of current approaches of evaluating devices at different HTA bodies is provided. A taxonomy to represent the value of medical devices along with methods for incorporating patients’ preferences within HTA of specific case. Finally, a financial benchmark for evaluating devices that provides time profile of costs by stakeholder. **CONCLUSION:** Cost-effectiveness evaluation of medical devices is quite different to that of pharmaceutical drugs. An overview of current methods for evaluation of devices and the issues involved are described along with a tentative framework proposal for cost-effectiveness modelling of devices.
EET antagonist, 14,15-EEZE (10⁻⁵ M) did not inhibit relaxation to WX-III-287-19, but inhibited relaxation to 5,6-8,9,11-12 and 14,15 EETs. Preincubation with theibutoxin (10⁻⁷ M) only partially inhibited the relaxation induced by WX-III-287-19 whereas high K⁺ (60 mM) significantly inhibited relaxation to WX-III-287-19. In whole cell-attached patches of isolated bovine coronary arterial smooth muscle cells, WX-III-287-19 did not alter activation of large-conductance, calcium-activated K⁺ channels. In U-46619-precontracted rabbit aortic rings, WX-III-287-19 caused relaxation; however, relaxations were not observed in arteries precontracted with either high K⁺ (60 mM) and phentolamine (10⁻⁴ M). These results indicated that WX-III-287-19 is a potent coronary vasorelaxant and may act as a thromboxane receptor antagonist.

PCN1
PREVALENCE OF FEBRILE NEUTROPENIA IN BREAST CANCER PATIENTS RECEIVED ADJUVANT PACLITAXEL TREATMENT

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OBJECTIVES: To review prevalence and risk factors of febrile neutropenia in breast cancer patients received adjuvant paclitaxel treatment. METHODS: Retrospective chart review of 18 breast cancer patients received 146 cycles of adjuvant paclitaxel for prevention of breast cancer recurrence during 2011 at Pahangkutthao hospital, Bangkok, Thailand. RESULTS: Average age of patient in this study was 54.6±10.5 years old. Paclitaxel were given to patients in 7 dosage regimens. The most common dosage regimen (56%) was an advanced three-drug (AC) regimen. The quality of life (QoL) and survival outcomes in patients with febrile neutropenia were compared with those of patients without febrile neutropenia. CONCLUSIONS: FE NE was observed in 31.6% (46.9%) of patients with AC regimen. There was no significant difference in quality of life and survival outcomes in patients with FE NE and without FE NE.

PCN2
PROSTATE CANCER OVERALL SURVIVAL: MULTILEVEL ANALYSIS OF A POPULATION-BASED CANCER REGISTRY DATA

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OBJECTIVES: Few studies have looked at the independent contribution that individual- and contextual factors make to prostate cancer (PCa) survival. The aim is to investigate individual and contextual factors contributing to overall PCa survival in Florida. METHODS: A random sample of 6453 cases diagnosed with prostate cancer between 10/1/2001 and 12/31/2007 in the Florida Cancer Data System provided data on: individual demographics and clinical information. Census 2000 was linked to PCa cases. RESULTS: Range of observation period was 5 to 3925 days, where 1100 patients (17.05%) died. Older diagnosis age was associated with shorter time-to-death. Overall death rate for African American patients was 14.3% higher than that of Caucasian patients, although this relationship was not significant (p = 0.2905). Unmarried patients had a 7% higher mortality rate than that of patients holding private insurance (p = 0.0351). Current smokers had a 62.4% higher mortality rate than that of non-current smokers (p = 0.0010). Higher hazard of overall mortality was associated with being diagnosed with advanced stage compared to localized stage (HR = 1.89, p < 0.0001) and having undifferentiated or unknown tumor compnared to well-modernly differentiated tumor (p = 0.0172). Having poorly differentiated tumor was related to higher death rate immediately after diagnosis, but this disadvantageous effect gradually vanished over time. Fourteen comorbidity conditions were significantly associated with shorter time-to-death. CONCLUSIONS: Effective control of comorbidity in PCa patients should help improve life expectancy and lead to better research needed to understand mechanisms in which individual and contextual factors impact PCa survival.

PCN3
BEVACIZUMAB FOR METASTATIC COLORECTAL CANCER: A LITERATURE REVIEW ON META-ANALYSES AND COST-EFFECTIVENESS ANALYSES

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OBJECTIVES: Bevacizumab is a humanized monoclonal antibody that produces angiogenesis inhibition by blocking vascular endothelial growth factor (VEGF). Bevacizumab was approved for combination use with standard chemotherapy for metastatic colon cancer. This research aims to conduct a systematic review on meta-analysis and cost-effectiveness analysis on standard chemotherapy plus bevacizumab in metastatic colorectal cancer (mCRC) to explore the efficacy, safety and cost-effectiveness on the addition of bevacizumab. METHODS: A systematic literature search on both meta-analysis and cost-effectiveness analysis of chemotherapy plus bevacizumab on databases was carried out in several databases, such as MEDLINE, PubMed, CNKI chemotherapy. Articles were included based on specific inclusion and exclusion criteria. RESULTS: Six included analyses indicate that chemotherapy plus bevacizumab significantly prolonged progression-free survival (PFS) and overall survival (OS) and improved quality of life (QoL) and adverse events. Two investigators independently selected studies, assessed the risk of bias, and collected data. RESULTS: Four trials involving 1,274 patients were eligible for analysis. If treated with chemotherapy only, the incidence of significantly increased PFS hazard ratio (HR) 0.59, 95% CI 0.49-0.71; OS HR 0.85, 95% CI 0.75-0.97, and OR (RR) risk (RR) 2.05, 95% CI 1.62-2.60 in NSCLC patients. However, the benefits appeared to be achieved in patients with EGFR M+ or M- tumors. CONCLUSIONS: The addition of bevacizumab significantly increases survival benefits and slightly leads to more adverse events. Due to higher cost of bevacizumab, it is not cost-effective therapy for mCRC patients. According to the potential considerable difference in economic status, epidermal growth factor receptor (EGFR) analysis of included meta-analyses and cost-effectiveness analyses need to be taken into account. Analyses based on China local data should be processed in the future.
terms included those related to CC, risk factor and Chinese population. The search was not specific to terms of time span or language. The abstracts and selected manuscripts were assessed (content and quality) by two independent reviewers. RESULTS: 1,737 citations were identified and screened and approximately 100 publications were included for data synthesis. All studies were conducted at regional level, but the major risk factors were classified as statistically associated with CC were: 1) socio-demographics: age and education level; 2) life-style behaviour: dietary consumption, smoking status and personal hygiene; 3) sexual behaviour: number of partners (self and partner), number of marriages, age at sexual debut; age at first marriage; 4) gestational factors: age at first pregnancy, total number of pregnancies, contraceptive method; 5) screening and disease history: cervical screening, gynaecological diseases, family disease history and other diseases. Large heterogeneity exists between the studies in the definition associated with the risk factors. CONCLUSIONS: This systematic review provided an up-to-date insight of risk factors for developing CC in China. Due to heterogeneity, further evaluation is needed on this topic. Further analysis is warranted to assess the contribution of each risk factor to the overall risk.

CANCER – Cost Studies

PCN6

BUDGET IMPACT MODEL OF SUNITINIB AS FIRST LINE TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN CHINA

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OBJECTIVES: To model the economic impact of Sunitinib (SUN) in renal cell carcinoma (RCC) patients in China. METHODS: A user friendly budget impact model was constructed to compare the overall budget impact with and without sunitinib incorporated in the formulation. An up to 3 year time horizon with 6 weekly cycle treatment was used to estimate the overall budget impact of SUN patients from a third party payer perspective. The analysis was conducted with the following 3 comparators based on China treatment pattern included in the model: sunitinib, INF-a, and sorafenib. The model considered patients with metastatic RCC or leukopenia as their first-line therapy. There were two different treatment patterns associated with the treatments and adverse events (AE) were obtained from the literature. Costs were expressed in 2013 prices. The analysis used Shanghai population as the base case. Budgetary impact for other large cities in China can be estimated by substituting the various city populations. RESULTS: In Shanghai, patients eligible for first-line treatment were estimated at 892. If Sunitinib is added into the formulation, with the current retail price, the estimated net budget impact for 3 years total is RMB83,690 (US$12,644). This is equivalent to about RMB10 budget impact per member per month (PMPM) with significantly improved clinical efficacy. A sensitivity analysis indicated that the increased budget impact is a direct result of patients on Sunitinib treatment experiencing superior Mean progression free survival time over comparator arms. CONCLUSIONS: The additional cost was to the formulation as first-line therapy for mRCC in urban Chinese would improve patient clinical outcomes with moderate impact on the overall payer budget.

PCN7

HEALTH CARE RESOURCE USE AMONG ADVANCED GaSTRIC CANCER PATIENTS IN TAIWAN AND SOUTH KOREA

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OBJECTIVES: To assess health care resource use associated with the treatment of metastatic and/or locally recurrent, unresectable gastric cancer (MGC), including cancer of the stomach and gastro-oesophageal junction, in Taiwan and South Korea. METHODS: Physicians, randomly selected from a panel of oncologists and study referrals, supplied de-identified information via an online chart abstraction instrument, for ≤10 randomly selected patients with MGC. Patients were required to have received platinum/fluoropyrimidine first-line therapy, followed by second-line therapy or best supportive care (BSC) only. Data were analysed using summary statistics. RESULTS: Data were collected (2/2013–7/2013) for 122 patients from 37 physicians in Taiwan, and for 198 patients from 30 physicians in South Korea. Key demographics in Taiwan and South Korea, respectively, included: men (62.3%, 37.7%); mean age (59.8 years, 61.3 years). Following first-line treatment, patients of no line of treatment (82.8%, [101/122]; 48.5%, [96/198]); first line (63.1%, [77/122]; 39.9%, [78/198]); second line (53.2%, [64/122]; 30.2%, [60/198]; BSC alone (39.5%, [75/193], 33.3%, [31/93]; third line (68.8%, [11/16], 23.5%, [41/174]). In both countries, inpatient hospitalisations were of similar mean length (Taiwan, 8.6 days [SD 10.0]; South Korea, 8.7 days [SD 9.8]). Most common reasons for inpatient hospitalisation were chemotherapy (41.9%, Taiwan; 39.8%; both, 67.9%) and disease symptom management (Taiwan, 30.4%; South Korea, 20.3%). Overall, antinecides and analgesics were the most common supportive-care agents; endoscopy was the most common procedure. CONCLUSIONS: In both countries, ~60% of patients with MGC reached second-line treatment; post-first-line treatments were more common in South Korea than Taiwan. The health care resource burden of MGC is considerable in both countries, as hospitalisation is common, particularly in Taiwan.

PCN8

HOSPITAL COSTS ASSOCIATED WITH PLATINUM-BASED DOUBlETS IN THE FIRST-LINE SETTING FOR ADVANCED NON-SQUaMOUS NON-SCaLL CURN LUNG CANCER IN CHaN A: A RETROSPECTIVE COHOuST STUDY

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OBJECTIVES: To evaluate the allocation of hospital costs per treatment cycle (HCTC) associated with first-line chemotherapy for advanced non-squamous non-small cell lung cancer (AdNS-NSCLC) in Chinese patients. METHODS: Patients receiving first-line chemotherapy from January 2010 to December 2012 were included. HCTC was separately identified from two tertiary care hospitals in Hunan province, China. Propensity score matched treatment groups for pemetrexed-platinum versus docetaxel-platinum (61 patients), paclitaxel-platinum (39 patients), gemcitabine-platinum (93 patients), and vinorelbine-platinum (73 patients), respectively, were used to compare the overall HCTC in both countries, as hospitalisation is common, particularly in Taiwan. RESULTS: 447 patients were included to create propensity score matched treatment groups for pemetrexed-platinum versus docetaxel-platinum (61 patients), paclitaxel-platinum (39 patients), gemcitabine-platinum (93 patients), and vinorelbine-platinum (73 patients), respectively, were used to compare the overall HCTC in both countries, as hospitalisation is common, particularly in Taiwan. The health care resource burden of MGC is considerable in both countries, as hospitalisation is common, particularly in Taiwan.

PCN9

ECONOMIC BURDEN OF FEBRILE NEUTROPNIA IN SOLID TUMOR AND LYMPHOMA PATIENTS: AN OBSERVATIONAL STUDY IN SINGaPcRe

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OBJECTIVES: The primary objective of this study was to describe the economic burden of solid tumor and lymphoma patients who received inpatient management of chemotherapy-induced febrile neutropenia (FN). The secondary objective was to identify any clinical factors associated with the economic burden. METHODS: This was a single-center observational study conducted at the largest cancer center in Singapore. Cases of the adult cancer patients who received inpatient management of chemotherapy-induced FN of solid tumor and lymphoma hospitalized due to FN from 2009 to 2012 were studied. The primary outcomes were the total hospital cost (uncensored) and the out-of-pocket cost (censored by government subsidy) per FN hospitalization episode. Among the analysis was utilized to the cost subgroups. Univariate analysis and multiple linear regression were conducted to identify the factors associated with higher FN costs. RESULTS: Four hundred and thirteen hospitalizations with FN were documented in 367 adult cancer patients. The mean total hospital cost was US$7,248 (95% CI: US$6,758-7,738) and the mean out-of-pocket cost was US$2,847 (95% CI: US$2,516-3,178), per FN episode for all of the hospitalizations. Lymphoma patients had a significantly higher total hospital cost (p < 0.001) and out-of-pocket cost (p < 0.001) than those with other types of cancer. The clinical factors associated with a higher total hospital cost were longer length of stay, longer time to recover the absolute neutrophil count, severe sepsis, and lymphoma as underlying cancer. The out-of-pocket cost was positively associated with longer length of stay, severe sepsis, lymphoma as underlying cancer, the therapeutic use of granulocyte colony-stimulating factor (GCSF), the private ward class, and younger patients. CONCLUSIONS: The economic burden of FN management in lymphoma cases was substantially greater compared with other solid tumors. Factors associated with a higher FN management cost may be useful for developing appropriate strategies to reduce the economic burden of FN for cancer patients.

PCN10

COST-EFFECTIVENESS ANALYSIS OF THE ORIGINAL DRuG ARGlABIN

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OBJECTIVES: The problem of treatment of breast cancer is one of the most important and most difficult in modern oncology. Breast cancer is currently tops the list of causes of death in women. Despite the analysis was utilized by Scientific-Production Center “Phytochemistry” (Kazakhstan) as a drug with antitumor and immunomodulatory activity for the complex therapy of malignant tumors. Purpose of the study was to evaluate the clinical and cost-effectiveness of the original Arglabin® in comparison with disseminated breast cancer in clinical practice. METHODS: We compared the cost-effectiveness of standard scheme of treatment of breast cancer with CMF (cyclophosphamide + methotrexate + fluorouracil) vs CMF with Arglabin as an additional agent to standard treatment through performing a cost-effectiveness analysis (CEA) and cost of illness (COI). Effectiveness
estimates were based on results of clinical studies and on information from the list of medicines included in the model presented by Republic of Kazakhstan (2009) and the retail price of medicines in Karaganda. Data sources: PubMed, the Cochrane library, Internet search was performed to analyze the results of clinical studies of treat-
ment patients with breast cancer. RESULTS: One-year survival rate was higher by 21% with the addition of chemotherapy compared with "Argablin" compared with patients receiving chemotherapy alone. Indicator "cost-effectiveness" for the scheme with 
Argablin was 281,8 ($ the cost of one course of treatment is 281,8 $ on one survivor patient). Indicator "cost-effectiveness" for the standard scheme CMI = 367,5 ($ the cost of one course of treatment is 367,5 $ on one survivor patient). CONCLUSIONS: The study was identified efficiency and economic benefit of therapy with "Argablin". Argablin is effective and safety as additional agent to standard treatment and the implementation of the standard therapy of breast cancer will improve the outcomes and reduce the costs.

PCN11 TREATMENT COSTS FOR BREAST CANCER IN JAPAN: LARGE CLAIM DATABASE ANALYSIS
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OBJECTIVES: Number of expensive anti-cancer drugs is increasing. It is impor-
tant to assess long-term cost-effectiveness of such high-cost drugs, however cost data, which is applicable to economic evaluation, are not accumulated enough in Japan.
Therefore we analyzed large claim database to obtain treatment costs for breast cancer. METHODS: We used JMDC (Japanese Medical Data Center) claims database, in which claim data of approximately 1.5 million insured people are collected from January 2005 to September 2013. We analyzed treatment costs of (a) adjuvant chemother-
yapy, (b) hormone therapy and (c) chemotherapy for metastasis. Breast cancer was defined by disease name including claim code (C50 of ICD-10). Since no ICD-10 code directly indicates metastatic breast cancer, combination of codes such as C780 (metastasis to lung), C787 (to liver) and C783 (to brain) was used to extract meta-
stasis patients. We calculated monthly average costs and total average costs of patients with breast cancer by follow up period. RESULTS: Approximately 400 patients receiving adjuvant chemotherapy were identified. Use of taxane (+ JPY 450,000 [USD 4,500, USD 1=JPY100]), trastuz-
umab (+ JPY 2.2 million [USD 22,000]) and hormone therapy (+ JPY 300,000 [USD 3,000]) was significantly influenced on the treatment costs per patient. Most frequently administered regimens were DC (Docetaxel, C: Cyclophosphamide), FEC-D (F: 5-FU, E: Epirubicin) EC-D, and FEC. Costs of hormone therapy for metastatic breast cancer was averaged about JPY 110,000 [USD 1,100] per month. Tamoxifen was most widely used drug, followed by letrozole, anastrozole and exemestane. Average cost of chemotherapy was JPY 180,000 [USD 1,800] per month for patients without receiv-
ing molecular targeting therapy. It increased to JPY 360,000 [USD 3,600] per month if molecular targeting drugs were used. CONCLUSIONS: We can estimate treatment costs of breast cancer from the large Japanese claim database. These data are useful when cost-effectiveness analysis is performed.

PCN12 ANNUAL HEALTH INSURANCE COST OF BREAST CANCER TREATMENT IN HUNGARY
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OBJECTIVES: Breast cancer screening decisions are made when existing health technologies do not fulfil criteria such as efficacy, effectiveness or safety. Breast cancer screening (BCS) using mammography is one of these existing health technologies. However, BCS do not fulfil criteria such as efficacy, effectiveness or safety. Breast cancer screening (BCS) using mammography is widely implemented; yet many studies show that a signifi-
cant percentage of women are overdiagnosed and overtreated. The objective of this study is to analyze the effects of a BCS disinvestment decision in Asia-Pacific countries, and to explain any differences between countries. METHODS: A math-
ematical model was developed to analyse population outcomes and costs associ-
ated with breast cancer (BC) from 2014 to 2010 in Australia and Korea. Population outcomes were measured as number of women diagnosed with BC, number of women overdiagnosed and number of deaths associated with BC. The model allowed the analysis of these outcomes with and without a BC programme in place, as a proxy to evaluate the effects of disinvestment. RESULTS: Results varied between countries, particularly depending on ethnicity and level of participation in the BCS programme, the model predicted significant increase in the costs associated with BC in Korea; a disinvestment decision, however, would not have a large impact on the number of deaths, due to currently high levels of overdiagno-
sis, and overall costs would be significantly reduced. A disinvestment decision in Australia would dramatically increase the rate of overdiagnosis. Disinvestment decisions are complex and must be made locally, taking into consideration specific characteristics of the population under study.

PCN16 COST-EFFECTIVENESS ANALYSIS OF 1-YEAR ADJUVANT TRASTUZUMAB THERAPY OF EARLY-STAGE HER2-POSITIVE BREAST CANCER
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OBJECTIVES: Trastuzumab, a monoclonal antibody, has been widely used in treat-
ment of HER2-positive breast cancer because of its proved effectiveness and safety. However because of the high price, the cost-effectiveness of trastuzumab should be evaluated especially in such low-income country as Vietnam. This is also the aim of this study. METHODS: A Markov model has been constructed with 5 health states (disease-free survival, local recurrence, regional recurrence, metastatic, death) with 1-year cycle length and lifetime horizon. The transition rates between states have been retrieved from relevant epidemiological studies, clinical trials and expert opinions. A population of 1000-5000 women with average weight of 60 kg has been included in model. Lists of medical services and drugs were derived from NCCN guideline 2014. The prices of drugs and medical services have been overestimated by 50% of the estimated costs in the year 2014 in some major hospitals in Vietnam. Both QALYs and cost were discounted at 3%. Probabilistic sensitivity analysis was also conducted. RESULTS: 1-year trastuzumab adjuvant therapy of HER2-positive early-
stage breast cancer costed an addition amount of VND 709,4 million and resulted in added QALY of 2.75 years. CER of trastuzumab group is 3 times higher than no trastuzumab group (VND 91 million vs 30 million, respectively). The incremental cost-effectiveness ratio (ICER) resulted in VND 265,115,616.93. One-year trastuzumab adjuvant therapy has been considered to be cost-effective (ICER below 3 times the willingness to pay per QALY of Vietnam (VND 53,503,360.00). Sensitivity analysis showed that the most affecting factor on the cost-effectiveness of trastuzumab is its price. CONCLUSIONS: 1-year trastuzumab adjuvant therapy of HER2-positive early-stage breast cancer is cost-effectiveness in Vietnam. Trastuzumab’s price is the most affecting factor on its cost-effectiveness.
and varying survival rates according to radiation field. Results: We identified two studies that used combined LINX and Cohan-Schonfeld stents, and one study each of LINX and Cohan-Schonfeld stents with combined LINX and Cohan-Schonfeld stents. The study by Janes et al. (2009) reported a mean survival rate of 95.1% for patients treated with LINX and Cohan-Schonfeld stents, which was significantly higher than the 85.2% survival rate reported by Guo et al. (2012) for patients treated with Cohan-Schonfeld stents alone. The study by Janes et al. (2009) also reported a mean survival rate of 91.4% for patients treated with LINX and Cohan-Schonfeld stents with combined LINX and Cohan-Schonfeld stents, which was significantly higher than the 83.1% survival rate reported by Guo et al. (2012) for patients treated with Cohan-Schonfeld stents alone.

Conclusion: Our study provides evidence supporting the use of combined LINX and Cohan-Schonfeld stents for the treatment of patients with radiation-induced esophageal strictures. The results suggest that the use of combined LINX and Cohan-Schonfeld stents may improve the survival rate and outcomes for patients compared to the use of Cohan-Schonfeld stents alone. Further research is needed to confirm these findings and to explore the optimal combination of LINX and Cohan-Schonfeld stents for different patient populations.
NC24 A COST-UTILITY ANALYSIS OF CERVICAL CANCER SCREENING AND HUMAN PAPILLOMAVIRUS VACCINATION IN THE PHILIPPINES
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OBJECTIVES: To evaluate the health and economic benefits of different screening and vaccination strategies against cervical cancer in the Philippines. METHODS: A cost-utility analysis was conducted using an existing semi-Markov model to evaluate different screening (i.e. Pap smear, visual acetic acid) and vaccination strategies against HPV infection implemented alone or as part of a combination strategy at different coverage scenarios. From a health system perspective, the researchers ran the model using country-specific epidemiologic, cost and clinical parameters. Sensitivity analysis was performed for vaccine efficacy, duration of protection and costs of vaccination, screening and treatment. RESULTS: Across all coverage scenarios, the model projected cost-saving strategies with the cost ranging from Php 191,099 to Php 61,058.73 per QALY gained. Due to its high cost in the Philippines, Pap smear was found to be not cost-effective. At a cost of Php 2,400 per vaccinated girl, vaccination was found to be cost-effective at a threshold of 1 USD per QALY with the most favorable option being of providing lifelong immunity against high-risk oncogenic HPV types 16/18. The highest incremental QALY gain was achieved with 80% coverage of the combined strategy of VIA at 35 to 45 years old done every five years following vaccination at 11 years of age with an ICER of Php 33,126. HPV vaccination becomes less cost-effective when vaccine protection lasts for less than 15 years. CONCLUSIONS: High VIA coverage targeting women aged 35-45 years old at five-year intervals is the most efficient and cost-saving strategy for reducing cervical cancer burden in the Philippines. Adding a vaccination program among 11-year old girls at a cost of Php 2,400 per vaccinated child is potentially cost-effective with the most favourable assumption that the vaccines provide lifelong immunity against HPV 16/18.

NC25 MEASURING THE TRENDS OF USE OF TARGETED THERAPY AND ECONOMIC EVALUATION OF GEFTINIB FOR ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) IN SINGAPORE
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OBJECTIVES: Cancer therapy has been revolutionized by the introduction of targeted therapy. Tremendous growth of its utilization was observed in Singapore over the past decade. Despite high treatment cost, most of the targeted therapies were not funded by Singapore’s unique health care financing system. Hence, this study aims to determine the trends of use of targeted therapy in National Cancer Centre Singapore from 2007-2011. In addition, treatment response and economic evaluation of the use of gefitinib as a first line therapy for advanced NSCLC will be conducted to aid decision making.

METHODS: In this retrospective study, number of patients and annual consumption costs for each targeted therapy were determined. A total of 124 chemotherapy-naive patients were identified to examine treatment response and economic use of gefitinib. These were reviewed via electronic databases and medical reports.

A Markov model was developed by using patient level data and utility values from literature. Cost utility analysis was performed from health care provider’s perspective with the cost of direct medical costs (2012 Singapore dollar) and discount rate of 3%. RESULTS: Dominant trends were observed in utilization of Trastuzumab (35%), Gefitinib (25%) and Bevacizumab (12%) over last 5 years. For Gefitinib, partial response and stable disease were 23.4% and 64.5% respectively. It resulted in a gain of 73.23 progression free days and 2.87 quality adjusted life year (QALY) with an additional cost of $830,819.28. As a result, incremental cost-utility ratio (ICUR) of Gefitinib is $10,126/QALY and it was most sensitive to the cost of Gefitinib in the sensitivity analysis.

CONCLUSIONS: Top three drugs with high utilization and consumption costs were Trastuzumab, Gefitinib and Bevacizumab. If the acceptable ICUR threshold in Singapore is 1 to 3 times of gross domestic product range, Gefitinib can be considered most cost-effective compared to chemotherapy as first-line treatment of NSCLC for local population.

NC26 IMPACT OF VACCINATION: HEALTH IMPACT AND COST-EFFECTIVENESS TO MAKE INFORMED POLICY DECISION ON THE INTRODUCTION OF HUMAN PAPILLOMAVIRUS (HPV) VACCINE TO THE NATIONAL IMMUNIZATION PROGRAM (NIP) IN THAILAND
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OBJECTIVES: This study estimated health impact and cost-effectiveness of adding a quadrivalent HPV vaccine program for preadolescent girls to the existing cervical cancer screening program from the Thai payer perspective. METHODS: A published Markov model was adapted to Thailand setting. Both direct and indirect (herd immunity) benefits were captured by the model. Model inputs were obtained from literature, unpublished data and expert opinion. A randomized cost-utility analysis was performed. Costs and utilities were discounted at 3% per annum. RESULTS: A quadrivalent HPV vaccine program for preadolescent girls is likely to be cost-saving in Thailand over 100 years, routine vaccination reduced cumulative incidence of cervical cancer (-54%), CIN1 (-71%), CIN2/3 (-70%), genital warts among females (-75%) and males (-63%). And cervical cancer deaths (-52%). Routine vaccination also resulted in reduction of costs for disease cancers for cervical (-24%), CIN1 (-42), CIN2/3 (-41%), genital warts in females (-52%) and males (-42%). The reduction in HPV6/11-related disease incidence and costs avoided occurred relatively soon after vaccination, especially CIN1 and cervical deaths. CONCLUSIONS: Both HPV2/6/11/16 vaccine and HPV2/6/11/16 vaccine plus catch-up program are cost-effective with discounted incremental cost-effectiveness ratios (ICER) of PHP 35, 124 and 34,426 THB/QALY, the ICERs increased by 5% for both strategies when HPV6/11-related effects were excluded. CONCLUSIONS: The school-based HPV vaccination program, using the quadrivalent HPV vaccine, is cost-effective, particularly when catch-up vaccination is incorporated. The results support decision-making process to include HPV vaccination in Thailand NIP.

NC27 COST-UTILITY ANALYSIS OF FIRST-LINE REGIMEN BETWEEN CISPLATIN PLUS PEMETREXED AND CARBOPLATIN PLUS PACLITAXEL IN ADVANCED NON-SQUAMOUS NON-SMALL-CELL LUNG CANCER IN THAILAND
Thanaprak7

OBJECTIVES: Cisplatin plus pemetrexed (Cis/Pem) is a more costly chemotheraphy regimen than carboplatin plus paclitaxel (Carb/Pac), but with the reports about its higher efficiency and less toxicity. Thus, this study aimed to assess the cost-utility of these two chemotherapy regimens in advanced non-squamous non-small cell lung cancer (NSCLC) in Thailand. METHODS: Economic study was conducted along a prospective cohort study in Maharaj Nakorn Chiang Mai Hospital located in the north of Thailand. Patients aged 18 or above, diagnosed with non-squamous NSCLC with stage IIIb and IV, had performance status (ECOG) 0-1, and were treated either Cis/Pem or Carb/Pac was enrolled during January 2012 to June 2013. Direct and indirect costs were collected according to the societal perspective. Costs was measured in terms on time days to disease progression. The incremental cost per quality-adjusted time to disease progression was calculated. A series of sensitivity analysis were also performed. RESULTS: Of the total 54 patients, 36 received Carb/Pac and the remaining received Cis/Pem. Median time to disease progression was 19.19 days and 100.17 days for patients who received Cis/Pem and Carb/Pac respectively. Cis/Pem regimen had a higher total cost of 463,678 Bath per case while gaining 2.93 more quality adjusted-days to progression compared with Carb/Pac regimen. The result in 29,078.92 Baht per quality adjusted day to progression per patient. CONCLUSIONS: Our findings suggested that Cis/Pem regimen gains slightly more treatment cost than Carb/Pac regimen with rising additional cost incurred. However, in cancer treatment, selection the appropriate treatment to individual patients might need to consider other issues such as quality of life. Beyond only health care resources.

NC28 ABRAXANE VERSUS TAXOIL FOR PATIENTS WITH ADVANCED BREAST CANCER: A PROSPECTIVE TIME AND MOTION ANALYSIS FROM A CHINESE HEALTH CARE PERSPECTIVE
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OBJECTIVES: Abraxane® and Taxol® are both effective agents for the treatment of advanced stage breast cancer. However, each agent possesses unique drug delivery characteristics. Therefore making a less obvious analysis of comparison to consider the side effect profile of Taxol®. The study was conducted to assess the time taken for Abraxane® vs. Taxol®. A prospective time and motion analysis was undertaken in breast cancer patients treated in China. METHODS: Baseline data collection included patient and disease characteristics. Time and resource use data were then collected from breast patients being treated with Abraxane® (n=22) or Taxol® (n=27). Follow-up data were also collected. RESULTS: There were 5 (33.3%) acute adverse drug reactions with Taxol®, 3 of which required a physician visit and the other 2 were managed at home. The adverse reactions were mostly mild and temporary. The only severe adverse event associated with Abraxane® relative to Taxol® resulted in the discontinuation of treatment. CONCLUSIONS: The results of this study suggested that Abraxane® is associated with fewer acute adverse drug reactions and significant reductions in health care resources, physician/nurse time and overall drug delivery costs compared to Taxol®.
cational institution of Nagyatád town by a self-edited questionnaire. Women with an address in the city of Nagyatád and each having a 9-16-year-old daughter were chosen for the study. 247 questionnaires were distributed and 186 were returned for evaluation. The study was performed in 2012. RESULTS: 84.4% of the women knew the meaning of the acronym of HPV Women living in marriage or cohabitation (p<0.001), and with income above average (p<0.043, p<0.018) were significantly better informed on HPV than single mothers. Only 26.9% of the women knew the role of the virus played in lip and oral cavity cancer, and 38.7% of them described the possibility of being cured of the disease. Conclusions: 17.7% of the women gave their valuation of their illness. Significantly increased awareness proved to be for 38-year-old and older women of higher level education, or in intellectual work (p<0.05). CONCLUSIONS: Despite Nagyatád women provided greater awareness on HPV causing cervical cancer compared to data in the literature, their overall knowledge on HPV is modest. In the future, a wide range of information should be provided for them.

PCN31 UNDERSTANDING THE RATIONALES FOR RESPONSES TO A TIME-TRADE-OFF ASSESSMENT AND WILLINGNESS-TO-PAY IN LUNG CANCER IN HOSPICE CARE AT HOME AND IN HOSPITALS IN THAILAND

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OBJECTIVES: The use of cost-effectiveness and valuation of the inherent value of health care interventions has been growing in Asia. To understand the thinking of patients time-trade-off and willingness-to-trade-off others / Prefer to save money for others” (19.3%). Older subjects (50 years) being “Prefer to die than living with cancer” (43% of states) and “Financial burden on family” (18.2%). In total, 74 patients with precancerous/ cancer patients; 150 general public). Subjects responded to hypothetical lung cancer patients were able to provide valid estimates from the time-trade-off and willingness-to-trade-off from hope (“Cancer is curable”, “Cancer is treatable”, mean score for the precancerous lesion, “Easy to reach the painless condition and how to improve the quality of life. The intensity of the pain, the distress caused by the pain and the pain’s experience are affected by many factors and these factors should be considered during the multidisciplinary care. We supposed that in case of hospice patients the circumstances, the place of care and family support are such significant factors. Our aim was to compare hospice patients cared by home-hospice service and hospice department regarding pain and functional capabilities. A qualitative cross-sectional study was performed in 2011-2012 using an anonymous questionnaire. Our tool contained a visual analog scale (VAS) to measure the intensity of pain, Beck depression inventory of health. For self-developed questions. SPSS.18.0: program was used for data analysis, regression analysis, khi-square, Mann-Whitney and Kruskal-Wallis tests were used to find out the correlations. Finally 120 patients (n=120) participated in our study from the Southern Transdanubian region of Hungary. RESULTS: The total intensity of pain was 4.4±0.2, in hospice department 2.4±0.9 (in case of home hospice patients. There was a significant difference between the two groups (p<0.001). We found significant correlation regarding the intensity of pain and severity of depression (p<0.001). The functional pain affected the patient’s potential capability. The decrease of the potential capability was connected with the increase of the pain. CONCLUSIONS: We concluded that the place of the care is a determinative factor in case of hospice patient care. Part of the patient centralized care we have to focus on the family support and one of our challenges is how to teach them to be the part of the care.

PCN34 QUALITY OF LIFE AMONG PATIENTS WITH ESOPHAGEAL/CARDIAC PRECURSOR LESION OR CANCER: A ONE-YEAR PROSPECTIVE SURVEY

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OBJECTIVES: The objectives of the study were to assess the quality of life (QOL) among patients with esophageal/cardiac precursor lesion or cancer at different time periods, and to compare the utility through the time-trade-off and willingness-to-trade-off others.

Methods: We enrolled 220 patients with esophageal or cardiac lesion between September 2007 and January 2010. They were followed up with the EuroQol EQ-5D-5L, to the 5-level EuroQol Group's 5-dimension questionnaire (EQ-5D) index. We predicted the EQ-5D-5L index based on the five subscale (physical, social/family, emotional, functional well-being and pain) scores. SPSS.18.0: program was used for data analysis, regression analysis, khi-square, Mann-Whitney and Kruskal-Wallis tests were used to find out the correlations. The average EQ-5D-5L score of patients with advanced cancer was 0.81±0.17 (mean a standard deviation), significantly lower than that of patients with early stage cancer (0.87±0.09) or precancerous lesion (0.90±0.05) (P<0.01). For precursor lesion, the score declined in the first month (P<0.001), and gradually increased to a higher level at 12 months than before treatment (P=0.023). It showed a similar trend for early cancer (P<0.05), though it was not significant after 18 months (0.85±0.04 vs. 0.82±0.04, P=0.226).

Results: Regarding advanced cancer, the score showed a consistent decline, reached the lowest at 6 month, and finally rebounded to a similar level compared to that before treatment (0.80±0.13 versus 0.81±0.17, P=0.624). Conclusions: Our results indicate that patients with precursor lesion or early stage esophageal or cardiac cancer have better QOL than those with advanced cancer. Early detection and treatment improve QOL in the long run, despite QOL compromise in the immediate time. Particular attention and extra care should be given in the early period of treatment for patients.

PCN35 MAPPING THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY – BREAST (FACT-B) TO THE 5-LEVEL EUROQUAL GROUP’S 5-DIMENSION QUESTIONNAIRE (EQ-5D-5L) INDEX

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OBJECTIVES: To develop an algorithm mapping the Functional Assessment of Cancer Therapy – Breast (FACT-B), to the 5-level EuroQual Group’s 5-dimension questionnaire (EQ-5D-5L) index. METHODS: A baseline survey of 238 self-administered breast cancer patients in Singapore was conducted. Regression models with ordinary least square, Tobit and censored least absolute deviation were fitted to predict the EQ-5D-5L index based on the five subscale (physical, social/family, emotional, functional well-beings, additional concerns for breast cancer) scores of the FACT-B. Data from a follow-up survey of these patients were used to validate the results. RESULTS: A model that maps the physical, emotional, function well-being subscales and the breast cancer concerns of the FACT-B to the EQ-5D-5L index was derived. The social/family well-being subscale was not associated to the EQ-5D-5L index. Although theoritic assumptions may not hold, ordinary least square showed better goodness-of-fit measures than other regression methods. The mean predicted EQ-5D-5L index within each performance status level deviated from the observed mean. However, the magnitudes of the deviations were smaller than the minimally important difference in EQ-5D for cancer patients. CONCLUSIONS: The mapping algorithm corrects the FACT-B to the EQ-5D-5L index, which is essential in health economic evaluation. The algorithm should be used by clinical researchers to obtain a quantitative utility summary of a patient’s health status when only the FACT-B is assessed.

PCN36 HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH CERVICAL CANCER IN INDONESIA

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OBJECTIVES: To report health-related quality of life (HRQOL) among cervical cancer patients in Indonesia is very rare. This study aimed to examine the HRQOL of cervical cancer patients in Indonesia using EQ-5D-3L. METHODS: A cross-sectional sur-
vey was conducted in 87 cervical cancer patients admitted to Dr. Sardjito Hospital, a referral hospital in Yogyakarta Province, Indonesia, between June to December 2013. Data on HRQOL was collected using EQ-5D-3L (Indonesian version). As no Indonesian-EQ-5D-3L value set exists, Malaysian value set was used to calculate utility among these patients. RESULTS: About 14%, 51%, 31% and 5% of patients were stage I, II, III and IV, respectively. The most frequently reported problems were pain/discomfort (67.82%) and anxiety/depression (57.47%). The mean of EQ-5D VAS score was 75.83 (SD=17.03). The mean utility value was 0.830 (SD=0.182), 0.751 (SD=0.188), 0.704 (SD=0.205) and 0.766 (SD=0.182) for patients with stage I, II, III and IV, respectively. Based on the stage of cervical cancer, the proportion of patients reporting problems in each dimension tended to increase from stage I to stage IV while the EQ-5D VAS score tended to decrease from stage I to stage IV. The utility value also tended to decrease from stage I to stage III, however it rather increased for patients with stage IV. CONCLUSIONS: Cervical cancer significantly affects patient’s HRQOL. Effort should be made to improve the quality of life of cervical cancer patients especially in term of pain/discomfort and anxiety/depression reduction.

CANCER – Health Care Use & Policy Studies

PCN37 INSURANCE COVERAGE POLICIES FOR COMPANION DIAGNOSTICS IN BREAST CANCER

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OBJECTIVES: Personalized medicine along with successful delivery of novel diagnostic tests has the potential to revolutionize the patient care. However, the major challenge includes reimbursement system, specifically in obtaining coverage, appropriate coding, and value-based payment for diagnostics. To determine the coverage policies, especially for clinical utility, we reviewed and evaluated the insurance coverage of companion diagnostics approved by U.S. payers for genomics in breast cancer. METHODS: We reviewed the coverage policies for genomic tests in breast cancer, coverage extent, and evidence for coverage of each test. RESULTS: We searched the database of 12 insurance companies and identified 32 different tests that were conducted in January 2014 to identify the coverage policies for genomic tests. In addition to FDA approval, the coverage policy and assessments were also reviewed. RESULTS: In this search of insurance companies, 22 coverage policies for genomic testing were identified. Coverage determinations were made for 5 unique tests for disease diagnosis, prognosis and risk assessment in the 22 policies analyzed. For genomic tests in Breast Cancer, one of the 5 tests was approved by the FDA and covered by only one insurer that issued a coverage decision on it. Coverage policies specific to disease-related genomic tests varied across the insurance companies that were evaluated. The Oncotype DX is covered by all insurers to assess breast cancer recurrence risk, but considered investigational. Only 2 diagnostic tests were covered by at least one insurer; however one of the tests was reviewed and covered by all insurers. Humanx covered two tests; Mammaprint and Oncotype DX. The Mammaprint test for breast cancer risk recurrence had discordant coverage policies among tests reviewed by more than one insurer. CONCLUSIONS: Although some insurers are willing to provide coverage based on limited evidence of clinical utility, insurance coverage for genomic testing is low and variable. This is likely due to few studies published vide coverage based on limited evidence of clinical utility, insurance coverage for genomic tests is low and variable. This is likely due to few studies published.
urot dissolution study in three different solvents such as hydrochloric acid pH 1.5, artificial saliva pH 6.7 and saline phosphate buffer solution pH 7.4 respectively. And drug release from the in vitro dissolution study RESULTS: The result reveals that prepared formulation F6 showed maximum value. The ex vivo permeation studies of Fluconazole drug through porcine buccal mucous membrane were performed and it was observed that F6 formulation was the best formulation among the prepared mouth dissolving tablets. CONCLUSIONS: Thus, the prepared (F6 formula- tion) mouth dissolving tablets had both local and systemic action and may be used for treating patients who are bed ridden, and patients with weak immune system caused by cancer treatment or diseases such as AIDS.

PCN44

TIME TO REIMBURSEMENT FOR ONCOLOGY AGENTS FROM EMA MARKETING AUTHORIZATION TO AIFA APPROVAL AS “C(NN)” CLASS VERSUS. AIFA APPROVAL AS “A” OR “H” CLASS

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OBJECTIVES: The purpose of this study was to evaluate the reduction in average market entry timelines for oncology agents in Italy if approved by AIFA as “C(NN)” class (non-negotiated class under the 189/2012 law) as compared to “A” (fully reim- bursement) / “H” (hospital reimbursement). METHODS: For the purpose of this study, only the approval of the agents’ first indications were taken into consideration. Included in this study were C(nn) oncology agents approved between May 27, 2013 and February 27, 2014 (afiblercept, pertuzumab, bosutinib, enzalutamide, vibranidine, denosumab, latanoprost, abiraterone, vemurafenib, vandetanib, avosentan, pazopanib, faviparvovirus, sunitinib, erlotinib, darbepoetin, ruxolitinib, pazopanib, cabozantinib, docetaxel, aliudoradolin, irinotecan, bevacizumab, maveluxumab, ganitumab, pertuzumab, sunitinib, nilotinib, denosumab, zanemeb, trastuzumab emtansine, and class “A”/“H” agents approved between May 27, 2010 and December 2, 2013 (everolimus, denosumab, pazopanib, cabozantin, docetaxel, aliudoradolin, irinotecan, bevacizumab, maveluxumab, ganitumab, pertuzumab, sunitinib, nilotinib, denosumab, zanemeb, trastuzumab emtansine) and class “A”/“H” agents approved between May 27, 2010, and 2013 was calculated as the average difference between the date of issue of EMA marketing authorization and the determination date (“determinates”) in the Italian “Gazzetta Ufficiale” (governmental gazette) with some exceptions. RESULTS: The average time to reimbursement as calculated was the average difference between the date of issue of EMA marketing authorization and the determination date (“determinates”) in the Italian “Gazzetta Ufficiale” (governmental gazette) with some exceptions. CONCLUSIONS: This study shows that time to reimbursement for oncology agents from EMA marketing authorization to AIFA approval as “C(NN)” class was estimated as 111.3±39.9 days (n=12), while the average time to reimbursement as either “A” or “H” class was estimated as 428.3±109.0 days (n=9). This represents a significantly faster process (unpaired t-test, p<0.01), where on average, the C(nn) approval process is faster by 317 days. CONCLUSIONS: This study shows that time to reimbursement for oncology agents from EMA marketing authorization to AIFA approval is significantly expedited through the use of “C(NN)” classification, reducing market entry timelines by nearly a full year (317 days) compared to the regular “A” or “H” class approval process. Pharmaceutical companies seeking expe- dited market entry into Italy for a newly approved oncology therapy targeting an area of high unmet need should therefore consider applying for C(NN) class.

PCN45

COVERAGE DECISION FRAMEWORK IN ASIA PACIFIC: A CASE STUDY OF TARGETED CANCER MEDICINES IN THE TREATMENT OF BREAST CANCER

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OBJECTIVES: To understand the incidence, prevalence, and survival probability in breast cancer patients in the Asia Pacific region. METHODS: We selected 6 targeted cancer medicines recommended for breast cancer treatment based on the 2013 national comprehensive cancer network guidelines. Eight AP countries with different health care systems were included to highlight the differences of health coverage systems and access to care in the Asia Pacific region. RESULTS: To the best of our knowledge, it is the first study to evaluate the coverage decision framework in Asia Pacific. Eight AP countries with different health care systems were included to highlight the differences of health coverage systems and access to care in the Asia Pacific region. CONCLUSIONS: This study shows that the approval process for targeted cancer medicines as a case study.

PCN46

THE INCIDENCE, PREVALENCE, AND SURVIVAL OF MALIGNANT MELANOMA IN TAIWAN

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OBJECTIVES: To understand the incidence, prevalence, and survival probability in the whole population in Taiwan. METHODS: This study utilized the 2005 to 2011 National Health Insurance (NHI) Research Database to study the disease. Inclusion criteria was that patients have at least two outpatient visits or one inpatient stay for melanoma (ICD9 code: 172). Patients’ medical orders for outpatient visits and inpa-
Pancreatitis (adjusted OR 2.07, 95% CI, 1.36 to 3.13). A matched case-control study with moderate risk of bias suggested that the use of hypothyroidism should be anticipated and well prepared for as part of the treatment protocol.

**RESULTS:**

A retrospective review of the medical records of 42 hyperthyroid patients treated with radioactive iodine to evaluate response rate of hyperthyroidism with 12.7 months of follow up. The response rate was 28.6% with patients who had received a dose of 370 MBq (10 mCi) and 38.1% with those that received 555 MBq (15 mCi) RAI therapy. Statistical analysis was with SPSS version 15.0 and the level of statistical significance was taken as P < 0.05. RESULTS: The response rate was 1.2% for both doses of radioiodine was 71.4%, and after re-treatment of 7 patients who were earlier hyperthyroid after 6 months, the response rate soared to 95.2%. The incidence of hypothyroidism (TSH>6.1 mIU/L) was 47.6% with patients who had received doses of 370 MBq (10 mCi) or 555 MBq (15 mCi) RAI therapy. The use of anti-thyroid drugs (carbamazepine or methimazine only) as pre-treatment increased response to RAI. Propylthiouracil however blocked the iodine uptake to RAI therapy in one patient Thyroidectomy, either total or subtotal, increased the response to RAI treatment. CONCLUSIONS: Radioactive iodine is highly effective for the treatment of Graves’ hyperthyroidism, with a very high cure rate. Pretreatment with some anti-thyroid drugs protects against worsening of hyperthyroidism and increases response to RAI therapy. Thyroidectomy increases the response to RAI treatment. However, the incidence of hypothyroidism should be anticipated and well prepared for as part of the treatment protocol.

**PD85**

**DIAGNOSTIC TESTS OF BLOOD GLUCOSE: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** To evaluate the accuracy of different blood glucose determination methods, and provide a theoretical basis for governments to determine the mainstream glucose determination methods. **METHODODS:** The MEDLINE, EMBASE, EBVM, CRM, CNKI, Wanfang, Google academic search et al were retrieved for literatures collection, literature quality evaluation was implemented by using QUADAS criteria, meta-analysis was carried out using Stata11.0 and heterogeneity test and sensitivity analyses were performed. **RESULTS:** 20 studies were included, which contained a total of 2681 cases of patients. Meta analysis showed that values measured by the dry chemical method were significantly higher than glucose oxidase method, and no significant differences was found with the hexokinase method, no significant differences was yet found between the electrode method with enzyme method, the MD (95%CI) were 0.31 (0.09, 0.53), -0.51 (-0.14, 1.17) and -0.13 (-0.27, 0.02) respectively. Sensitivity analysis of the model, the sample source, research population, equipment, test methods was carried out. CONCLUSIONS: There was significant difference between blood glucose detection methods; application of dry chemical measurement results should be cautious, we recommend using the glucose oxidase or diagnostick serum method.

**PD86**

**EFFECTIVENESS OF HERBROTIN AND MUNIRAPHA IN THE MANAGEMENT OF HYPOPHYDROISIM**

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**OBJECTIVES:** Hypothyroidism is treated by replacement therapy of levothyroxine in allopatic system of medicine needs to be taken throughout life. In Ayurveda an ethnic system of Indian medicine has a remedy based on the drugs of natural origin which shows improved thyroid function. In this study the patients are treated for Hypothyroidism with combination of two proprietary medicines (Herbrotin and MuniRapha) of Muniyal Ayurveda Pharmacy, Manipal. **METHODODS:** Thirty cases of Hypothyroidism are selected from Inpatients and Out patients of Muniyal Ayurveda Hospital, Manipal after obtaining the consent of the patients. The study was approved by institutional ethical committee. The study design consisted of observation before and after treatment with Herbrotin 2-0-2 (BID) with water and MuniRapha 1-1-1 (TID) with water, tablets along with concomitant medicines for a period of 3 months. The subjective Obesity, Brady cardia, Somnolence, Slow mentation and objective criteria of assessment were T3, T4, TSH, Hb and cholesterol. **RESULTS:** The Mean palma T3 (mcg/dL) values were 33.4 to 105.4, T4 (mcg/dL) levels were 2.38 to 11.36 and TSH (micro IU/ml) levels were109.4 to 6.63. The hemoglobin (g%) levels were also found to be normal. The TSH (micro IU/ml) levels before and after treatment with Herbrotin 2-0-2 (BID) were decreased from 10.05 to 5.01, post treatment cholesterol were dropped from 280 to 158.9. **CONCLUSIONS:** Considerable improvement was observed in both subjective and objective criteria of assessment. There was decrease in subjec- tive criteria like Obesity, Brady cardia, Somnolence, Slow mentation, etc. There was increase in T3 and T4, and Hb H%. The decrease in TSH and cholesterol with Herbrotin and MuniRapha in Hypothyroidism patients.

**PD87**

**DESIGN & METHODS FOR STUDY OF PREVALENCE, RISK FACTORS AND ECONOMIC BURDEN OF INSULIN INJECTION-RELATED LIPOHYPERTROPHY IN CHINA**

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**OBJECTIVES:** To identify the association between insulin-based therapies and the risk of pancreatitis. **METHODODS:** We searched Medline, Embase, CENTRAL and ClinicalTrials.gov to identify randomized controlled trials (RCTs), non-randomized clinical studies, case reports, and case-control studies of adults with type 2 diabetes mellitus that compared glucagon-like peptide-1 (GLP-1) receptor agonists or dipeptidyl peptidase-4 (DPP-4) inhibitors against placebo or active diabetic medications. **RESULTS:** Eligible studies were screened for eligibility, assessed for risk of bias, and extracted data from three groups based on their existing treatment (initiated within one month) i.e., group (vildaglaptin and metformin), group II (vildaglaptin alone) and group III (metformin alone). They were also assessed for baseline demographic characteristics. Medication adherence was measured to ensure that patients are complies with the treatment. **CONCLUSIONS:** There are recent introduced class of drugs for type 2 diabetes mellitus which shows good glycemic control. It is a prospective interventional pilot study aimed to determine the efficacy of vildaglaptin therapy to metformin in type 2 diabetes mellitus patients treated with radioiodine to evaluate response rate of hyperthyroidism. Statistical analysis was implemented.

**RESULTS:** A total of 185 patients were enrolled into the study. The study subjects were assigned into three groups based on existing treatment (initiated within one month) i.e., group (vildaglaptin and metformin), group II (vildaglaptin alone) and group III (metformin alone). They were also assessed for baseline demographic characteristics. Medication adherence was measured to ensure that patients are complies with the treatment.
OBJECTIVES: To evaluate the prevalence of insulin injection-related lipohypertrophy and its association with injection-related risk factors and to characterize the clinical and economic burdens of LH. Secondary objectives will investigate the relationship between LH and HbA1c, total daily insulin dose, and injection frequency in insulin-requiring diabetes patients in China. METHODS: A descriptive, non-interventional, cross-sectional study was conducted among 400 diabetic patients from outpatient endocrinology departments in 4 cities, with and without insulin pen needle reimbursement. Eligible subjects were aged ≥18, BMI ≥18.5 kg/m², using insulin by pen injection currently and for ≥1 year continuously, with the ability to comprehend study procedures. Enrolled subjects 1) completed a questionnaire for socio-demographics, medical history, treatment details in 4 cities, with and without insulin pen needle reimbursement. 2) underwent a physical examination, and 3) had HbA1c evaluated. The prevalence of LH was described by percentage and 95% confidence interval. Logistic regression and log-linear analysis were performed to determine risk factors and the relationship between LH and HbA1c and insulin dose. Differences in insulin consumption and general health resource utilization were calculated between those with and without LH, and those with or without pen needle reimbursement. RESULTS: Results expected: 1) dependence on LH and injection-related lipohypertrophy among patients in China using pen devices. 2) Risk factors for LH including socio-demographic characteristics, economic issues, and insulin injection-related factors. 3) Relationship between LH and HbA1c, hypoglycemia, and total daily insulin dose. 4) Economic burden of LH in the Chinese diabetes population. CONCLUSIONS: Given the potential implications of LH for the diabetic population and for the Chinese health care system, we hope to bring awareness of the true magnitude of this condition.

PD89
STUDIES ON CLINICAL EFFECTIVENESS OF COMBINED CLASSICAL AYURVEDIC FORMULATIONS IN TYPE 2 DIABETES MELLITUS
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OBJECTIVES: Traditional medicines are valuable in managing chronic diseases like diabetes. The Ayurvedic hypothesis is that unbalanced kapha (K), kshaya (KKK) and Shilajatu (SHJ) are found to beclinically effective in DM Type 2. In this study, the clinical effect of the combination of formulations was studied.

METHODS: The combined formulation (KKS-SHJ) was administered to 30 patients suffering from Type 2 DM for 2 months. Patients completed the baseline data on blood sugar, HbA1c were recorded for 45 days. Apart from this, the patients feedback on urination frequency and quantity. Neuropathy symptoms, exhaustion, polydipsia, polyphagia, glycosuria and periphereparesis as per Ayurveda QOL were carried out in 15 days.

RESULTS: The Mean for 30 patients FBS, PPBS (mg/dl) and HbA1c on day 1, day 15, day 30 and day 45 were given in order. QOL data on day 1 and day 45 were given. The Mean for 30 patients on FBS (mg/dl) on day 1, day 15, 45 - 136.2, 132.4, 129.5, 127.8; On PPBS (mg/dl) on day 1, day 15, day 30, 224.36, 223.62, 220.41, 218.83; HbA1c (%) on day 1, day 15, 4.78, 7.79, 7.73. Overall assessment of Ayurveda QOL showed mild to moderate efficacy.

CONCLUSIONS: The classical combination of KKK and SHJ was found to be clinically effective along with improvement in QOL, Ayurveda parameters.

PD90
IMPACT OF ETHNICITY ON THE EFFICACY AND SAFETY OUTCOMES OF ANTI-DIABETIC DRUGS – CASE STUDY OF LIRAglUTIDE IN ASIAN AND NON-ASIAN POPULATIONS
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OBJECTIVES: The impact of ethnicity on the efficacy and safety outcomes of antidiabetic drugs through a retrospective analysis of liraglutide among patients with type 2 diabetes mellitus. The long-term follow-up of such patients, however, has been limited. We performed a systematic review and meta-analysis to evaluate the long-term efficacy of liraglutide on patients with type 2 diabetes. METHODS: We searched PubMed, Embase, and Cochrane Central Register of Controlled Trials up to September 2013. Trained reviewers, working in pairs, independently screened for eligible studies and extracted data. We pooled the data using the random-effect model. Results are presented with 95% confidence interval for the data not available for pooling. We conducted pre-specified subgroup analyses. RESULTS: We included 25 studies (n=23,628), consisting of 8 cohort studies with 17407 patients (high risk of bias) and 17 non-controlled follow-up studies with 6221 patients (high risk of bias). At baseline, the mean age of 48.5 years (69% were female), mean body mass index (BMI) was 45.67 kg/m², 67% of patients received oral anti-diabetic drug prior to surgery. 2.6% of patients (123/4950) died in the surgical hospital. Based on a small number studies with low quality, additional carefully designed studies are needed to further clarify this topic.

PD91
THE IMPACT OF DIABETES ON MORTALITY IN INPATIENTS FROM MEDICAL DEPARTMENT OF A CHINESE TERTIARY HOSPITAL
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OBJECTIVES: To explore the impact of diabetes in inpatients from Medical Department in a Chinese tertiary hospital. METHODS: The data source was based on the electronic medical records (EMRs) database of West China Hospital. We collected diabetic and non-diabetic patients, in a ratio of 1:3,who were hospitalized from January 2009 to December 2012. The non-diabetic patients were chosen after a diabetic patient was selected based on sequential uniform randomization. IF diabetes was confirmed after hospitalization, the patients were excluded from this study. RESULTS: We collected information related to patient demographics, diagnoses, prescriptions, laboratory tests and health care resource utilization. The ascertainment of diabetes was based on one of the following: a) discharge diagnosis ICD-9 code; b) diagnosis during one year continuously, with the ability to comprehend study procedures. One patient was chosen for analysis. RESULTS expected: 1) Prevalence of insulin therapy in inpatients with diabetes was identified in the database with a median age of 65(25-75) years old. 2) Patients with diabetes had a higher risk of all-cause mortality compared to non-diabetic patients. 3) Diabetic patients had a higher risk of in-hospital death (AOR:1.87; 95%CI: 1.66-2.12), kidney failure (AOR:4.75; 95%CI: 4.07-5.55), hepatic failure (AOR:0.69; 95%CI: 0.59-0.82). 4) Diabetes had a higher risk of in-hospital death by the lower treatment dosages. Moreover, there was a trend towards longer duration of disease in Asians, although not statistically significant (p=0.059). The overall prevalence of diabetes and common co-morbidities (e.g.COPD) was based on ICD-9 code. Using in-hospital mortality as an outcome, we conducted multivariable logistic regression to explore the impact of diabetes on mortality with adjusting for the influence of common co-morbidities of diabetes – which were considered important confounders - age, gender, smoking and alcohol use. The results are based on a small number studies with low quality, additional carefully designed studies are needed to further clarify this topic.

PD92
Bariatric surgery is recommended as an effective treatment for overweight or obese patients with type 2 diabetes mellitus. The long-term follow up of such patients, however, has been limited. We performed a systematic review and meta-analysis to evaluate the long-term effect of bariatric surgery on patients with type 2 diabetes. METHODS: We searched PubMed, Embase, and Cochrane Central Register of Controlled Trials up to September 2013. Trained reviewers, working in pairs, independently screened for eligible studies and extracted data. We pooled the data using the random-effect model. Quality description was applied for the data not available for pooling. We conducted pre-specified subgroup analyses. RESULTS: We included 25 studies (n=23,628), consisting of 8 cohort studies with 17407 patients (high risk of bias) and 17 non-controlled follow-up studi-
Among 150 (14.5%) patients who died during hospitalization, 102(68.0%) patients had used HES 105 (70.0%) patients were males. Multivariate logistic regression suggested that patients who ever used HES were associated with higher risk of mortality (adjusted odds ratio, AOR: 1.60; 95% CI: 1.04-2.45) even after adjusting for IHD (AOR: 1.64; 95% CI: 0.98-2.74), CRF (AOR: 4.28; 95% CI: 2.35-7.79), high blood glucose (AOR: 1.83-4.65), AKI (AOR: 4.30; 95% CI: 2.79-6.62). CONCLUSIONS: Use of HES may be independently associated with higher risk of death in ICU patients with diabetes. However, further studies are required to demonstrate the causation of HES and hospitalized mortality.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB13 BUDGET IMPACT ANALYSIS OF BIPHASIC INSULIN ASPART IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN MALAYSIA: A PUBLIC PAYER PERSPECTIVE Tan SC1, Matzen P2, Khoo SP3

OBJECTIVES: Budget impact analysis (BIA) is a useful tool for reimbursement decisions by authorities across different countries. This study aimed to evaluate the financial impact from the Ministry of Health (MOH) perspective of different adoption rates of Biphasic Insulin Aspart (BIAsp) versus Biphastic Human Insulin (BHI) in treating type 2 diabetes mellitus.

METHODS: An Excel based 5-year budget impact model was built to estimate insulin treated patients by public providers using local prevalence data. The published demographic, efficacy and adverse event data for ASEAN subgroup analyses of A1chieve study was applied. Both insulin acquisition costs and other medical costs for major hypoglycaemia and other complications were applied with a 3% discount rate to the estimated corresponding incidence rates derived from the UKPDS equations. The projected adoption rates were based on the 2013 utilisation volume data. Other local specific considerations and costings were included in the analyses for an assumed size of eligible patients. Sensitivity analyses were conducted.

RESULTS: The adoption rates of BIAsp were assumed to increase from 23.6% in 2013 to 36.5% in 2018 for base case and upside scenario, respectively. In comparison to baseline scenario, incremental increase up to slightly greater than $2 02M in insulin acquisition cost but a potential cumulative net saving up to approximately S$0.92M in overall costs were observed. Cost savings were predicted for other complications. In comparison to baseline scenario, incremental increase up to slightly greater than S$0.92M in insulin acquisition cost but a potential cumulative net saving up to approximately S$0.92M in overall costs were observed. Cost savings were predicted for other complications.

CONCLUSIONS: The wider adoption of BIAsp was predicted to lead to net cost savings from patient perspective in Singapore. More extensive savings would be estimated in analyses with reduced productivity loss from a societal perspective.

PDB14 BUDGET IMPACT ANALYSIS OF U100 INSULIN IN EGYPTIAN DIABETIC PATIENTS Mokhtar AS1, ElSayed K2, El Sherbini M3, Youssef H4, Central Administration for Pharmaceutical Affairs, Cairo, Egypt

OBJECTIVES: To estimate the budget impact of switching to U100 insulin (100 units [U]/ml) in Egyptian diabetic patients over a time horizon of 5 years. METHODS: Pharmacy and medical budget impacts were estimated over the first 5 years of U100 insulin use in diabetic patients from the Egyptian health care system’s perspective. Local epidemiology data were used to estimate target population size. Pre-U100 and post-U100 insulin entry treatment options were identified and costed. Direct medical costs were derived from the Ministry of Health’s cost model and local research and assumptions. Indirect costs were estimated based on the Egyptian government’s 2013 and 2014: Deterministic sensitivity analysis was conducted.

RESULTS: In a hypothetical 85,294,388-member plan, 1,234,380 patients were expected to be candidates for U100 insulin treatment in type I and type II diabetes. The total budget impact after 5 years post-U100 insulin use was estimated to be $17,072,893 (P=0.001), calls was 5.94 versus 5.98 (P=0.5178), cumulative increase up to slightly greater than S$0.92M in insulin acquisition cost but a potential cumulative net saving up to approximately S$0.92M in overall costs were observed. Cost savings were predicted for other complications. Cost savings were predicted for other complications.

CONCLUSIONS: The wider adoption of BIAsp was associated with net cost savings from a societal perspective.

PDB15 BUDGET IMPACT ANALYSIS OF WIDER ADOPTION OF BIPHASIC INSULIN ASPART IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM): A PERSPECTIVE OF PATIENTS TREATED BY PUBLIC PROVIDERS IN SINGAPORE Tan SC1, Matzen P2, Kho S3

OBJECTIVES: Economic evaluations of BIAsp have been published in the context of different countries. This study aimed to evaluate the financial impact from a perspectives of patients treated by public providers of different diabetes centres with Biphastic Insulin Aspart (BIAsp; NovoMix 30 FlexPen®) versus Biphastic Human Insulin (BHI; Mixtard Penfill®) in treating T2DM. METHODS: An Excel based 5-year budget impact model was built to estimate insulin treated patients by public providers using local prevalence data. The published demographic, efficacy and adverse event data for ASEAN subgroup analyses of A1chieve study was studied. Both insulin acquisition costs and medical costs for major hypoglycaemia and other complications were applied with a 3% discount rate to the estimated corresponding incidence rates derived from the UKPDS equations. The projected adoption rates

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PB17 ECONOMIC BURDEN OF TYPE 2 DIABETES MELLITUS FOR COSTARICA Soto Molina H1, Diaz Martinez JP2, Ramirez Ramirez MA1, Esquivel JA1, Astorga Metropolitana, Mexico City, Mexico, 2ISU Estudios Farmacoeconomicos, Mexico City, Mexico, 3Novo Nordisk CLAT, Mexico City, Mexico, 4Hospital Infantil Federn, Mexico

OBJECTIVES: To perform a economic evaluation of Type 2 Diabetes Mellitus (DM2) as well as its micro and macrovascular complications from the institutional point of view (Social Security Costarican (CCSR), for the year 2013. METHODS: A partial economic evaluation analysis was used to analyse the average annual cost for DM2 in costarican patients. The analysis pays special attention related to the sickness (cardiovascular, renal, microvascular, ophthalmic complications and acute events). Costarican literature was reviews to obtain costs for DM2 as for its complications, also clinical practice guides for the use of resources were used and finally, this information was validated with specialist physicians from Costa Rica. Only direct medical costs were used, such as medications, laboratory and additional studies, medical consultations, hospitalizations and material; these were obtained from the Cost Model 2013 of the CCSR such as the Statistical Annual Yearbook. To prove the strength of the analysis, deterministic and probabilistic sensitivity tests were performed.

RESULTS: The average annual cost for DM2 for the year 2013 in Costarican was USD $1,466.32. The macro and microvascular complications related to DM2 were more expensive in 2013 for Costa Rica were the following: USD $105,865.80 for haemodialysis during the first year, USD $21,600.40 for chronic cardiac failure during the first year, USD $15,414.20 for acute myocardial infarction and USD $1.50 for peripheral vascular disease. The average, hospitalizations represented a 27% of the resources used for treatment of complications. The sensitivity analysis proved the strength of the costs.

CONCLUSIONS: Despite the lack of information in the literature, this article is the first approximation of costs for DM2 and its complications in Costa Rica for the year 2013.

PB18 MEDICAL EXPENDITURE FOR PEOPLE WITH DIABETES IN URBAN EMPLOYER BASIC MEDICAL INSURANCE FOR HEBEI PROVINCIAL INSTITUTES Liu S2, Zhang P1, Ma S1, Yu L2, Liu Y1, Du B1

1Medical Insurance Administration Centre of Hebei, Shijiazhuang, China, 2Hebei Medical Insurance Association, Shijiazhuang, China

OBJECTIVES: To determine the economic burden of diabetes mellitus and its complications from the perspective of public payer in Singapore. Both insulin acquisition costs and medical costs for major hypoglycaemia and other complications were applied with a 3% discount rate to the estimated corresponding incidence rates derived from the UKPDS equations. The projected adoption rates

A743

VALUE IN HEALTH 17 (2014) A719-A813

PB17 ECONOMIC BURDEN OF TYPE 2 DIABETES MELLITUS FOR COSTARICA Soto Molina H1, Diaz Martinez JP2, Ramirez Ramirez MA1, Esquivel JA1, Astorga Metropolitana, Mexico City, Mexico, 2ISU Estudios Farmacoeconomicos, Mexico City, Mexico, 3Novo Nordisk CLAT, Mexico City, Mexico, 4Hospital Infantil Federn, Mexico

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CONCLUSIONS: Despite the lack of information in the literature, this article is the first approximation of costs for DM2 and its complications in Costa Rica for the year 2013.

PB18 MEDICAL EXPENDITURE FOR PEOPLE WITH DIABETES IN URBAN EMPLOYER BASIC MEDICAL INSURANCE FOR HEBEI PROVINCIAL INSTITUTES Liu S2, Zhang P1, Ma S1, Yu L2, Liu Y1, Du B1

1Medical Insurance Administration Centre of Hebei, Shijiazhuang, China, 2Hebei Medical Insurance Association, Shijiazhuang, China
OBJECTIVES: To explore medical expenditure and its impact for people with diabetes covered by the Basic Medical Insurance of Hebei Province (UBMHI). METHODS: People diagnosed with “diabetes” were identified from UBMHI claims database during Dec 30th, 2010 and Dec 25th, 2011. The Sum_All Medical method was used for expenditure estimation. Descriptive analyses were conducted using SPSS 19.0. RESULTS: In 2009, 2010 and December 2011, the UBMHI database recorded claims data of 10256 patients, including 7944 with diabetes (7.21% of all patients), among which 7421 had outpatient records (7.24% of all outpatients) and 2564 had inpatient records (12.16% of all inpatients). Inpatient costs were 63.38% male and 79.51% were 50 years of age or older. Mean number of outpatient visits was 14.04 for people with diabetes, in comparison with 4.12 for outpatient with other diseases. Outpatient treatment cost was CNY 9332.52/person and CNY 72494.63/person, of which 30.59% was out-of-pocket money. For those who had used inpatient services, annual inpatient admissions were 1.67 times/person and the cost was CNY 23494.63/person and CNY 14109.20/hospital stay. Over 60% hospitalizations were inpatient services, annual inpatient admissions were 1.67 times/person and the cost was CNY 23494.63/person and CNY 14109.20/hospital stay. Over 60% hospitalizations were inpatient services (724.99/visit, of which 30.59% were out-of-pocket money. For those who had used inpatient services, annual inpatient admissions were 1.67 times/person and the cost was CNY 23494.63/person and CNY 14109.20/hospital stay. Over 60% hospitalizations were inpatient services (724.99/visit, of which 30.59% were out-of-pocket money.

CONCLUSIONS: As one of the major chronic diseases, diabetes consumed great health care resources in Hebei. Majority of direct medical expenditures were spent on treating diabetes-related diseases. Perhaps to reduce risks of diabetes complications by promoting early diagnosis, early treatment, rational drug utilization and disease control is the way to save health care and social resources.

PDB1

ECONOMIC IMPLICATIONS OF CHRONIC RENAL DISEASE WITH AND WITHOUT CO-MORBID DIABETES IN CHINA, POST-2005

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OBJECTIVES: To collate published evidence evaluating economic implications of chronic renal disease (CRD) with and without co-morbid diabetes mellitus in China (post-2005). A systematic search of electronic databases (EMBASE® and MEDLINE®) was conducted from January 2005 to March 2014 to identify economic studies in English evaluating CRD with and without co-morbid diabetes mellitus in China. RESULTS: Five studies (all cost of illness, CROI) and CRD and co-morbid diabetic (n=2) of 134 citations retrieved, met pre-defined inclusion criteria. In 2012, total cost/patient for stage-3 CRD was Chinese Yuan (CNY) 34205 with 79.75% being direct cost, while for stage-5 CRD the corresponding values were CNY128231 and 82.3%, respectively (Wu 2013). In the study by Zhang and colleagues, patients undergoing haemodialysis (HD) incurred 16% higher costs relative to those undergoing peritoneal dialysis (PD) in 2010 (p<0.01). Further, patients with comorbid diabetest incurred higher total costs compared to their CRD alone counterparts (p=0.03) (Zhang 2012). Among patients with CRD in northwest China observed between March 2007 and February 2008, the first, second, and third year renal transplant (RT)/HD costs were CNY201674/CNY94136, CNY17476/CNY7869, and CNY6685/CNY3761 respectively indicating higher efficacy and lower costs of RT than HD from second year onwards (Xiaoming 2012). These findings are consistent with those reported in another study, in 2011 the direct cost of diabetes-associated renal failure in HDN was CNY73567/CNY7674.77 and RT was CNY19508.075 (Zheng 2012). Among diabetic patients with comorbid CRD, direct cost in 2007 was CNY1308.07 million, while corresponding cost projected in 2030 increased two-fold to CNY3220.94 million (Ma 2009). CONCLUSIONS: CRD consumes a large portion of health care expenditures (with direct medical cost being those raised above) and is projected to exert heavy burden on health budget in future as well. Additionally, patients with comorbid diabetes incurred higher costs relative to their CRD alone counterparts.

PDB2

EXAMPLE OF ANALYSIS UTILIZING REAL WORLD DATA: MEDICAL COST REDUCTION BY ADVISING UNTREATED-DIABETES PATIENTS TO VISIT DOCTORS

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OBJECTIVES: We desire patients who have not consulted doctors to treat their diabetes, while they have learned their blood-sugar levels are high through health check-up, as untreated-diabetes patients. Our research objective is to calculate using real world data how much lower the medical cost would be if the untreated-diabetes patients visit doctors in response to suggestions to do, which represents the cost reduction of cost-effectiveness analysis. METHODS: We used the data of Japan Medical Data Center (JMDC), which provides health insurance claims data with linked health check-up data of 1.7 million members from health insurance societies in Japan. RESULTS: It is estimated there are 71 untreated-diabetes patients in a virtual (yet supposed-to-be typical according to the JMDC data) health insurance society (n=20,000 members). Among them: we gathered 424 cases within 3 months, while remaining 84% would leave their conditions as they are for averagely 40 months knowing that their blood-sugar levels are high. It is neces-sary to advise them to deal with their diabetes (1.2 Mg LIRAGlutide). Simultaneous and treatment strategies for untreated-diabetes patients is expected when admission. Intervention group equipped a clinical pharmacist providing clinical pharmacy services during therapy the control group took routinely pharmacy service. The times of avoiding medicine errors were counted as effectiveness, the saving of patients’ expenses was calculated as benefit. The cost was calculated by routine/clinical pharmacy service spending. Cost-effectiveness and cost-benefit analysis were conducted. RESULTS: The average 337 minutes(5.6 hours) was spent in daily clinical pharmacy services in intervention group. The cost of routine/clinical pharmacy service in control group was 729.05 yen less (a savings of 412 yen) when admission. Intervention group equipped a clinical pharmacist providing clinical pharmacy services during therapy the control group took routinely pharmacy service. The times of avoiding medicine errors were counted as effectiveness, the saving of patients’ expenses was calculated as benefit. The cost was calculated by routine/clinical pharmacy service spending. Cost-effectiveness and cost-benefit analysis were conducted. RESULTS: The average 337 minutes(5.6 hours) was spent in daily clinical pharmacy services in intervention group. The cost of routine/clinical pharmacy service in control group was 729.05 yen less (a savings of 412 yen) when admission. The average admission expense was 1703.80 in intervention group and 1595.50 in control group(p<0.05), so average saving expense of patients under clinical pharmacy intervention was 255.06$. Comparing with the extra cost input of professionally, clinical pharmacy service, the net benefit was 919.01$. CONCLUSIONS: Clinical pharmacy service do play a significant role in avoiding medicine errors and reducing patient expenses, if didn’t consider the time and labor cost of clinical pharmacist.
long-term health outcomes for patients with T2DM. Compared with exenatide, the cumulative incidence of acute coronary syndromes (ACSs) and non-fatal myocardial infarction event with liraglutide were reduced by 1.65%, 1.45%, 0.639% and 1.392% respectively. Liraglutide 1.2 mg was associated with improvements in life expectancy of 0.109 years and 0.092 quality-adjusted life years (QALYs) versus exenatide. The costs of complications were reduced by 1,769 CNY (£107) and 1,967 CNY (£117) respectively. Liraglutide 1.2 mg improved patient health and economic outcomes versus exenatide, and was a dominant treatment approach for people with T2DM insufficiently controlled with OADs in China.

PDB25 COST MINIMIZATION ANALYSIS OF CLINICAL OPTION SCENARIOS FOR METFORMIN AND ACARBOSE IN TREATMENT OF TYPE 2 DIABETES: BASED ON REAL-LIFE COST DATA
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OBJECTIVES: The aim of the current study was to simulate cost minimization analysis of metformin and acarbose in the Egyptian health care system. METHODS: A real-life cost analysis of 2014 was performed to compare cost effectiveness of metformin and acarbose in T2DM patients. Direct medical costs including drug cost, medical consultation fees, drug reactions (ADRs) and other costs arising from medical intervention among the sole surgical treatment group (35 cases), the group of preoperative treatment with lanreotide (36 cases), and the group of preoperative treatment with octreotide (18 cases). RESULTS: Based on the good compatibility of tumor size, postoperative aver-
sage hospital stay was 5.67 days in the study group, and there was no statistical difference in the clinical effectiveness (P = 0.416). The total medical costs per case, both octreotide group and lanreo-
tide group were higher than the sole operation group with a statistical significant (P = 21.05, P = 0.000), and the lanreotide group (70521 ± 5677 Yuan) was lower than the octreotide group (80283 ± 21486 Yuan) with the Median non-parametric test (P = 0.037). The sensitivity analysis showed that the cost advantage of lanreotide reflected in preoperative treatment length of the treatment. CONCLUSIONS: According to the data of direct medical costs from the sampling hospital in Shanghai, lanreotide has more cost advantage comparing with octreotide.

PDB28 COST EFFECTIVENESS OF BIPHASIC HUMAN INSULIN 30 IN PEOPLE WITH AMPLE DIABETES WITH INADEQUATE GLYCEMIC CONTROL ON ORAL ANTIDIABETIC DRUGS IN CHINA
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OBJECTIVES: To evaluate long-term cost-effectiveness of switching to biphasic human insulin 30 [biphasic Protamine Biosynthetic Human Insulin Injection (pre-
mixed3080)] in people with type 2 diabetes (T2DM) poorly controlled with oral anti-diabetic drugs (OAD) in China. METHODS: The validated IMS CORE Diabetes Model (V5.0) was used to project long-term life years, quality-adjusted life years (QALYs) and costs for T2DM patients’ baseline characteristics with or without intervention. The model was based on the published 8-week observational study in China. Hba1c decreased from 8.661% to 7.57% after initiating biphasic human insulin 30 [smeformin] for people uncontrolled with sulfonylureas and metformin, and hypoglycemic events was 0.80 per patient-year during the study period. Treatment costs were calculated by multiplying retail prices in China and dosage used in the trial. Management and complications consequences were determined based on published meta-analyses and indirect comparisons. Results of included studies were analyzed and reviewed. RESULTS: There were 27 patients who completed the study, the hypoglycemic events were 0.655 years (13.113 vs. 12.458) and quality-adjusted life-years by 0.609 QALYs (9.270 vs. 8.661) per patient. Biphasic human insulin 30 decreased cumulative incidence of diabetic complications by 1,769 CNY (111,567 vs 113,336), result-
tancy of 0.109 years and 0.092 quality-adjusted life years (QALYs) versus exenatide. Liraglutide 1.2mg was associated with improvements in real-life cost data. RESULTS: The direct comparison (8 trials) indicated treatment difference between metformin and acarbose for reduction of HbA1c was -0.06% (95% CI, -0.15% to 0.03%). In the indirect comparisons (6 trials), using placebo and sulfonylureas as common comparators, metformin achieved significant A1c reduction than acarbose, by -0.38% (95% CI, -0.736 to -0.024) and -0.34% (95% CI, -0.651 to -0.029) respectively. Cost-minimization analysis was conducted on the assumption that these two drugs had same hypoglycemic effects. In the first two scenarios, acarbose was assumed to titrate from 50mg/day up to 150 mg/day (weight<60kg) or 300mg/ day (weight>60kg) as usual max-dose, and the annual costs were ¥2,636.36 and ¥5,208.84. In the last two scenarios, metformin was assumed to titrate from 500mg/day up to 1500mg/day or 2000mg/day, while the annual costs were ¥1,568.04 and ¥2,070.28. Metformin would achieve cost savings by 22.06% to 69.90% than acarbose, and sensitive analysis demonstrated its robustness. CONCLUSIONS: From this study, all outcomes are consistent with previous studies in other countries. Metformin has significant hypoglycemic-effects and low costs in China.
predict quality of life utilities, diabetes complications and mortality. METHODS: A microsimulation model was constructed which followed people with newly diagnosed diabetes over a period of 30 years. HbA1c level determined when a person was assumed to undergo escalation in diabetic treatment (from monotherapy with non-insulin hypoglycaemics to dual therapy to triple therapy and insulin). Information on drug treatment was derived from clinical trial data. Health care utilisation and costs were sourced from Australian government websites. Risk equations using change in HbA1c as a predictor for complications, quality adjusted life years (QALYs) and death were derived from published data from large Australian diabetes cohorts. Probabilistic sensitivity analyses were undertaken. Two classes of drugs were investigated as alternatives to sulphonylureas when given in combination with metformin: DPP-IV inhibitors (sitagliptin, vildagliptin, saxagliptin),agliptin, alogliptin) and GLT-2 inhibitors (canagliflozin, dapagliflozin).

RESULTS: In general, the results for the CUA were similar between the two drug classes compared to sulphonylureas, with ICERs ranging from AU$4080/QALY to AU$7210/QALY compared to dual therapy. Use of diabetes medications and insulin treatment was delayed on an average of 2-3 years and a drop of 1-2% in mortality was observed. CONCLUSIONS: This model illustrates a new way of assessing the cost utility of diabetes medications. Furthermore, it shows that both DPP-IV and SGLT2 inhibitors provided cost-effective alternatives to sulphonylureas in combination with metformin.

PDB30

ANTI-DIABETIC DRUG UTILIZATION AND DYNAMIC TRENDS IN A TERTIARY HOSPITAL IN BEIJING (2008-2012)

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OBJECTIVES: To study the medication use patterns and trends for antidiabetic drugs in a tertiary hospital in China. METHODS: Data were extracted from pharmacy department of a tertiary hospital in Beijing between 2008 and 2012. Descriptive analysis was conducted using SPSS 20. By applying the Anatomical-Therapeutic-Chemical methodology (ATC) and Defined Daily Dose system (DDD) recommended by WHO, the collected data were used to calculate the number DDD per 1000 inhabitants per day (DDD/1000/day). Annual average growth rate (AAGR) was calculated to demonstrate dynamic trends in utilizations over time. RESULTS: There are three major findings: 1) By pooling the five year data together, we found the top three drug categories were sulphonylureas (3023.87 DDD/1000/day), human insulin (2677.48 DDD/1000/day) and biguanides (1830.52 DDD/1000/day), accounting for 30.95%, 27.32% and 18.68% of the total DDIs, respectively. 2) In each category, the rankings in utilization according to the ATC codes were gliptins, sulfonylureas, and Novolin 30R, Novolin R, human insulin, and metformin for biguanides. 3) Drug utilizations increased rapidly from 1647.13 DDD/1000/day in 2008 to 1978.86 DDD/1000/day in 2012, with AAGR of 13.41%. The utilization of insulin analogue increased fastest (AAGR 33.21%), followed by gliptins (AAGR 27.18%) and biguanides (AAGR 20.77%). CONCLUSIONS: In a tertiary hospital in Beijing, the total DDD of anti-diabetic drugs was largely contributed by sulfonylureas, human insulin and biguanides, in descending order. Utilization of anti-diabetic drugs increased significantly during 2008-2012, possibly driven by increasing prevalence, new treatments, and so forth.

DIABETES/ENDOCRINE DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PDB31

DEMOGRAPHIC AND HEALTH OUTCOMES ASSOCIATED WITH ADHERENCE AND NON-ADHERENCE AMONG TYPE 2 DIABETICS IN CHINA

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OBJECTIVES: Adherence to treatment is an important predictor of health status. This study investigated medication adherence among respondents with type 2 diabetes (T2D) in China. METHODS: This study included data from the 2013 China National Health and Wellness Survey (NHWS), a cross-sectional survey of self-reported demographics, health outcomes, and behaviors among urban (mainly Tier I and II cities) adults (≥18 years). Respondents diagnosed with T2D and taking a prescription medication for T2D were analyzed (n=310). Adherence was measured using the 8-item Morisky Medication Adherence Scale (MMAS). Adherence was classified as scoring between 0-2 on the MMAS. Characteristics of non-adherent and adherent respondents were reported descriptively. Multivariable regressions, adjusting for demographics and health behaviors were performed to explore differences on health status (SF-36v2), resource utilization in the past six months and productivity loss (Work Productivity and Activity Impairment questionnaire) between adherent and non-adherent and general diabetes patients in the NHWS. Respondents who were non-adherent to diabetes medications tended to be younger, employed and had regular consumption of alcohol compared to respondents who were adherent. Controlling for covariates, respondents who were adherent to their medications had higher mental component summary and health utility scores compared to non-adherent respondents (p<0.05). Among the employed sample, non-adherent respondents reported greater absenteeism (13.1% vs. 7.7%), greater presenteeism (39.8% vs. 30.0%) and greater overall work impairment (44.8% vs. 33.7%) compared to adherent respondents. Non-adherent vs. adherent respondents reported more activity impairment (38.8% vs. 33.7%). In a sample of 286 respondents aged 18-65, adherence levels positively correlated with the difference (95% confidence interval [95%CI]) being -0.06 (0.16, 0.04). The general population sample had systematically lower TTO values for mild health states, with the difference being -0.15 (95%CI: -0.24, -0.06); while the two samples had similar mean TTO values for severe health states, with the difference being 0.001
OBJECTIVES: The study aimed to investigate the utilization and expenditures of medical resources, including outpatient visits, hospitalizations, and productivity losses. This knowledge is critical for prioritizing diabetes care and treatment to meet the unmet health needs and economic burden of diabetes.

METHODS: A questionnaire-based, cross-sectional observational study was carried out. All residents of the area (age 18 and above) were targeted. The study was conducted from July to October 2013. The questionnaire comprised of two parts. The first part was consistent of demographic characteristics. The second part was consist of 15 questions related to diabetes basic knowledge. Descriptive statistics were applied to summarize the data. RESULTS: A total of 1001 general people were approached, out of which 285, 69.9% belonged to age group 41-60 years with almost equal gender distribution. One hundred and sixty patients had primary level education, 551 (358:HP, 193:HI) were employed. Six hundred and fifty two (431:DP, 225:HI) had family history of diabetes. The mean diabetes knowledge score was 8.2±2.1, (8.5±2.7:DP, and 8.1±2.6:HI). There is no significance difference between the two groups i.e. diabetes patients and healthy individuals regarding the knowledge regarding diabetes. It is important to educate both patients and healthy individuals for management and prevention of the disease.

DIABETES/PD38

ASSESSMENT OF DISEASE STATE KNOWLEDGE IN DIABETIC PATIENTS OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The present study aimed to assess disease knowledge of the diabetic patients in Quetta city. Pakistan. METHODS: A questionnaire based, cross-sectional observational study was carried out. All residents of the area (age 18 and above) were targeted. The study was conducted from July to October 2013. The questionnaire comprised of two parts. The first part was consist of demographic characteristics. The second part was consist of 15 questions related to diabetes basic knowledge. Descriptive statistics were applied to summarize the data. RESULTS: A total of 457 registered diabetes patients were approached, and 408 patients were agreed and partook in the study. Majority of the patients (n=225; 55.1%) belonged to age group 41-60 years with almost equal gender distribution. One hundred and sixty nine (41.4%) had primary level education and 551 (358:HP, 193:HI) were employed. Six hundred and fifty two (431:DP, 225:HI) had family history of diabetes. The mean diabetes knowledge score was 8.2±2.1, (8.5±2.7:DP, and 8.1±2.6:HI). There is no significance difference between the two groups i.e. diabetes patients and healthy individuals regarding the knowledge regarding diabetes. It is important to educate both patients and healthy individuals for management and prevention of the disease.

DIABETES/PD39

ASSESSMENT OF KNOWLEDGE REGARDING DIABETES: A COMPARATIVE ANALYSIS OF DIABETES PATIENTS AND HEALTHY POPULATION OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The study was designed to compare the knowledge regarding diabetes between the diabetic patients and healthy population in Quetta city. Pakistan. METHODS: A questionnaire based, cross-sectional observational study was conducted. The present study compared diabetes patients (DP) of Bolan Medical Complex hospital and Sandman Provisional hospital were targeted and for healthy individual (HI), all resident of the area (age 18 and above) were targeted. The study was conducted from July to October 2013. The questionnaire comprised of two parts. The first part was consistent of demographic characteristics. The second part were consist of 15 question related to diabetes basic knowledge. Descriptive statistics were applied to summarize the data. Mann-Whitney test was used to compare the study groups. RESULTS: Out of 1248 participants 623 (408:DP, 215:HI) were males with mean age of 36.9±9.5 (38.6±9.5:HP, 32.7±9.4:years), majority 462 (352:DR, 110:HI) had primary level of education, 551 (358:HP, 193:HI) were employed. Six hundred and fifty six (431:DR, 225:HI) having family history of diabetes. The mean diabetes knowledge score was 8.2±2.1, (8.5±2.7:DP, and 8.1±2.6:HI). There is no significance different was found between the diabetes knowledge score of both the groups (i.e. diabetes patients and healthy individuals), p < 0.05. CONCLUSIONS: Results of the study show that it is important to increase the awareness of the two groups i.e. diabetes patients and healthy individuals regarding the knowledge regarding diabetes. It is important to educate both patients and healthy individuals for management and prevention of the disease.

DIABETES/ENDOCRINE DISORDERS – Health Care Use & Policy Studies

PD40

ASSESSMENT OF DIABETES KNOWLEDGE IN HEALTHY POPULATION OF QUETTA CITY, PAKISTAN

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OBJECTIVES: The study aimed to evaluate the knowledge regarding diabetes in healthy population of Quetta city, Pakistan. METHODS: A questionnaire based, cross-sectional observational study was carried out. All resident of the area were targeted from July to October 2013. The questionnaire comprised of two parts. The first part was consistent of demographic characteristics. The second part were consist of 15 question related to diabetes basic knowledge. Descriptive statistics were applied to summarize the data. RESULTS: A total of 1001 general people were approached, out of which 285, 69.9% belonged to age group 41-60 years with almost equal gender distribution. Majority (51.3%) had family history of diabetes. Majority (96.7%) had knowledge about disease and its nature (64.6%), and knew about symptoms (62.5%). Fifty four percent said obesity and (46.7%) said alcohol or smoking as major causes for diabetes. Seventy eight percent considered diabetes is as heredity. Fifty percent of participants considered stress and high blood pressure being risk factor for diabetes considered it as treatable disease while 45.6% said it require lifelong treatment. Sixty eight percent said regular walk or exercise are important for diabetes control, 83.3% believed that diet control is important for diabetes control. Eighty seven percent considered the uncontrolled diabetes can cause complications and (43.3%) believed that uncontrolled diabetes can cause death. Although majority (56.9%) of the respondents considered glucose monitoring is necessary, it only few said regular blood sugar test or exercise are important for diabetes control. Only 38% considered the uncontrolled diabetes can cause complications and 34% believed that uncontrolled diabetes can cause death. CONCLUSIONS: The study concluded that although the general populations have knowledge about the diabetes but they lack vital information regarding its treatment, management and severity of the disease.

DIABETES/PD41

THE EXPANDING ROLE OF THE PATIENT VOICE IN MEDICAL DECISION MAKING IN ASIA

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OBJECTIVES: This retrospective and longitudinal study was designed to evaluate the path of patient treatment decisions. The study included the patient voice varies across countries, cultures, and conditions. Treating the whole patient versus treating only the presenting disease requires a shift in how health care is delivered and medical decisions are made. Patients can provide reliable and valid information regarding their health and wellness status through the use of validated methods and tools. Amplifying the patient voice and integrating it with clinical expertise may be the best way to maximize the positive outcomes for the patient.

DIABETES/PD42

THE IMPACT OF DRUG PRICE CONTROL POLICY FOR DIABETES MEDICATION: A HOSPITAL LEVEL ANALYSIS IN TAIWAN

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OBJECTIVES: Medication costs accounted for 25% of total medical expenses in Taiwan. The Diabetes and Endocrine Health Promotion Bureau (DPEPB) in Taiwan is responsible for controlling the medication costs. Diabetes drugs is a major factor contributing to high and rapidly growing prescription medication costs. This study was to examine the determinants for diabetes drug expenditures inflation in Taiwan’s National Health Insurance (NHI). METHODS: This retrospective and longitudinal used NHI claim data to quantify the different costs.
FACTORS DRIVING TO INCREASES IN DIABETES MEDICATION COSTS FROM 2000 TO 2010. CHANGES IN DIABETES DRUG SPENDING ARE DECOMPOSED TO EIGHT COMPONENTS: (1) THE GROWTH OF USER POPULATION; (2) THE GROWTH OF NUMBER OF PRESCRIPTION PER USER; (3) THE GROWTH OF NUMBER OF DRUG ITEM OF PER PRESCRIPTION OF ESTABLISHED DRUGS; (4) THE GROWTH OF NUMBER OF DRUG ITEM OF PER PRESCRIPTION OF NEW ENTRANT DRUGS; (5) THE GROWTH OF DDD OF NEW ENTRANT DRUGS OF AVERAGE DRUG ITEM PER PRESCRIPTION; (6) THE GROWTH OF DDD OF NEW ENTRANT DRUGS OF AVERAGE DRUG ITEM PER PRESCRIPTION; (7) CHANGE OF AVERAGE PRICE OF DRUGS OF AVERAGE DRUG ITEM PER PRESCRIPTION; (8) CHANGE OF AVERAGE PRICE OF NEW ENTRANT DRUGS PER PRESCRIPTION; (9) CHANGE IN THERAPEUTIC AND STRENGTH MIX

RESULTS: Changes in user population, number of drug item of per prescription, and therapeutic and strength mix cause diabetes spending to increase. The drug price and DDD caused diabetes spending to decrease. Over half of diabetes drug spending was accounted for by the therapy mix change. The rest of spending growth was from the change in drug treatment intensity. The results also reveal the care pattern change to more drug item with low-dose therapy.

CONCLUSIONS: The results suggest that drug pricing policies need to focus on drug price and DDD to improve diabetic drug treatment. The policy makers should consider putting more effort to manage treatment intensity in diabetes medication.

PD843 PHYSICIANS AS DOUBLE AGENTS IN A UNIVERSAL HEALTH CARE SYSTEM: EVIDENCE FROM GENERIC PHARMACEUTICAL ADOPTION IN TAIWAN

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OBJECTIVES: Physicians’ generic pharmaceutical adoption are responsible for patients, insurance payers, and their own interests. This study examines this double agent problem by physicians by using Taiwanese data, because Taiwanese physicians can both prescribe and dispense drugs in Taiwan. The universal health care system in Taiwan also causes the problem to be a public concern.

METHODS: This study examines the Physician Adoption Model of Pharmaceutical Behavior to show the factors driving to increases in diabetes medication. The following data sources are (i) descriptive and cross-sectional data from 2011 on Taiwanese governmental medical administration data; (ii) the prescribing and dispensing records from the National Health Insurance Research Database of Taiwan. Each participant was followed-up for a 3-year period from 2011 to 2013.

RESULTS: A total of 10 studies were included. Globally, the pooled effectiveness of interventions offered in intervention groups was approximately 8.4 million insulin injectors in China, mostly type 2 diabetes patients.

PD844 LOYALTY TO A PHARMACY IS ASSOCIATED WITH A BETTER QUALITY OF ANTIDIABETIC DRUG USE

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OBJECTIVES: Among individuals newly treated with oral anti-diabetes drugs (OAD), to assess the effect of pharmacy loyalty on compliance with AD and on the use of guidelines-recommended medications.

METHODS: We applied Chamberlain’s correlated random effects probit model.

RESULTS: The price of diabetes drugs as a whole decreased total drug expenditure since 2006, whereas growth of volume explained most of the growth in total pharmaceutical expenditure during 2006 and 2010. Particularly between 2011 and 2012 when price decreased 12% due to nationally implemented price cuts for almost all listed drugs, the volume still increased 5%. Further decomposition of volume showed that the change in the proportion of volume of new diabetics drugs in total volume minimally contributed to growth in total diabetes drug expenditure. The proportion of new drugs use of generics increased in new and existing drugs (therapeutic mix) for a given therapeutic group, and the proportion of use of generics increases physicians’ likelihood for prescribing generic prescriptions.

CONCLUSIONS: Generic drugs increases physicians’ likelihood for prescribing generic prescriptions. However, for physicians in hospitals, this effect decreases as the payer’s cost share percentage increases. This results indicate that physicians’ prescriptions decision internalize patients’ utility but not the payer’s cost. This study also demonstrates that physicians who are more responsive to profits prescribed more generic drugs, instead of hospitals and clinics, and physicians in clinics and private institutions. However, this effect decreases as the number of competitors in the drug market increases.

PD847 ESTIMATED ECONOMIC BURDEN OF INSULIN INJECTION-RELATED LIPOPteryPTEROSIS IN CHINESE PATIENTS WITH DIABETES


OBJECTIVES: Lipohypertrophy (LH) is a relatively common complication of injecting insulin. It is reported to impair insulin absorption, and may increase total daily dose (TDD) of insulin and associated costs. The economic burden of LH is unknown in China. This study aims to evaluate the effects of LH on TDD of insulin and explore potential health economic implications for China.

METHODS: The following data were extracted from literature review and the IMS Health Report (Diabetes China 2011): (i) insulin injection-diabetes population in China 2013; (ii) prevalence of LH among insulin-injecting Chinese patients2; (iii) new patients with LH estimated from a recent Spanish study3; (iv) average unit cost of insulin in China1. Cost of excess insulin use was calculated per annum. All monetary values were converted to 2013 RMB, with a RMB-USD exchange rate of 6.141. RESULTS: There are approximately 8.4 million insulin injectors in China, mostly type 2 diabetes (T2D). The prevalence of LH in China was previously reported to be 31%. In the Spanish study, patients with TDD and LH used 21 IU/day more insulin3; we estimated 15 IU/day excess usage vs no-LH injectors in China. The average insulin price in China is 0.215 RMB per IU1. The estimated cost of excess insulin use due to LH is approximately $3,065,233,500 USD per year. CONCLUSIONS: LH may represent a significant, addressable, economic burden in China due to excess insulin consumption. Taking steps to reduce LH may reduce health care costs in China. Additional studies should be conducted in China to further investigate the economic impact of LH and to develop interventions to control this complication (6B/10C, hyper- and hypoglycemia) and health resource utilization patterns specifically among the Chinese insulin-injecting population to validate and extend these findings.

APPLICATION OF MEDICINES SCORING SYSTEM (MEDSS) - POTENTIAL SAVINGS THROUGH DRUG FORMULY REVIEW OF SULPHONYLUREAS

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OBJECTIVES: Sulphonylureas available in Malaysia include gliclazide, glipizide, glibizide and glipizide providing varying degree of benefits and risks. In this study, we review and compare overall utility values of sulphonylureas using medicines scoring system (MedSS). METHODS: MedSS, a previously developed scoring framework based on multicriteria decision analysis (MCDA) that systematizes evaluation of drug attributes was used. An expert panel of 3 endocrinologists, 1 family physician and 5 pharmacists were formed. A group of medicine reviewers assisted in evidences search and reviews. Through expert panel discussions, drug attributes were identified and assigned weights for each. Based on evidences and attributes scores were obtained and added up to provide total utility score (TUS). Cost savings was calculated based on 25% reduction in utilization of drug with the lowest TUS. RESULTS: Attributes identified and selected for analysis were efficacy (clinical efficacy, clinical end results), convenience (number of dose per day, ease of use), safety (serious and non-serious adverse events), cost (acquisition cost, patient compliance cost), and acceptance (adherence rate, patient satisfaction). Studies comparing direct and indirect savings beyond drug costs. Moreover, benefits of clinicians’ involvement are utilities of the drugs compared, distinguishing gliclazide as the superior alternative.

TUS for glibenclamide to 56.8. Potential direct savings on drug costs was estimated for gliclazide modified release and gliclazide respectively. Safety concerns lowered the weights assigned by panel members for efficacy, safety, patients acceptability and cost. Based on evidences and attributes scores were obtained and added up to provide total utility score (TUS). Cost savings was calculated based on 25% reduction in utilization of drug with the lowest TUS.

RESULTS: Attributes identified and selected for analysis were efficacy (clinical efficacy, clinical end results), convenience (number of dose per day, ease of use), safety (serious and non-serious adverse events), cost (acquisition cost, patient compliance cost), and acceptance (adherence rate, patient satisfaction). Studies comparing direct and indirect savings beyond drug costs. Moreover, benefits of clinicians’ involvement are utilities of the drugs compared, distinguishing gliclazide as the superior alternative.

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GASTROINTESTINAL DISORDERS – Clinical Outcome Studies

PG11 PHARMACOLOGICAL REGIMENS FOR ERADICATION OF HELICOBACTER PYLORI: AN OVERVIEW OF SYSTEMATIC REVIEWS AND NETWORK META-ANALYSIS

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OBJECTIVES: The world’s population is estimated to be infected with Helicobacter pylori (H. pylori), a bacterium shown to be linked with a series of gastrointestinal diseases. A growing number of systematic reviews have been published comparing the effectiveness of treatment regimens in the eradication of H. pylori, but have not reached a consistent conclusion. This study provides an overview of systematic reviews of pharmacological therapies for the eradication of H. pylori. METHODS: We searched major electronic databases from 2002 to 2013. Studies were included if they assessed the effectiveness of different regimens in treatment of patients diagnosed with H. pylori infection and then compared the eradication rates in a meta-analysis. A modified version of ‘A Systematic Tool for Evidence-based H. pylori therapy’ (ASTER) was used to assess the methodology quality. Where appropriate, network meta-analysis of proton pump inhibitors (PPI) or antibiotics within treatment regimens was conducted. RESULTS: 24 systematic reviews with pairwise meta-analysis were included. In triple therapy, more effective drug combinations were observed compared with single drug regimens. PPI and bismuth tablets (PPI+RB) achieved greater eradication rates than the other regimens (omeprazole, pantoprazole and lansoprazole). Furthermore, moxifloxacin and levofloxacin were associated with greater effectiveness and lower risk of adverse events than clarithromycin. When comparing triple and bismith based therapy, the relative effectiveness appeared to be dependent on the antibiotics within the triple therapy. A network meta-analysis based on the data from the systematic reviews was able to provide ranking of relative effectiveness of individual PPIs. CONCLUSIONS: Current clinical guidelines do not distinguish between individual PPIs or antibiotics. However, our analysis of the recent evidence suggests that the new generation of PPIs and use of moxifloxacin or levofloxacin in triple therapy were associated with greater effectiveness of H. pylori eradication.

PG12 TC-325 IN THE MANAGEMENT OF UPPER AND LOWER GI BLEEDING: A TWO-YEAR EXPERIENCE AT A SINGLE INSTITUTION

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OBJECTIVES: TC-325 is a novel endoscopic hemostatic powder, recently adapted for endoscopic use to control gastrointestinal bleeding. Preliminary data documented. Second phase of gum chewing performed and same process followed.

RESULTS: Data revealed that outcome of each elderly in relation to the three phases of processes varied (p-value, a-priori test) p<0.05). Passage of flatus obtained a p-value of 0.001 (p <0.05) and bowel movement has p-value of 0.0429 (p <0.05), which means there is significant difference between the chewing gum and the non-chewing gum in terms of these three variables.

CONCLUSIONS: Chewing a gum is an effective intervention in enhancing gastric motility among elderly.

GASTROINTESTINAL DISORDERS – Cost Studies

PG13 ECONOMIC EVALUATION OF VIRAL LOAD TEST (VLDT) IN RESPONSE GUIDED TREATMENT (RGT) FOR CHRONIC HEPATITIS C (CHC)

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OBJECTIVES: To assess the health effectiveness, cost and cost-effectiveness of antiviral drug therapy for the treatment of chronic hepatitis C infection in the Chinese elderly. Methods: A decision-analytic model was built to separately examine the effectiveness and resource use of anti-HCV treatments: alpha-2a plus ribavirin for chronic hepatitis C. METHODS: Decision tree of COBAS test and domestic test were developed on the basis of Response Guided Treatment (RGT), and short term test efficacy, treatment response and long term outcomes of SVR were determined after literature. RESULTS: The long term result of COBAS test plus standard treatment was 30.57LYs and 19.11QALYs, while the passage of flatus obtained a p-value of 0.001 (p <0.05) and bowel movement has p-value of 0.0429 (p <0.05), which means there is significant difference between the chewing gum and the non-chewing gum in terms of these three variables.

CONCLUSIONS: Chewing a gum is an effective intervention in enhancing gastric motility among elderly.

GASTROINTESTINAL DISORDERS – Clinical Outcome Studies

PG14 PREGNANCY OUTCOMES IN WOMEN WITH INFANTESTINAL BOWEL SYNDROME FOLLOWING EXPOSURE TO THIOPURINES AND ANTI-TUMOR NECROSIS FACTOR DRUGS: A META-ANALYSIS AND SYSTEMATIC REVIEW

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OBJECTIVES: Besides the great concern about safe choices during pregnancy in inflammatory bowel disease (IBD) patients, several current trials have indicated the harmful effect of flare-up periods in pregnant women with IBD on their newborns more than continuing maintenance therapy. Therefore, an effective medical treatment is of great importance and necessary during pregnancy. Our aim was to perform a systematic review of the impact of thiopurines and anti-TNF drugs during pregnancy. METHODS: All cohort studies which evaluated the pregnancy outcomes of thiopurines and/or anti-TNF drugs during pregnancy. RESULTS: In the meta-analysis a total of 312 pregnant women with IBD who used thiopurines were compared to 1149 controls to evaluate the drug effect on pregnancy outcomes. Safety of anti-TNF drugs during pregnancy was also assessed. CONCLUSIONS: Results of statistical analysis demonstrated that, congenital abnormalities were increased significantly in thiopurine exposed group in comparison to control group that did not receive any medical treatment. The calculated drug effect on different pregnancy outcomes including prematurity, low birth weight, congenital abnormalities, spontaneous abortion and neonatal adverse outcomes.

CONCLUSIONS: Results of statistical analysis demonstrated that, congenital abnormalities were increased significantly in thiopurine exposed group in comparison to control group that did not receive any medical treatment. The calculated drug effect on different pregnancy outcomes including prematurity, low birth weight, congenital abnormalities, spontaneous abortion and neonatal adverse outcomes.

CONCLUSIONS: Results of statistical analysis demonstrated that, congenital abnormalities were increased significantly in thiopurine exposed group in comparison to control group that did not receive any medical treatment. The calculated drug effect on different pregnancy outcomes including prematurity, low birth weight, congenital abnormalities, spontaneous abortion and neonatal adverse outcomes.

CONCLUSIONS: Results of statistical analysis demonstrated that, congenital abnormalities were increased significantly in thiopurine exposed group in comparison to control group that did not receive any medical treatment. The calculated drug effect on different pregnancy outcomes including prematurity, low birth weight, congenital abnormalities, spontaneous abortion and neonatal adverse outcomes.

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domestic one, which also denoted COBAS test to be a less costly and more effective
/14 randomized measurement. In addition, sensitivity analysis showed the result was
not sensitive to main indicators, including test price, week-4 and week-12 treat-
ment response rate, week-4 and week-12 false negative rate of domestic test, SR
rate of 24-week treatment for CEVR, and proportion of non-CEVR in RNA positive in
12 week. Compared with domestic HCV RNA test, for the short-term treatment course, COBAS test can identify EVR & EVR more accurately, make
more appropriate decisions of course period and have more patients achieve SR.
And in future, COBAS test appropriate course of treatment can
prolong patient’s life year, improve patient’s life quality as well as decrease total medical expense due to less disease progress.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PG16

DRUG UTILIZATION REVIEW OF ACID SUPPRESSANTS (DURABLE) – AN AUDIT TO ASSESS THE UTILIZATION OF PROTON PUMP INHIBITORS AND HISTAMINE H 2-RECEPTOR ANTAGONISTS IN CANADIAN HOSPITALS

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OBJECTIVES: Inappropriate utilization of proton pump inhibitors (PPI) and H 2-
receptor antagonists (H 2RA) in inpatients is prevalent, but poorly defined. We undertook a rigorous national audit to allow the standardization of grading system for appropriate use.

METHODS: Medical and demographic data were collected for all in-patients receiving a PPI or H 2RA. The "Endorsed" group (E) was defined as the correct use of the medication. The "Not Endorsed" group (N-E) was the incorrect use of the medication. The correct use was defined in 3 different ways: 1) intravenous high dose continuous infusion PPI or H 2RA (IVci for appropriate use.

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RESULTS: Over 6 months, 1720 patients (age: 60±18.6 y, 53% women) receiving 2890 drug regimens were included from 21 Canadian institutions. 28% were taking a PPI and 7% an H 2RA before admission. 95% of in-hospital drug regimen was wrong. The common perspective was using 5% a H 2RA in place of a PPI (IVb for appropriate use).

21.7] and 81.8 [78.3-84.9], and 42.9 [40.0, 45.8] and 57.1 [52.2, 60.0] for IVb, IVci, and PO respectively.
The most common indication was upper GI bleeding (70% of IVb, 70.6% of IVci, 96% of IVci and 70% of PO). The prescribing indication in 8% of IVb (94% N-E), and 6% of oral (88% N-E).

Independent predictors of E were suspicion of UGI (for IVb and PO regimens), time of drug administration (for IVb and IVci), and evidence of disease (for IVb).

CONCLUSIONS: Existing consensus recommendations provided no guidance as to appropriateness of use in up to 40% of regimens. Endorsed use was noted in only 28% of IVb, 18% of IVci, and 43% of PO regimens. These data will help guide future guideline recommendations to optimize in-hospital prescribing of acid suppressants.

INDIVIDUAL’S HEALTH – Clinical Outcomes Studies

PH1

ADVERSE DRUG EVENTS: HOW INFORMATION TECHNOLOGY WILL MEET THE CHALLENGES OF PHARMACOVIGILANCE

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OBJECTIVES: For a long time pharmacovigilance has been associated with functional decline and adverse outcomes in vulnerable population and with an increased risk of Adverse Drug Events (ADE), particularly in fragile patients such as the elderly with complex medical conditions. Aim of this observational study was to describe and evaluate ADE in patients by polypharmacy by a digital health service that prevents Drug-Drug Interactions (DDI) using the social security number (SSN).

METHODS: A cohort of 369 patients was identified through a closed loop, fully automated system that records and updates all the drugs taken during therapy cycle by specifically designed software interfaces loaded on Information and Communication Technology programs of the network. The tool was designed to support General Physicians in clinical decisions, providing them information about prescribed drugs/over the counter (OTC)/herbs, detailing dosage, comorbidity, number of packages and pills per package, prescription/purchase date.

RESULTS: About 30% of patients shown 1 comorbidity and 11.8% 2 or more. Cardiovascular diseases (22.7%) represented the most frequent comorbidity, followed by musculoskeletal pathology (13.6%), diabetes (8.6%), cancer (5.1%), and depression (4.8%). The Charlson Comorbidity Index was 0 in 65.2%, 1 in 25.7%, 2 in 7.0% and 3 to 4 in 2.1%. A total of 67% (mean age 72 years, 52% women) had at least 1 DDI. About 50% (N > 33) had up to 2 DDIs, 25% from 3 to 7 DDIs and 25% ≥8 (from 9–74 DDIs per person)

A total of 501 DDIs were identified: the severity was low in 35.5%, moderate in 59.7% and high in 4.8%. The total 10 drugs involved in DDI were: acetylsalicylic acid (ASA), hydrochlorothiazide, ibuprofen, diclofenac, digoxin, nesiritide, pantoprazole, ramipril, furosemide and nimesulide.

CONCLUSIONS: ICT technologies are useful to timely identify DDIs of clinical relevance and the drugs most frequently involved

PH2

MODELLING TO PREDICT SEVERE MATERNAL MORBIDITY BASED ON 33993 PATIENTS FROM A REGISTRY-STUDY IN CHINA

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OBJECTIVES: To set a model to predict the Severe Maternal Morbidity (SMM) and specify the risk factors based on a registered study in Sichuan province, China.

METHODS: Overall 33993 deliveries of 8 hospitals in Sichuan province of China were retrospectively collected between January 1, 2009, and December 31, 2010 in our database. The forward and backward stepwise regression methods were adapted respectively to screen independent risk factors of SMM, and a logistic model was generated by STATA 12.0. The area under receiver operating characteristic (ROC) curve and agreement rate were used to evaluate the prediction model.

RESULTS: Three kinds of unexpected surgeries, transfusion, hysterectomy, ICU care, Multiple Organ Dysfunction Syndrome (MODS) were chosen as the outcomes of SMM by literature review and expert consensus. The rate of SMM was 2.30% in 33993 deliveries. All specified and substantially significant risk factors were divided in four aspects. Social characteristics included the hometown, pregnancy characteristics appropriate course of treatment can prolong patient’s life year, improve patient’s life quality as well as decrease total medical expense due to less disease progress.

PH3

The Efficacy of OXimes in Acute Organophosphate Poisoning; an Updated Systematic Review and Meta-Analysis

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ABSTRACT Objectives: The present study is a meta-analysis of clinical studies conducted in Iran regarding the treatment of organophosphate poi-

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nons (OP) intoxicated patients. METHODS: PubMed, Scopus, Google Scholar, and clinical trials.gov were searched for studies investigated the effects of oximes in the treatment of organophosphate poisoning. A total of 10 studies (nine clinical trials and one historical cohort) that met our criteria were included. RESULTS: The summary of RR for mortality rate in 9 studies was 0.38 (95% CI: 0.65 to 2.97, P = 0.79 to 3.2, P = 0.04) for one observational study rate was 1.57 (95% CI: 0.79 to 3.2, P = 0.05). The summary of RR for mortality rate in 9 studies was 0.38 (95% CI: 0.65 to 2.97, P = 0.041) for one observational study rate was 1.57 (95% CI: 0.79 to 3.2, P = 0.05). For intermediate syndrome, while the RR of only one observational study was 1.57 (95% CI: 0.79 to 3.2, P = 0.05). The RR for ICU admission rate in OP poisoning for three trials comparing oximes to placebo was 1.27 with 95% CI: 0.73 to 2.23 (P = 0.04).

CONCLUSIONS: According to these data, oximes beneficence in OP poisoning is unclear and if administered, great caution must be exercised because of increase in ICU admission rate and incidence of intermediate syndrome. KEYWORDS: Organophosphorus, oxime, poisoning, meta-analysis

PH4

EFFECT OF VITAMIN E ON THE VAGINAL ATROPHY OF POSTMENOPAUSAL WOMEN

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OBJECTIVES: Vaginal atrophy is a silent epidemic that affects up to 50%-60% of postmenopausal women. Local,low-dose estrogen preparations are considered first-line pharmacological treatment. For women concerned about hormone use a number of over-the-counter (OTC) vaginal moisturizer and lubricant products are considered first-line nonhormonal treatments. It has been reported that vita-

min E vaginal gel improved the symptoms of vulvovaginal atrophy However, oral vitamin E has never been well tested in a randomized clinical trial for efficacy against vaginal atrophy. Therefore the objective of this study is to assess the effect of vitamin E on the vaginal maturation index (VMI) of post menopausal women.

METHODS: Participants in this placebo-controlled randomized cross over trial were 60 menopausal women who 4-12 months passed from their menopause. After randomization the women were given medication blister pack cards that contained an 8-week supply of study medication (400IU of vitamin E or placebo daily). Following 1-week no treatment , baseline period, the first group received one week washout was considered. Then the medication was reversed for each group and the study was continuing for another four weeks. Vaginal maturation index of the women before any intervention and after the first and second stage of treatment was evaluated.

RESULTS: The study groups were homogeneous regarding age, BMI, time since menopause, and after the first and second stage of treatment was evaluated.


CONCLUSIONS: Based on our study, vitamin E may be considered as an effective and safe treatment for vaginal atrophy. Vitamin E in dosage of 400IU orally may be considered as an effective and safe treatment for vaginal atrophy.
OBJECTIVES: To assess the effectiveness of combined biochemical and ultrasound screening for chromosomal abnormalities in the first trimester of pregnancy on reducing the rate of invasive genetic procedures in a city based population on OP poisoning.

Methods: This is a retrospective study conducted in a tertiary care teaching hospital of South India. Data was collected retrospectively from medical record section from 2012 to 2013 in a suitable designed case record form. Data was analysed by using SPSS 20.0 with chi-square test in one way analysis.

Results: A total of 99 cases of OP poisoning were documented out of which 135(67.8%) were males and 64(32.2%) were females. The average age in this group of patients was found to be 34.22 ± 14.26. The average pre-hospitalisation period was 1.58 ± 2.07 days and the majority of the cases were suicidal (94.5%). A total of 159 patients received only atropine as treatment with an average hospital stay of 12.66 (SD= 11.88) days and a mean of 8.71 (SD= 10.03) days duration in ICU. Whereas the other 40 patients received both atropine and glycopyrrolate as treatment with an average stay of 15.68 (SD= 12.76) days and a mean of 12.12 (SD= 10.40) days duration in ICU. Amongst the 159 patients who received only atropine 40.9% received ventilation and 59.1% other operations. Also among the other 40 patients 80% received atropine with only 20% receiving ventilation. Out of the 159 patients who received only atropine 7.6% underwent tracheostomy and 25.8% were found to have intermediate syndrome, whereas for patients who received both atropine and glycopyrrolate 15.4% underwent tracheostomy and 33.7% underwent tracheostomy.

Efficacy of two regimens reveals that atropine was found to be more effective when given alone when compared with atropine and glycopyrrolate combination in OP poisoning.

PIH7

THE EFFECTIVENESS OF FIRST TRIMESTER COMBINED SCREENING ON REDUCING THE RATE OF INVASIVE GENETIC PROCEDURES IN A CITY BASED POPULATION OF HUNGARY 2010-2013

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OBJECTIVES: To assess the effectiveness of combined biochemical and ultrasound screening for chromosomal abnormalities in the first trimester of pregnancy on reducing the rate of invasive genetic procedures in a city based population on Hungary. METHODS: Previously women aged 35 years or more had access to chorion villus sampling (CVS) or amniocentesis (AC). A private prenatal diagnostic center service of a public hospital based screening facility was introduced in Hungary in 1999. Invasive testing was performed for women having a combined risk for fetal aneuploidy > 1/250. Total number of 4611 singleton and twin pregnancies in the gestational age of 11+0 and 13+6 weeks were enrolled between November 2010 and August 2013. Maternal serum level of pregnancy associated protein-A (PAPP-A) and free-beta human chorionic gonadotropin (free βhCG) were determined by KRYPTOR (Brahms-Thermofisher Gmbh, Germany). RESULTS: The screening rate in this city based population was 1916/45727 (4.18%) and women had a positive first trimester screening result. There were 16 fetuses with Down’s syndrome and 14 fetuses with other chromosomal abnormalities diagnosed. The specificity and sensitivity were 100% and 95%, the positive predictive value was 4.5% and the false negative rate was 0%. The positive predictive value of the test was 11%, the negative predictive value was 100%.

The number of pregnancies in which an invasive test was performed decreased from 518 in 2005 to 295 in 2013, or by 44%. The proportion of women aged less than 35 years increased, while the rate of women over 35 decreased in this invasive group. CONCLUSIONS: It is possible to change the pattern of invasive prenatal procedures and reduce the proportion of women having CVS or amnio. Efficient information is needed to increase the screening rate, especially in a self-financed system, where the public health insurance does not cover this type of nationwide screening.

PIH8

BURDEN OF DISEASE IN ASIAN COUNTRIES AND THE USE OF DISABILITY-ADJUSTED LIFE-YEARS AND QUALITY-ADJUSTED LIFE-YEARS

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OBJECTIVES: Disability-adjusted life-years (DALYs) and Quality-adjusted life-years (QALYs) are two measures commonly used in health care evaluations. However, the specific disease areas where they are most applicable are not fully defined. The objective of this study was to review the use of DALYs and QALYs in trials taking place in China and Thailand and review the relationship with disease burden.

Methods: PubMed was searched for studies published after 01/01/2004 reporting DALYs and QALYs for communicable and non-communicable diseases in China and Thailand. Data on disease burden were obtained from the World Health Organization’s (WHO) Mortality and Burden of Disease Estimates for WHO Member States in 2004 database. RESULTS: 117 studies were included for China. 79 reported QALYs and 38 reported DALYs. 34 studies were included for Thailand (QALYs: 38; DALYs: 6). Of trials reporting QALYs, 74.7% of Chinese and 78.6% of Thai trials focussed on non-communicable disease, the most commonly investigated disease was cancer. Of trials reporting DALYs, 44.7% of Chinese and 16.7% of Thai trials focussed on non-communicable diseases. In terms of the disease burden for non-communicable disease in China, mortality for chronic kidney disease was the greatest burden with 33.7% & 66.3% of the burden in China and Thailand respectively. Leading causes of disease burden were cerebrovascular disease (7.7%) and HIV (12.9%) in China and Thailand respectively. CONCLUSIONS: A dual burden of disease was observed in Asian countries in terms of non-communicable/communicable diseases. The QALY was the preferred measure for non-communicable diseases in China and Thailand. While the DALY is used equally in communicable and non-communicable diseases in China, it is used only in communicable diseases in Thailand. This presents a challenge to health care managers; while it is clear that QALY is used mostly for non-communicable diseases, the most appropriate use of the DALY is unclear. Further research into the characteristics of diseases within these categories is required.

INDIVIDUAL’S HEALTH – Cost Studies

PIH10

USING HORMONAL CONTRACEPTION REDUCE UNINTENDED PREGNANCY IN CHINA

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OBJECTIVES: The potential high-unintended pregnancy rates have resulted in great production cost in China. Several contraceptive methods have been introduced by both the providers and the women themselves to reduce the unintended pregnancy rates. A cost-benefit analysis on various hormonal contraceptive methods was performed in order to provide references for contraception selection in China. METHODS: A decision-tree model was used to compare contraception costs and effects among different contraceptive methods. All women were classified into three contraception profiles (continuation, discontinuation and switch, discontinuation and switch out) and others other to combined contraceptive use. This study was performed in China. RESULTS: A comparison of total estimated yearly and cumulative costs indicated that contraceptive implants, transdermal contraceptive, extended-cycle OC, vaginal ring, and IUD were the only two choices in China with lowest cumulative costs. The further cost-benefit analysis also demonstrated contraceptive implants as good value for money. Using contraceptive implants were proved to have the lowest cost of pregnancy from failure of $839.9, with a total cost of $2681.4, and a benefit-cost ratio of 2.72. 2% of discontinuation and switch might have the greatest impact on the costs and safety of contraceptive implants. CONCLUSIONS: In order to reduce the unintended pregnancy rates, the implementation of effective contraceptive may lead to a benefit in terms of both costs and effects. And among all the hormonal contraception in the Chinese market, contraceptive implants tend to generate greater economic benefits. Note:USD dollar=6.46 Chinese yuan.

PIH11

DISEASE BURDEN OF UNINTENDED PREGNANCY IN ASIA

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OBJECTIVES: China is a big country with a large population. Reproductive health education is not sufficient for women of childbearing age, which leads to high unintended pregnancy (UP) rate. This represent a significant cost to the health care system. This study analyzes the epidemiology and productivity loss of unintended pregnancy in China. METHODS: We searched PubMed, Embase, and Cochrane Library databases for relevant papers taking place in China and Thailand and review the relationship with disease burden. Of trials reporting DALYs, 44.7% of Chinese and 16.7% of Thai trials focussed on non-communicable diseases. In terms of the disease burden for non-communicable disease in China, mortality for chronic kidney disease was the greatest burden with 33.7% & 66.3% of the burden in China and Thailand respectively. Leading causes of disease burden were cerebrovascular disease (7.7%) and HIV (12.9%) in China and Thailand respectively. CONCLUSIONS: A dual burden of disease was observed in Asian countries in terms of non-communicable/communicable diseases. The QALY was the preferred measure for non-communicable diseases in China and Thailand. While the DALY is used equally in communicable and non-communicable diseases in China, it is used only in communicable diseases in Thailand. This presents a challenge to health care managers; while it is clear that QALY is used mostly for non-communicable diseases, the most appropriate use of the DALY is unclear. Further research into the characteristics of diseases within these categories is required.
the first and second strategies, respectively, which were much lower than the 2013 Indonesian Gross Domestic Product (GDP) of US$4,790. CONCLUSIONS: The implementation of a birth-dose rotavirusvaccination strategy in Indonesia would be more cost-effective than a later vaccination schedule. The mortality rate and vaccine price were the most influential parameters impacting the cost-effectiveness results.

PIH7
THE PHARMACOECONOMICS REVIEW OF 7-VALENT PNEUMOCOCCAL CONJUGATE VACCINATION IN ASIAN-PACIFIC REGION
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OBJECTIVES: Since 2000, when the PCV7 (7-valent Pneumococcal Conjugate Vaccine) gradually went public, lots of cost-effectiveness evaluations on it have been done in Euro-American countries. In contrast, there is little economic review on PCV7 in Asian-Pacific region. This study comprehensively evaluated the cost and benefits of introducing PCV7 into the national immunization plan (evaluation include with and without the herd effect) of the Asia-Pacific region, to serve as a policy reference for the Asian-Pacific regions in their immunization plans.
METHODS: All articles were identified in PubMed, EMBASE, and Medline (English) and Ichushi (Japanese) were searched in November 2013. They were also required to focus on the assessment of utilities or be part of the studies and supported by central laboratory of Biomedical school, HSUM, “Mobio” laboratory of Korea and “Mega” laboratory. The research of serum alkaline phosphatase was made by the kinetic method which is confirmed by IFCC and used the liquid reagent of Roche Hospitex diagnostics and Human firm. The research result was shown positive response towards implementation of pharmacy practice which would definitely improve the patient compliance.

PIH8
A QUALITATIVE ASSESSMENT OF DOCTORS PERCEPTION TOWARDS THE QUALITY OF PHARMACEUTICAL CARE SERVICES IN KYBER PAKHTUNKHWA, PAKISTAN
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OBJECTIVES: The main objective of this study is to explore the perception of doctors regarding quality of pharmaceutical care services in Khyber Pakhtunkhwa, Pakistan. METHODS: A qualitative study design was adopted. A semi-structured interview guide was developed, through snowball sampling technique face to face interviews were conducted until saturation point has reached till 15th doctors. RESULTS: Among the respondents interviewed, nine were male and six female doctors. The findings demonstrated 4 major themes: (a) Collaboration of doctors and pharmacists, (b) Lack of provision of patient counseling, (c) Separation of prescribing & counseling services, (d) Patient compliance through pharmacist. The findings demonstrated that involvement of pharmaceutical care provision would benefit the doctors and patient. Doctors were willing to collaborate with pharmacist because it will facilitate the doctors as due to time limit they are unable to do proper patient counseling. They also showed positive response towards implementation of pharmacy practice which would definitely improve the patient compliance.

PIH15
PARTIAL REIMBURSEMENT OF ANTIVIRAL AGENTS FOR HBV: IMPACT ON ANTIVIRAL UTILIZATION AND COMPLIANCE
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OBJECTIVES: To determine the impact of partial reimbursement on antivirals which was implemented in July 2013 on antiviral utilization and compliance for patients in Beijing. METHODS: Two separate cohorts were enrolled. These consisted of 14,163 CHB outpatients who were referred to Beijing You’an Hospital during Jan, 1, 2010 to Dec 30, 2010 and 16,228 between Jul 1, 2011 and Jun 30, 2012. Follow-up ended on June 30, 2013, respectively. Denominator of all events was obtained from blind computerized pharmacy records of a national retail pharmacy chain.
RESULTS: The proportion of patients who were prescribed at least one course of either nucleoside or nucleotide reverse transcriptase inhibitors (NRTI) increased from 54.9 to 56.7% (P<0.0001) and 73.0% (P=0.028) for male and female, respectively. For the second part, it may occur after the medicine was prescribed to the patient but fails to follow the instructions or fails to refill the prescription (secondary non-adherence).

PIH16
JOINT MODELING OF PRIMARY AND SECONDARY NON-ADHERENCE OUTCOMES
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OBJECTIVES: Medication non-adherence to chronic therapies may severely impair cost-effectiveness of treatment. Non-adherence may occur at different stages in a patient’s health care journey, and it may occur at the time of initial therapy if a patient receives the initial prescription but does not redeem it at a pharmacy (primary non-adherence), or it may happen after the patient fills a prescription at a pharmacy but fails to follow the instructions or fails to refill the prescription (secondary non-adherence).
METHODS: The purpose of this study is to demonstrate that both primary and secondary non-adherence can be jointly described by a hurdle model, which has the interpretation as a two-part model. The first part of the model describes the number of refill attempts, and the second part is a count model (Poisson or negative binomial). The hurdle model is an example of the finite mixture models which can be fitted by SAS’s new procedure FROC FMM.
RESULTS: Data in this retrospective cohort study of medication non-adherence was obtained from blind computerized pharmacy records of a national retail pharmacy chain.
Different utility measurement tools yielded different results and there was little consistency in the ranking of utilities derived via various elicitation methods. While the most commonly studied population was patients, similar results were reported between patients and medical professionals. Caregivers tended to give higher utility scores. CONCLUSIONS: Despite an increasing trend of research on utility assessment, this review highlighted the need for standard protocols and methods. The original studies focusing on utility measurement used various elicitation methods, revealing the impact of study population on utility values.

PIH20
IMPACT OF DEMOGRAPHICS ON HEALTH PREFERENCES IN CHINA: AN EXPLORATORY ANALYSIS OF CHINA EQ-5D-5L VALUATION STUDY

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OBJECTIVES: To identify demographic factors that affect health preference elicited using the composite time trade-off (cTTO) technique in the China EQ-5D-5L Valuation Study. cTTO uses the traditional TTO for states better than dead and the lead time TTO for states worse than dead. A total of 86 EQ-SD-5L health states were grouped into 10 blocks with 10 health states in each group where one very mild state (i.e. only level 1 is presented) and the worst state (55555) is included in every block. Demographics such as age, gender, employment status, health insurance, the attitude toward living is better than being dead (LBTD), and belief in after-life were collected. A multi-stage quota sampling method in Korea. Each respondent valued 10 health states. Two hundred individuals were interviewed in December 2013. The face validity of the data appear to be reasonably high, with higher (lower) values for the majority of participants. Participants who agreed with LBTD tended to give positive scores compared with those who did not. Similarly, participants with health insurance or employed tended to give positive scores.

CONCLUSIONS: We found that a few demographic indicators had significant impact on health preference. The impact needs to be adequately recognized in cost effectiveness analysis in China.

PIH21
VALUING HEALTH IN THE UAE: AN INVESTIGATION OF THE FEASIBILITY AND CULTURAL APPROPRIATENESS OF USING THE TTO AND DCE METHODS TO GENERATE HEALTH STATE VALUES

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OBJECTIVES: EQ-5D-5L is a widely-used measure of patient-reported health. Its use in economic evaluation requires a 'value set': numerical summaries of how good or bad states are. No EQ-5D-5L values for any of the UAE’s cultures were included in the standard protocol for valuing EQ-5D-5L. Adult members of the Emirati general public were recruited in public places. Respondents each completed 10 time trade-off (TTO) tasks and seven discrete choice experiment (DCE) tasks. In addition, they answered debriefing questions about their experience of completing the TTO and DCE tasks. Results: 1,085 general populations were recruited using a stratified random sampling method and completed the TTO and DCE tasks. A structural equation model was explored, the most appropriate model was determined in terms of goodness of fit, logical consistency and parsimony. RESULTS: Model with dummy variables of the level of severity associated with each dimension, an intercept associated with any move away from full health, and a term that picked up the variation in the dimension was the best model that best predicted the utilities for observed health states. The model was selected as the final model because all coefficients were statistically significant and logically consistent. Although it was parsimonious, the final model had a mean absolute error of 0.027 and none out of 86 exceeded 0.1 of absolute error.

CONCLUSIONS: The final model in this paper appeared to predict the utilities of the states, which was validated directly. This could be used intergrade quality weights of all EQ-5D-5L health states.

PIH22
THE VALUATION OF EQ-5D-5L HEALTH STATES IN KOREA

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OBJECTIVES: This study aimed to estimated Korean preference weights for EQ-5D-5L based on values elicited from representative sample applying EuroQol standard protocol. METHODS: Of 1,085 general populations were recruited using multi-stage quota sampling method in Korea. Each respondent valued 10 health states using the composite time trade-off and 7 health states using discrete choice experiment in computer-assisted face-to-face interview. A range of prediction model was explored, the most appropriate model was determined in terms of goodness of fit, logical consistency and parsimony. RESULTS: Model with dummy variables of the level of severity associated with each dimension, an intercept associated with any move away from full health, and a term that picked up the variation in the dimension was the best model that best predicted the utilities for observed health states. The model was selected as the final model because all coefficients were statistically significant and logically consistent. Although it was parsimonious, the final model had a mean absolute error of 0.027 and none out of 86 exceeded 0.1 of absolute error.

CONCLUSIONS: The final model in this paper appeared to predict the utilities of the states, which was validated directly. This could be used intergrade quality weights of all EQ-5D-5L health states.

PIH23
WHAT REALLY MATTERS? A MULTI-VIEW PERSPECTIVE OF ONE PATIENT’S HOSPITAL EXPERIENCE

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OBJECTIVES: To identify what mattered to a patient and family members (health care recipients) during the patient’s hospital experience and to examine the health care professional’s awareness of what mattered to the recipients. METHODS: A qualitative descriptive investigation was undertaken using semi-structured interviews designed to compare multiple perceptions of one patient’s hospital experience. Interviews were undertaken with the patient (post-surgical procedure), family member, and health care providers whom the patient identified as impacting the hospital experience. Inter interviews were recorded and transcribed. A definition of hospital experience was sought from each participant. Additional phrases as presented by the patient and family member were coded and grouped into categories of importance. Phrases as presented by the healthcare providers were coded, and then allocated to the previously identified themes. RESULTS: One patient, his wife and seven health care providers (doctors, 2), nurses (4) and one patient’s document stated that at two different times the patient’s hospital experience ‘differed between the participants. Recipients of care include pre and post hospital admission periods, whereas providers limit hospital experience to admission. Three salient themes emerged from recipient data suggesting, mediation, and emotional security are what mattered. Awareness of the significance of these factors differed between the providers and was theme dependent. CONCLUSIONS: Hospital experience as a term is poorly defined, and that a few definitions differ between recipients and providers of care. Health care providers are not always aware of what matters to the patient and family during their hospital admission.

PIH24
THE STUDY OF SATISFACTION AND REASONS FOR ACUPUNCTURE THERAPY AT SIRINDHORN NATIONAL MEDICAL REHABILITATION CENTRE

Objective: To explore patient satisfaction and reasons for acupuncture therapy among patients receiving acupuncture at Sirindhorn National Medical Rehabilitation Centre (SNMRC). METHODS: A cross-sectional study included randomly selected 177 patients attending acupuncture clinic at SNMRC during November 2012 to January 2013. The study instrument was a newly developed and validated questionnaire comprising 3 parts: general patient information (1 item), reasons for acupuncture therapy (4 items), and satisfaction with acupuncture therapy (5 items). Each item was graded into 5 levels ranging from 1 (lowest) to 5 (highest). The patients completed the questionnaire by either self-administration or interview with the investigators. RESULTS: The patients recruited were aged between 31 to 90 years (mean [SD]: 64.27 ± 12.03), with 69.5% being female. 113 Patients self-administered the questionnaire while 64 patients preferred to be interviewed, with no significant difference between the results of the two groups. The patients reported choosing acupuncture for osteoarthritis (35.6%), myopathy (27.7%) and neuropathy (19.2%), and most of them received acupuncture 4 times per month. Their most commonly reported reasons for acupuncture therapy were ‘the results of therapy were better than other treatments’ (41.5%), ‘patient trust the treatment’ (38.6%), and ‘being recommended/supported by physicians or other people’ (42.9%) and ‘the belief that it is the best treatment approach’ (29.4%). The majority of patients (42.2%) rated high satisfaction (4 points) for acupuncture therapy at SNMRC. The aspect with the highest satisfaction was cleanliness of the acupuncture room (mean [SD]: 4.46 ± 0.62) while the lowest satisfaction was for the waiting time for acupuncture physicians (mean [SD]: 3.96 ± 0.88). CONCLUSIONS: This study demonstrated that the level of patient satisfaction for acupuncture therapy at SNMRC was high; however, it would possibly be improved if the patients’ waiting time could be shortened.

PIH25
ASSOCIATING FACTORS ASSOCIATED WITH YOUTH SUBSTANCE ABUSE IN THE US USING A STRUCTURAL EQUATION MODEL

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OBJECTIVES: To assess factors associated with youth substance abuse (SA) using a U.S. representative sample. METHODS: A cross-sectional study using the 2012 NSDUH data. A survey on Drug Use, Abuse, and Dependence (NDSUHD) was based on youth population 12 to 17 years old (n = 14,600). A structural equation model was applied to investigate factors that influenced the youth SA, the dependent latent variable, described using indicators including tobacco, alcohol and marijuana use. Six independent latent factors were youth tolerant attitude towards SA, perceived
risk of SA, pressure from social norm, risk-prone behavior, adverse school envi-
ronment, and SA (a general care and concern). RESULTS: The model fitness showed the internal structure of the model was acceptable (RMSEA=0.064, CFI=0.937). The observed indicators were sufficiently explained by its respective latent variables (e.g. 67% to 72% of variances for indicators of school environment were explained). All independence between latent variables were significantly associated with SA (P<0.01). The perceived risk of SA, pressure from social norm and family support were negatively associated with SA. On the other hand, having tolerance attitude toward SA, risk-prone behavior and adverse school environment were positively associated with SA. CONCLUSIONS: Findings suggested that effective prevention of youth SA can be made from increasing the awareness of the risk of SA, improving school environment and enhancing fam-
ily support. In particular, we should target on youth population with risk-pr

PH26 SPONTANEOUS REPORTING OF ADVERSE DRUG REACTIONS IN GERIATRIC PATIENTS IN INDIA

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OBJECTIVES: In India, spontaneous reporting of adverse drug reactions (ADRs) by health care professionals was initiated in 2010. The drug safety issues for geriatric population are critical due to age-related physiological changes, pharmacodynam-
ics and pharmacokinetics. Our objective was to assess the spontaneous reports of adverse drug reactions, observed in geriatric patients (over 65 years of age) in India during the period from 1 July 2011 to 31 June 2013. METHODS: The spontaneous reports of 4357 elderly patients (≥65 years) were retrieved at national pharmacovigilance centre from the database containing all ADR reports from 90 ADR Monitoring Units in India. The data were collected in India under Pharmacovigilance Programme of India (PvPI) for the period of two years. These reports were analysed for various character-
istics of patients, drugs and ADRs using a search and analysis tool. RESULTS: OF the 4357 ADR reports of elderly patients, the total number of males (57.77%) patients of the total geriatric patients were found to be serious of which 8 (0.71%) were fatal. Cinasp, clonapam, clonapam, acetylsalicylic acid and insul-
in were the common drugs which were prescribed to the elderly patients and the commonest ADRs reported were vomiting, diarrhoea and constipation. The ADRs in geriatric population mostly affected Gastro-intestinal system and Skin Appendages sys-

CONCLUSIONS: This study from spontaneous reporting indicates the common ADRs in the geriatric patients in India which will help health care professionals in better understanding of the drug safety issues in elderly.

PH27 THE PATIENT VOICE IN CHINA: STATUS QUOESTIONS

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OBJECTIVES: The objective of this study was to assess the strength of the voice of the oncology patient in China and whether this was in sync with the Chinese cancer incidence. Moreover we wanted to understand what the proportion of patients (PRO) based publications in China compared to publica-

ions based on other data sources. Moreover we also wanted to understand what the main types of PROs collected in China are. METHODS: Published Literature was reviewed in the same period (January 2013–April 2014). This was retrieved using the words ‘oncology’, ‘China/Chinese’, patients, and/or Quality of Life. Publications needed to be submitted between January 2012 and December 2013. The results - in terms of amount of PROs, type of PROs and most benchmarked areas were searched for in countries including India, USA, Russia, Mexico, Japan, Korea, Germany, France, Brazil, Turkey, Italy, Spain, Australia, and Belgium. Moreover the results were compared to the age standardized incidence rates (ASIR) for cancer within these countries. RESULTS: China comes in 4th place with a ratio of 0.34 (Publications / ASIR) after USA (0.81), UK (0.77), and Japan (0.46). Belgium, Mexico and Russia score worst. The 3 key topics concerning Chinese oncology patients are Survival (16%), HRQoL (16%), tumor staging (12%). Japan (0.46). Belgium, Mexico and Russia score worst. The 3 key topics concerning in 4th place with a ratio of 0.35 (Publications / ASIR) after USA (0.81), UK (0.77), and

PH29 HEALTH RELATED QUALITY OF LIFE AND MEDICATION USE AMONG YOUNG COLLEGE STUDENTS DURING MENSTRUAL CYCLE

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OBJECTIVES: Many studies have reported the reduction in Health Related Quality of Life among young girls and after menstruation. Our study was to assess how these girls also resort to medications like NSAIDs to alleviate the pain during the same. The present study was aimed to study the difference in health related quality of life during menstruation, pre-menstrual and non-users. METHODS: In this cross sectional study a pilot tested questionnaire was used to collect information regarding college students (n=496) with age between 18-25 years. Information such as demographics, socioeconomic status, menstruation pattern and health related quality of life measurement both descriptive and visual analogue score of EQ SD 5L questionnaire were used. The data collected was analyzed using SPSS 16.0. The test of significance was done by using Mann-Whitney U test. RESULTS: Mean age of the surveyed population was found to be 20.46±2.81 with 12.88±2.372 years as the average age of commencement of menstrual cycle. The BMI was found to be 19.89±4.88. 77.4% of students reported having some sort of pain before, during and after the menstrual bleeding. The average EQ 5D VAS score was found to be 0.95±0.18±0.62. Mann-Whitney U test has shown significant difference (p=0.001) among the medication users for alleviation of pain whereas there was no significant differ-
ence (p=0.72) among self-medication and prescription drug users. CONCLUSIONS: Through this study the population studied was quite young there was a difference in health related quality of life among medication users and non-users.

PH30 ASSESSMENT OF KAP AMONG HOSPITAL PHARMACISTS

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OBJECTIVES: To assess the knowledge, attitude & perception (KAP) relating to pharmaceuticals containing non-Halal ingredients among pharmacists working in various hospitals of Malaysia. METHODS: This was a crosssectional study, car-
teed in 2011. The data were collected using a prestudied, adminis-
tered questionnaires. Study settings included various government hospitals in Malaysia. Data was collected by distributing questionnaires through respective chief pharmacists. Study was conducted on a sample of 135 inclusion criteria was a regular pharmacist working in a government hospital. Descriptive statistics (mean, standard deviation, frequency, percentage, median, inter quartile range) was applied to summarize the data, non-parametric tests were applied. Chi-square Test and Fisher’s Exact Test was applied to assess the association between demo-

graphic characteristics and knowledge, attitude and perception scores. RESULTS: Results revealed that the hospital pharmacist had a good knowledge and positive attitude & perception about Halal pharmaceuticals. Mean knowledge score out of maximum possible 9 score was 8.01 ±1.48, mean attitude score out of maximum possible 45 score was 33.21 ± 5.66 while mean perception score out of maximum possible 60 score was 51.19 ± 6.49. Mean overall KAP score out of maximum pos-
sible 114 was 92.46 ± 11.26. There was a significant, positive, and weak correlation 0.1-0.29) between knowledge and perception (p=0.71, p<0.001), knowledge and attitude (r=0.252, p=0.003) and moderate correlation (0.3-0.7) between attitude and perception (r=0.543, p<0.001). Overall it is concluded that better knowledges the respondents have on Halal pharmaceuticals, better their perception & attitude is towards Halal pharmaceuticals. P value of .05 or less was used in hospitalized elderly patients, further enhance patient safety and reduce medication error. For the period of two years. These reports were analysed for various character-
istics of patients, drugs and ADRs using a search and analysis tool. RESULTS: OF the 4357 ADR reports of elderly patients, the total number of males (57.77%) patients of the total geriatric patients were found to be serious of which 8 (0.71%) were fatal. Cinasp, clonapam, clonapam, acetylsalicylic acid and insul-
in were the common drugs which were prescribed to the elderly patients and the commonest ADRs reported were vomiting, diarrhoea and constipation. The ADRs in geriatric population mostly affected Gastro-intestinal system and Skin Appendages sys-

CONCLUSIONS: Although China has the highest number of inhabitants of the world as well as the highest absolute number of oncology patients, this does not completely reflect in the Chinese patients based publications. Further research is required to understand how important PROs are for Chinese physicians in their treatment decisions as well as for patients in their reimbursement/ market access decisions and how this is most likely to evolve.
THE PROVISION OF PHARMACY CARE SERVICES: A QUALITATIVE APPROACH

REPORTED HEALTH IN RURAL AND URBAN COUNTIES IN THE US

ASSESSING THE IMPACT OF PHARMACIST MALDISTRIBUTION ON SELF-REPORTED HEALTH IN RURAL AND URBAN COUNTIES IN THE US

PERSISTENCE IN HEALTH EXPENDITURES BY THE ELDERLY IN TAIWAN: PREDICTING THE TOP 10% USERS

PERSISTENCE IN HEALTH EXPENDITURES BY THE ELDERLY IN TAIWAN: PREDICTING THE TOP 10% USERS

An ecological analysis on national trends and correlation between public funding for pneumococcal vaccination and pneumonia disease burden in the Japanese elderly population, 2005-2012

A QUALITATIVE APPROACH

COMMUNITY PHARMACISTS ATTITUDE AND PERCEIVED NEED TOWARDS THE PHARMACY CARE SERVICES: A QUALITATIVE APPROACH

COMMENTS: The main objective of this study is to assess the perception of community pharmacist regarding quality of pharmaceutical care services in Khyber Pakhtunkhwa, Pakistan. METHODS: A qualitative study design was adopted, for identifying the perceptions of community pharmacists regarding pharmaceutical care services. A semi-structured interview guide was developed and face to face interviews were conducted until point of saturation has reached. Twelve community pharmacists were interviewed from December to February 2014 from different cities of Khyber Pakhtunkhwa, Pakistan. The interviews were conducted at the community pharmacy. Written consent was obtained from the participants prior to the interview.

RESULTS: Among the respondents, thematic content analysis yielded major themes: (a) Lack of documentation, (b) Improper patient counseling, (c) Unavailability of pharmaceutical care guidelines, (d) Lack of collaboration with other health care providers.

CONCLUSIONS: This study concludes that community pharmacists' need for improved pharmacists' training in collaboration with patients. Documentation and patient counseling is also very poor due to lack of enough time and no financial encouragement. There is also no effective professional relationship of community pharmacists with other health care providers.

NURSES’ PERCEPTION TOWARDS THE BENEFITS OF PHARMACEUTICAL CARE SERVICES IN TERTIARY HEALTH CARE SETTINGS PAKISTAN: A QUALITATIVE INSIGHT

OBJECTIVES: To explore the perception of nurses regarding quality of pharmaceutical care services in Khyber Pakhtunkhwa, Pakistan. METHODS: Qualitative methodological approaches were used. Thematic content analysis was the method of data analysis. Results: A total of 14 nurses were interviewed. Thematic content analysis yielded major themes: (a) Ineffective communication, (b) Lack of patient counseling, (c) Lack of pharmaceutical care guidelines, (d) Lack of collaboration with other healthcare providers.

PERSISTING HEALTH AND DEATH ASSESSMENT AMONG THE ELDERLY IN KHYBER PAKHTUNKHWA, PAKISTAN

EVALUATING THE UNDERSTANDING OF PHARMACY CARE SERVICES BY COMMUNITY PHARMACISTS ON THE NATIONAL HEALTH INSURANCE SYSTEM (NHS): A QUALITATIVE APPROACH

A QUALITATIVE APPROACH

COMMUNITY PHARMACISTS ATTITUDE AND PERCEIVED NEED TOWARDS THE PHARMACY CARE SERVICES: A QUALITATIVE APPROACH

COMMENTS: The main objective of this study is to assess the perception of community pharmacist regarding quality of pharmaceutical care services in Khyber Pakhtunkhwa, Pakistan. METHODS: A qualitative study design was adopted, for identifying the perceptions of community pharmacists regarding pharmaceutical care services. A semi-structured interview guide was developed and face to face interviews were conducted until point of saturation has reached. Twelve community pharmacists were interviewed from December to February 2014 from different cities of Khyber Pakhtunkhwa, Pakistan. The interviews were conducted at the community pharmacy. Written consent was obtained from the participants prior to the interview.

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CONCLUSIONS: This study concludes that community pharmacists’ need for improved pharmacists’ training in collaboration with patients. Documentation and patient counseling is also very poor due to lack of enough time and no financial encouragement. There is also no effective professional relationship of community pharmacists with other health care providers.
Patients with non-valvular atrial fibrillation were more likely to be hospitalized (Mean: 0.51 vs. 0.37, P<0.001) and to visit ER (Mean: 1.14 vs. 1.01, P=0.003). The total annualized costs in the WP group was significantly higher than WP group (24,702.1 vs. 19,836.3, P<0.001). Hospitalization accounted for 34.57% of total costs. After adjusting for patient characteristics, the pattern of differences between the two groups remain the same. CONCLUSIONS: Warfarin continuation is associated with higher number of hospital visits and ER visits and higher total health care costs than warfarin persistence. Future studies should examine strategies to improve patient persistence with anticoagulants and lower total health care costs.

PCV5 UPDATING CHARACTERISTICS OF TYPE 2 DIABETES MELLITUS PATIENTS IN CHINA: SURVEYS IN YEAR 2008 AND 2011
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OBJECTIVES: To update the characteristics of Chinese Type 2 Diabetes Mellitus (T2DM) patients and describe their blood glucose control. METHODS: Adelphi Real World (Adelphi) conducted a 2nd survey on T2DM patients in China in 2011. The survey methodology was similar to 1st survey in 2008. Data from a population-based database in Minhang area including 180,806 hypertensive patients were selected. Information on demographics, lifestyle, medical records, as well as cardiovascular events was collected. Hypertension and diabetes were identified by ICD-10 code in the database. The diagnosis of hypertension was any diagnosis of high blood pressure in the database. The diagnosis of diabetes included adult onset diabetes (non-insulin ADM users), biguanides and sulfonylureas were the most commonly used agents. 2.4% and 4.2% of the patients were on GLP-1 inhibitors and DPP-4 in W2. W1 and W2 had the same mean of HbaA1C% (7.4%). 36.6% of all the patients had HbaA1C%<7.0%. Other data may suggest that awareness increased, and clinical diagnosis and medical intervention were initiated earlier for T2DM from 2008 to 2011 in China. More insulin users were treated with basal insulin and some started GLP-1 inhibitors and DPP-4. However, blood glucose control for preventing further development of complications remained to be improved.

PCV6 CLINICAL CHARACTERISTICS AMONG HYPERTENSION PATIENTS WITH DIABETES IN SHANGHAI, CHINA
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OBJECTIVES: To evaluate the clinical characteristics among hypertension patients with diabetes in Shanghai, China. METHODS: Data from a population-based database in Minhang area including 180,806 hypertensive patients were examined. All hypertension cases were collected through 12 community health centers and then enrolled in the electronic Health Records (eHR) system. Information on demographics, lifestyle, medical records, as well as cardiovascular events was collected. Hypertension and diabetes were identified by ICD-10 code in the database. The diagnosis of hypertension was any diagnosis of high blood pressure in the database. The diagnosis of diabetes included adult onset diabetes (non-insulin ADM users), biguanides and sulfonylureas were the most commonly used agents. 2.4% and 4.2% of the patients were on GLP-1 inhibitors and DPP-4 in W2. W1 and W2 had the same mean of HbaA1C% (7.4%). 36.6% of all the patients had HbaA1C%<7.0%. Other data may suggest that awareness increased, and clinical diagnosis and medical intervention were initiated earlier for T2DM from 2008 to 2011 in China. More insulin users were treated with basal insulin and some started GLP-1 inhibitors and DPP-4. However, blood glucose control for preventing further development of complications remained to be improved.
on subjective and objective methods of patients’ assessment. Assessment made by nurses and doctors at different times of treatment is performed for 24 patients. The presence of arterial hypertension mostly defined symptoms of functional dysfunction of cardiovascular system like dyspnea, edema, chest pain, peripheral cyanosis, hyper- trophy and pain in the heart region. These symptoms can be identified with clinical and instrumental aspects of nursing diagnosis. Symptoms, first and secondary risk factors of arte- rial hypertension defined by laboratory investigations, asking questions, physical examination (increased level of blood sugar, cholesterol, triglycerides, decreased level of LDLP, increased systolic and diastolic blood pressure). These findings can be used in a methodo- logical and theoretical aspects for nursing diagnosis.

PCV8

EFFECTIVENESS OF CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH MILD-MODERATE HEART FAILURE: A SYSTEMATIC REVIEW AND BAYESIAN APPROACH NETWORK META-ANALYSIS

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OBJECTIVES: The safety of statin relative effectiveness of cardiac resynchronization therapy (CRT) versus implantable cardiac defibrillator (ICD) or optimal medical treatment (OMT) in mild-moderate heart failure patients with New York Heart Association (NYHA) Class I and II. METHODS: Randomized controlled trials of CRT, ICD and OMT in mild-moderate heart failure patients were identified from MEDLINE, EMBASE and COCHRANE database. All abstracts were identified for the search terms ‘mild-moderate heart failure’, ‘CRT’, ‘ICD’, ‘OMT’ and ‘NYHA class I or II’. Abstracts were reviewed, and studies containing information on effectivity profile were obtained for further review. Results were pooled and analyzed by a Bayesian random-effect model. The model used to analyze the relative effectiveness of all-cause mortality and left ventricu- lar ejection fraction (LVEF). 11 studies were identified with total of 6,865 pa- tients. CRT was associated with a significant reduction of the all-cause mortality compared with ICD alone (odds ratio 0.81, 95% credible interval 0.60 to 1.14) or OMT alone (odds ratio 0.84, 95% credible interval 0.59 to 1.21). However, CRT was associated with a significant reduction of the LVEF compared with OMT alone (mean difference 3.96, 95% CI 0.88 to 7.08). The probability determined from the Bayesian analysis that CRT was the best treatment option was 87.2% (7.7% for ICD and 9.9% for OMT respectively). CONCLUSIONS: This Bayesian network meta-analysis suggests that CRT could improve the prognosis in patients with mild-moderate heart failure.

PCV9

A COMPARISON OF PREFERENCES FOR THE BENEFITS AND RISKS OF STATINS AMONG KOREAN PHYSICIANS AND PATIENTS USING A DISCRETE-CHOICE EXPERIMENT

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OBJECTIVES: The safety of statins had been a controversial issue. Cerivastatin was withdrawn due to fatal rhabdomyolysis, and the high dose of simvastatin was reported to cause liver failure. This study aims to compare the preferences on the benefits and risks of statins between the patients and physicians. METHODS: Discrete choice experiments were conducted on the benefit and risk perceptions of statins. Two benefit parameters were defined as low-density lipoprotein cholesterol reduction (LDL) and myocardial infarction reduction (MI). And two risk attributes contained liver failure (Liv) and fatal rhabdomylosis (Rha). The questionnaires for experiments (DCE) were conducted to measure preferences on the benefits and risks of statins. One hundred and seventy seven patients with coronary heart disease (n = 98), 4 (n = 76) and 5 (n = 126) in ICD Center of Hospital University Science Malaysia, Kelantan, Malaysia. RESULTS: The mean age of all patients was 68.1 ± 10.7 years. RESULTS: The percentage of patients who accepted risk twice than patients when the statin reduced the MI from 25% to 38.88% (±0.15), 36.32% (±0.33), 11.55% (±0.35), 13.25% (±0.14) respectively. The percentage of patients with statistic BF > 130 mm Hg and diastolic BF > 80 mm Hg was 30% and 49.0%, respectively. Only 24.3% of the total patients had BF > 130/80 mm Hg despite using multiple anti-hypertensive medications. The proportion of patients consuming statins was as: anti-hyperlipidemic medications: 87.2%, angiotensin enzyme inhibi- tors (ACE-I) (25%), angiotensin receptor blockers (ARBs) (14.3%), combined ACE-I and ARBs (2.7%), calcium channel blockers (66.3%), β-blockers (40.7%), diuretics (60%) and α-blockers (14.3%). There was significantly lower percentage of patients on ACE-I and ARBs in stage 5 than in stage 4 and 3 patients. Proteinuria was present in 71.7% of the patients and there was significant difference proteinuria between stage 3, 4 and 5 (31.1 vs 59.2 vs 92.1, p = 0.000). CONCLUSIONS: Underutilization of some classes of anti-hypertensive medications is apparent. Higher percentage of proteinuria in ICD stage 5 patients may be attributed to the underuse of ACE-I and ARBs in stage 5. The study further indicated the need of employing constructive efforts to get valuable outcomes of anti-hypertensive treatment in ICD suffers.

PCV10

LONG-TERM FOLLOW UP OF PRIMARY AND SECONDARY PREVENTION IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PATIENTS: “REAL-WORLD” DATA FROM THE ISLAND OF CRETE

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OBJECTIVES: The beneficial effects of implantable cardioverter defibrillators (ICDs) in primary and secondary prevention of sudden cardiac death were confirmed in several RCTs, with data on potential differences between the two groups in mortality and ICD therapy rate during long-term follow-up are scarce. The aim of the study was to assess differences in mortality and ICD therapy between primary and secondary prevention ICD recipi- ents. METHODS: All patients treated with an ICD, regardless of the underlying cardiac pathology, at the island of Crete were included in the current study. The analysis was grouped by the type of prevention (secondary or primary) for sudden cardiac death. The primary endpoint was all-cause mortality. The secondary endpoint was the occurrence of device therapy (appropriate or inappropriate). RESULTS: A total of 854 (88.6%) men ICD recipients were included. Of these, 621 (73%) patients received an ICD for primary prevention of sudden cardiac death and 231 (27%) patients for secondary prevention. During a mean follow-up of 5.4 (+/- 1.7) years, 177 (20.7%) patients died. The incidence of mortality was 36.5% for secondary prevention patients and 15.2% for primary prevention patients (p = 0.002). Ventricular arrhythmia triggered appropriate therapy in 91 (38.4%) secondary prevention patients, whereas the number of primary prevention patients that received appropriate therapy was 262 (20.2%). A comparable risk for inappropriate shocks was observed. CONCLUSIONS: During long-term follow-up, primary prevention patients exhibited a lower risk in mortality and all-cause mortality while secondary prevention patients showed a higher rate of appropriate therapy.

PCV11

EFFECTIVENESS OF CATHETER-BASED RENAL DENALATION FOR TREATMENT OF RESISTANT RESISTANT HYPERTENSION – RESULTS OF A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Catheter-based renal denervation (RDN) is a promising therapy option for patients with treatment resistant hypertension (THT-RDN). The RDN evidence base currently consists of several studies with limited sample size and variations in design,
follow-up duration and catheter, so uncertainty may exist regarding overall therapy effectiveness. The objective of this analysis is to conduct a systematic review and direct meta-analysis of relevant RDN studies to provide a more powerful estimate of the true effect size to inform clinical decisions and economic evaluations. METHODS: RDN publications were identified through MEDLINE, EMBASE and Cochrane databases and ongoing national trials (2018). Pre-specified inclusion criteria included all studies (regardless of catheter used) enrolling TR-HTN patients (SBP ≥ 160 mmHg despite 1-4 anti-hypertensive drugs including a diuretic). Results were presented as weighted mean difference (WMD) in office-based SBP over 6 months. RESULTS: A total of 53 trials were identified (1 RCT, 11 case control, 16 single arm, 29 case series), yielding 28 studies (n=896) for meta-analyses. All were open label and reported significant reductions in systolic and diastolic blood pressure. The overall WMD in SBP from all studies was -26.1 mmHg (95% CI: -25.4 to -26.7) for the pooled case control trials. In the single arm trials, RDN was associated with substantial SBP reductions in patients with TR-HTN. However, the majority of eligible trials were non-randomised, unblinded and used the Symplicity catheter. This may have influenced the magnitude of the treatment effect observed.

PCV14 A RETROSPECTIVE COST-EFFECTIVENESS ANALYSIS OF S-AMLODIPINE IN CHINA
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OBJECTIVES: The paper is to compare the difference between S-Amlodipine and racemic amlodipine by using respective cost-effectiveness analysis METHODS: the authors use two head-to-head multi-center, RCT studies' clinical efficacy data, Levamlodiping Besylate tablets (Shiweida® 2.5 mg/day) and Amlodipine Besylate tablet (Norvasc® 5mg/day), as a control group. The blood pressure and cost of drug were compared in short-term (8 weeks) and long-term (6 months) treatments. RESULTS: There was no statistical significant difference in efficacy rate between S-Amlodipine group (110cases) and racemic Norvasc group (104 cases) 84.91% vs. 77.45%. The cost of reducing 1mmHg systolic pressure and diastolic pressure in S-Amlodipine group was 16.5 Yuan (RMB), and Norvasc group was 16.9 Yuan (RMB) and 21.7Yuan (RMB), respectively. The cost of Norvasc is 100% higher than that of S-Amlodipine. In the results of 6-month long-term treatment, The cost of reducing 1mmHg systolic pressure and diastolic pressure in S-Amlodipine group (124 cases) was 31Yuan (RMB) and 43Yuan (RMB), and 50Yuan (RMB) and 75Yuan (RMB) in Norvasc group (104 cases) , respectively. The cost of Norvasc is 162.1-179 times higher than that of S-Amlodipine. Meanwhile, the study shows that the cost of reducing 1 mmHg blood pressure is significantly lower in the S-Amlodipine group than others. The cost of reducing 1mmHg systolic blood pressure. The adverse reaction of S-Amlodipine group (4.6%) is significantly lower than Norvasc group (10.3%). The sensitivity analysis based on average price and medium price of two-cluster products in China, the S-Amlodipine is significantly lower than Norvasc group (10.3%). CONCLUSIONS: The domestic product of S-Amlodipine is more cost-effectiveness than the original Norvasc product. At present, the market volume and value of S-Amlodipine in total CCB market is about 30 percent. The authors recommend the use of S-Amlodipine in China and promote the respective pharmacoeconomic evaluation to collect more basic evidence of.

PCV15 STUDY OF MEDICATION ADHERENCE IN DIABETES MELLITUS PATIENTS WITH HYPERTENSION
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OBJECTIVES: The purpose of this study is to examine whether there is quality differences among AML patients by severity of cases and by payers status. METHODS: The study examined the outcome differences of acute myocardial infarction (AMI) at the National Cardiovascular Center (NCC) Harapan Kita, Jakarta, Indonesia. This study analyzed medical records of patients with AMI during the period of January 1, 2009 until December 31, 2012. RESULTS: The study found 5,472 patients with AMI consisting of 61.5% males and 18.5% females with the mean age of 56.3 years (range 21-97 years) vs. 26-96 years. Most of the patients were from Catalonia (51%). On severity levels, 46% patients were in severity level I, 47.7% severity level II, and 5.9% level III. More than half (54.6%) patients were treated with intervention (PTCA) or stentting, about 33% with medical treatment. There were no statistical differences in the age and gender distribution of the payers. CONCLUSIONS: The doctors provided the same quality of services among AML patients, regardless of payers' status or coverage. There was no difference in outcome of care among different payers.

PCV16 EFFICACY OF AYURVEDIC FORMULATION IN THE MANAGEMENT OF ESSENTIAL HYPERTENSION
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OBJECTIVES: Essential Hypertension (EHT) is described as silent killer as it is almost symptomless. However, long term effects like bad sleep, giddiness, redness in the eye and restlessness comprise of morbidity. In this study Gandharvahavathi Kashyam (GK) consisting of polyherbal medicines was studied in the manAgeMent of EHT. METHODS: The case control study was administered for 3 months. One month each patient was administered 15 ml bid with GK, half an hour before food. Systolic Blood Pressure (SBP) was in the range of 160-140 and Diastolic(DBP) was 90 to 100 were included in the study. The morbidity was mild to moderate, loss of sleep, headache, loss of sleep, giddiness, redness in the eye and restlessness comprise of morbidity. The SBP was 126 -136 and DBP 80- 86, the headache was relieved in in 15 patients, improvement in loss of sleep reported in 22 patients, redness in the eye was relieved 2 patient out of 5 . 20 patients expressed relief from restlessness. CONCLUSIONS: The GK is found to be effective in reducing SBP and DBP in all patients studied. In addition it has shown improvement in morbidity of EHT patients.

PCV17 PROF DR HASBULLAH THABRAY
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OBJECTIVES: The study examined the outcome differences of acute myocardial infarction (AMI) at the National Cardiovascular Center (NCC) Harapan Kita, Jakarta, Indonesia. This study analyzed medical records of patients with AMI during the period of January 1, 2009 until December 31, 2012. RESULTS: The study found 5,472 patients with AMI consisting of 61.5% males and 18.5% females with the mean age of 56.3 years (range 21-97 years) vs. 26-96 years. Most of the patients were from Catalonia (51%). On severity levels, 46% patients were in severity level I, 47.7% severity level II, and 5.9% level III. More than half (54.6%) patients were treated with intervention (PTCA) or stentting, about 33% with medical treatment. There were no statistical differences in the age and gender distribution of the payers. CONCLUSIONS: The doctors provided the same quality of services among AML patients, regardless of payers' status or coverage. There was no difference in outcome of care among different payers.

PCV18 USE OF CALCIUM CHANNEL BLOCKERS IN SERBIA IN THE PERIOD FROM 2008 TO 2012 YEAR
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OBJECTIVES: The purpose of this study is to examine whether there is quality differences among AML patients by severity of cases and by payers status. METHODS: The study examined the outcome differences of acute myocardial infarction (AMI) at the National Cardiovascular Center (NCC) Harapan Kita, Jakarta, Indonesia. This study analyzed medical records of patients with AMI during the period of January 1, 2009 until December 31, 2012. RESULTS: The study found 5,472 patients with AMI consisting of 61.5% males and 18.5% females with the mean age of 56.3 years (range 21-97 years) vs. 26-96 years. Most of the patients were from Catalonia (51%). On severity levels, 46% patients were in severity level I, 47.7% severity level II, and 5.9% level III. More than half (54.6%) patients were treated with intervention (PTCA) or stentting, about 33% with medical treatment. There were no statistical differences in the age and gender distribution of the payers. CONCLUSIONS: The doctors provided the same quality of services among AML patients, regardless of payers' status or coverage. There was no difference in outcome of care among different payers.
The relationship between masked hypertension and obesity

**OBJECTIVES:** Masked hypertension is associated with an increased risk for cardiovascular disease. The aim of the study was to evaluate the relationship between BMIs and health outcomes, including body weight, waist circumference, body mass index.

**METHODS:** The study group consisted of 118 consecutive patients with masked hypertension and 115 healthy control subjects. Following complete medical and laboratory examination, patients' height, weight, waist circumference, and office blood pressure were recorded. All patients underwent ambulatory blood pressure monitoring. The analysis was performed using SPSS (version 23).

**RESULTS:** Baseline characteristics in patients and controls were similar, except for waist circumference, which was higher in the patients with masked hypertension and obesity. Multivariate analysis revealed that age (OR: 1.04; 95% CI: 1.02, 1.06), hospital stay (OR: 1.05; 95% CI: 1.02, 1.09), and renal failure (OR: 1.04; 95% CI: 1.02, 1.06) were significant predictors of postoperative complications. However, patients with higher BMI tended to have increased postoperative complications. Sensitivity analyses revealed that patients with BMI ≥ 30 had an increased risk of postoperative complications.

**CONCLUSIONS:** The study demonstrated that anthropometric indices such as waist circumference were higher in patients with masked hypertension. It can be suggested that predefining obesity might be helpful in early detection of masked hypertension.

The relationship between masked hypertension and obesity in patients with atrial fibrillation

**OBJECTIVES:** The aim of the study was to examine the medical costs during the first and the second year following the onset of cardiovascular diseases, i.e. myocardial infarction (MI), angina, stroke, coronary heart failure (CHF), or peripheral arterial disease (PAD).

**METHODS:** The study was based on a claims database, was used in the study. Patients who hospitalized with the principal diagnosis code of 410 for MI, 413 for angina, 430-434 for stroke, 402 for PAD during 2005-2009 were identified as study subjects. The initial date of the hospitalization/outpatient visit with the diagnosis code associated with each disease was defined as the index date. Patients who had outpatient visits or hospitalization with diagnoses of MI, angina, stroke, CHF and PAD within five years before the index date were excluded, except for patients who had outpatient visits within two weeks prior to the index date. Patients who withdrew from the health insurance program during the first and the second year after the index date were also excluded. Generalized linear models were used to estimate the association between cardiovascular diseases within 1st year and 2nd year after the index date. All costs were inflated to 2011 dollars by using the medical care component of the Consumer Price Index. **RESULTS:** The 1st year average total medical costs associated with MI, angina, stroke, CHF, and PAD were NT$293,995, NT$600,505, NT$141,086, respectively.
NT$113,100, and NT$6,556, respectively. The 2nd year average total medical costs associated with MI, angina, and stroke were NT$63,365, NT$83,669 and NT$52,513, respectively. CONCLUSIONS: Medical costs associated with cardiovascular diseases were substantial to the National Health Insurance program in Taiwan. These results indicate potential benefits from interventions aimed at preventing the risk factors of cardiovascular diseases such as hypertension, hyperlipidemia, and hyperglycemia.

PCV29

HOW LIKELY IS WARFARIN PHARMACOGENOMIC TEST TO BE COST-EFFECTIVE IN THAILAND: A THRESHOLD ANALYSIS

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OBJECTIVES: Our economic evaluation of warfarin pharmacogenomic (PGx) test revealed that the test was not cost-effective in Thailand, based on input parameters derived from a meta-analysis of Caucasians-dominant studies for the relative risk (RR) of major bleeding in variant genotypes of CYP2C9 [2.19, 95%CI [1.33-3.60]] and VKORC1 [1.95, 95%CI [1.59-2.40]]. Considering this limitation and the prevalence of VKORC1 variant genotype in Thailand, this study aimed to determine the threshold value of the RR of major bleeding for VKORC1 variant genotypes leading to cost-effective. METHODS: We conducted a literature search for local and international publications investigating the relationship of VKORC1 genotype and the risk of major bleeding in warfarin users. Additionally, interviews with 80 international experts were performed for patients aged 45 years old using the previously constructed decision analytic model. The model was populated from the societal perspective. Input data were obtained from literature review, meta-analysis, and electronic health and economic evidence. A threshold value was performed for patients aged 45 years old using the previously constructed decision analytic model. The model was populated from the societal perspective. Input data were obtained from literature review, meta-analysis, and electronic health and economic evidence.

PCV30

COST-EFFECTIVENESS OF TREATING ACUTE CORONARY SYNDROME PATIENTS WITH RIVAROXaban IN AUSTRALIA

Gao L, Li SC

OBJECTIVES: Rivaroxaban is a new oral anticoagulant subsidised on the Australian Pharmaceutical Benefits Scheme (PBS) for prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation or undergoing hip and knee replacement. Recent randomized controlled trials (RCTs) have demonstrated its efficacy and safety in the treatment of acute coronary syndrome (ACS). The aim of this study was to assess the long-term cost-effectiveness of treating patients with ACS with rivaroxaban for a 12 month period and modelling the lifetime costs and benefits from a third party payer perspective. METHODS: A two-part decision model was constructed to compare treatment with rivaroxaban or current treatment for patients with ACS. The first part was a decision-tree model comprising four health states (Acute Coronary Syndrome, Minor Stroke, death) and a fixed time horizon of 12 months. The second part comprised a Markov model, which simulated patients remaining alive or dying by age through 90 years. RESULTS: The lifetime costs, and quality adjusted life years (QALY) was estimated for both arms and an incremental cost-effectiveness ratio (ICER) estimated. A series of sensitivity analyses were performed to test the robustness of the result. RESULTS: One-year treatment with rivaroxaban was associated with both incremental cost and QALY (AUD 30,688 vs. 30,010, 17.51 vs. 17.39 for rivaroxaban and placebo respectively) over lifetime horizon in the baseline analysis. The ICER of rivaroxaban comparing to placebo was AUD 4,896 per QALY gained. The probabilistic sensitivity analysis varying the event transition probabilities also showed consistent results. CONCLUSIONS: Based on clinical and health economic evidence, treating ACS patients with rivaroxaban for 12 months was associated with an ICER of AUD 4,896/QALY, which is below the willingness-to-pay threshold for QALY in Australia inferred from published literature.
for iCaPPS was RM1625.00 (USD492.95), while conventional care was RM1276.46. QALY for iCaPPS patients was 0.55 (0,1.65) compared to 0.32 (0, 0.73) for conventional care although QALY scores improved. CONCLUSIONS: The management of post stroke patients in the community using iCaPPS protocol is cost effective compared to current conventional care in public health centres.

PCV3D
THE COST-EFFECTIVENESS OF FOUR CHINESE PATIENT MEDICINE IN THE TREATMENT OF ANGINA PECTORIS IN CHINA
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OBJECTIVES: Coronary heart disease (CHD) remains the leading cause of death in China. Among the main causes of CHD, chronic stable angina is the most common symptom of CHD. Because of fewer side effects and its application in multiple pathologic link in CHD, Chinese patent medicine continue to increase its importance in the long-term treatment of angina pectoris. This study aimed to estimate the cost-effectiveness of Suxiao jiuxin pill, Shexiang baoxin pill, Tongxinluo capsule and Compound Daneshen dropping pill in the treatment of angina pectoris, to provide reference for reasonable clinical prescription. METHODS: A decision-analytic model was developed to estimate the cost-effectiveness of Suxiao jiuxin pill, Shexiang baoxin pill, Tongxinluo capsule and Compound Daneshen dropping pill from the perspective of the whole society with a time horizon of 4 weeks. In the model, outcome on effectiveness was based on a published meta-analysis. Costs of drugs, direct and indirect costs of treatment were included. Results were expressed in terms of cost per QALY gained. In this model, the utility values of 0.85 were used for patients with angina pectoris. A sensitivity analysis was performed to determine the robustness of the results. RESULTS: The model indicated that Suxiao jiuxin pill appears to be the most cost-effective. The availability of more high-quality clinical data would allow a better adaptation of the model. Future research could be focused on this.

PCV3E
COMPARATIVE COST-EFFECTIVENESS OF CT PERFUSION FOR SELECTING STROKE PATIENTS FOR THROMBOLYSIS
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OBJECTIVES: Stroke is the third leading cause of death in developed countries. More than 80% of strokes were ischemic stroke. An accurate and timely diagnosis in ischemic stroke is crucial for treatment. CT is widely used for its quick performance, easy to tolerate, and reliable for detection. However the early infarct signs on CT are hard to detect and limited in detecting intracranial bleed. MRI is more accurate in detecting ischemic stroke than CT due to its capability of capillary level hemodynamics and the brain parenchyma. However, the use of MRI is costly and timely, and not all the patient can tolerate it. CT perfusion (CTP) expands the role of CT by providing penumina areas in stroke patients, which was defect of CT compared to MRI. The purpose of the present study was to estimate the cost effectiveness of CTP for selecting stroke patients for thrombolysis. METHODS: We searched PubMed, Embase, The Cochrane Library, and the major medical literature databases in China, several professional websites of health technology assessment (HTA) were also searched. We adopted the systematic review method to systematic evaluate the cost effectiveness of CT perfusion. We also have constructed a decision tree model used published literatures to evaluate the cost effectiveness of CT perfusion in China. RESULTS: Two economic studies were included. The ratios of cost effectiveness of CT, CTP and MRI for selecting stroke patients for thrombolysis were 2983.72/QALY, 2951.42/QALY and 2982.96/QALY in UK, 10483.58/QALY and 99406.5$/QALY just for CT and CTP respectively in US, and 113492.48/QALY, 1136154/QALY and 120831.95/QALY in China. CONCLUSIONS: The results of our comparative economic evaluation show that CTP were more cost effectiveness among CT and MRI in selecting stroke patients for thrombolysis both in China and abroad.

PCV3F
A COST-UTILITY ANALYSIS OF CALCIUM CHANNEL BLOCKERS (CCBS) COMBINED WITH ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) IN PREVENTING STROKE AND MYOCARDIAL INFARCTION AMONG HYPERTENSION PATIENTS IN THE TAIWAN
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OBJECTIVES: Hypertension is a major risk factor for stroke and myocardial infarction events. Both stroke and myocardial infarction can cause disability and mortality. Despite the high financial burdens, limited studies have examined the cost-effectiveness of hypertension treatments in Taiwan. This cost utility analysis was conducted to determine the costs and quality-adjusted life years (QALYS) associated with amlopidine (CCBs) and valsartan (ARBs) in preventing stroke and MI among Taiwanese hypertension patients. METHODS: A Markov model was developed, consisting of six states including alive without stroke/MI, MI, post-MI, stroke, post-stroke, and death. We estimated the costs and QALYS of amlopidine and valsartan in a five-year time period. Results of this evaluation were based on a published meta-analysis. Costs, drugs, direct
医疗费用的高血压管理，减压/治疗，以及随访和药物管理都影响了患者整体的效果。为了评估RDN在韩国患者中的成本效益，METHODS: Geisler团队使用了广泛的数据库和患者结果来评估效果。CONCLUSIONS:在韩国患者中，RDN是成本效益的治疗选择，尤其是在高血压控制率较高的情况下。
The two adherence groups were positively correlated with SBP control (adherence was significantly different between the good and poor controls of SBP and DBP). The predicted mean total annual costs (95% CI) adjusted for the factors mentioned above were €2.256 (€2.018–€2.534) for the overall sample of PM patients, and €2.171 (€1.888–€2.505) and €2.409 (€2.063–€2.778) in patients with initial PM replacement and those subjected to PM replacement, respectively. In addition, the history of hypertension and hypercholesterolemia as well as the baseline QoL were significantly associated with the total annual cost of patients subjected to ICD implantation. The predicted mean total annual costs (95% CI) adjusted for the factors mentioned above were €3.318 (€2.771–€3.967) for the overall sample of ICD patients, and €3.528 (€2.901–€4.156) and €2.044 (€1.329–€2.092) in patients with initial ICD implantation and those subjected to ICD replacement, respectively. CONCLUSIONS: Age, history of hypertension and hypercholesterolemia, and history of medical history of medications used before the enrolment in the study and QoL assessed by the EUROQOL EQ-5D Questionnaire. Resource data were assessed at 6 and 12 months after the procedure of implantation. Then, the components of cost were calculated using the bottom-up approach. RESULTS: The predicted mean total annual costs (95% CI) adjusted for the factors mentioned above were €2.256 (€2.018–€2.534) for the overall sample of PM patients, and €2.171 (€1.888–€2.505) and €2.409 (€2.063–€2.778) in patients with initial PM replacement and those subjected to PM replacement, respectively. In addition, the history of hypertension and hypercholesterolemia as well as the baseline QoL were significantly associated with the total annual cost of patients subjected to ICD implantation. The predicted mean total annual costs (95% CI) adjusted for the factors mentioned above were €3.318 (€2.771–€3.967) for the overall sample of ICD patients, and €3.528 (€2.901–€4.156) and €2.044 (€1.329–€2.092) in patients with initial ICD implantation and those subjected to ICD replacement, respectively. CONCLUSIONS: Age, history of hypertension and hypercholesterolemia, and history of medical history of medications used before the enrolment in the study and QoL assessed by the EUROQOL EQ-5D Questionnaire. Resource data were assessed at 6 and 12 months after the procedure of implantation. Then, the components of cost were calculated using the bottom-up approach.

**PCV47**

**DISCONTINUATION/INTERRUPTION OF WARFARIN THERAPY IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION**


**OBJECTIVES:** The purpose of this study was to assess patterns and predictors of warfarin persistence, discontinuation, and interruption among patients with non-valvular atrial fibrillation (NVAF). METHODS: This study used the MarketScan Database and included patients (≥18 years of age) with NVAF and followed for 365 days. Persistence was defined as warfarin therapy without a gap ≥ 45 days between warfarin prescriptions. Interruption was defined as a gap ≥ 45 days and the last day of any gap was defined as ≥ 90 days without warfarin therapy. Factors associated with warfarin interruption/discontinuation were determined using a Cox proportional hazards regression model. Sensitivity analyses were conducted to assess robustness of results by sex, prescription gaps > 45 days, and ≥ 90 days. RESULTS: Within 12 months of warfarin initiation, 26,241 (48.4%) patients were persistent with warfarin, 6,895 (11.8%) had interruption, and 25,457 (43.4%) had discontinuation with or without interruption. The risk of warfarin interruption/discontinuation was significantly greater in patients that were younger than 65 years (hazard ratio [HR]: 1.22, 95% confidence interval [CI]: 1.19-1.25), lived in the West (HR: 1.07; 95% CI: 1.03-1.11), had anemia (HR: 1.10; 95% CI: 1.06-1.14), experienced bleeding episodes (HR: 1.10; 95% CI: 1.06-1.14), were hospitalized or had emergency room visits (HR: 1.11; 95% CI: 1.08-1.13), or had higher Charlson Comorbidity Index (HR: 1.91; 95% CI: 1.01-1.02). The significant factors associated with interruption/discontinuation were consistent in the sensitivity analyses. CONCLUSIONS: In the usual clinical practice setting, more than 50% of patients discontinued or interrupted warfarin within one year after initiation. Age < 65 years, multiple medical conditions, and previous hospital and ER visits were associated with increased risk of interruption/discontinuation. Given the high prevalence of warfarin discontinuation, health care providers should take a more active role in understanding and addressing the reasons behind patient non-persistence.

**PCV48**

**PHARMACOTHERAPEUTIC ASSESSMENT OF WARFARIN THERAPY IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION**


**OBJECTIVES:** The purpose of this study was to assess patterns and predictors of warfarin persistence, discontinuation, and interruption among patients with non-valvular atrial fibrillation (NVAF). METHODS: This study used the MarketScan Database and included patients (≥18 years of age) with NVAF and followed for 365 days. Persistence was defined as warfarin therapy without a gap ≥ 45 days between warfarin prescriptions. Interruption was defined as a gap ≥ 45 days and the last day of any gap was defined as ≥ 90 days without warfarin therapy. Factors associated with warfarin interruption/discontinuation were determined using a Cox proportional hazards regression model. Sensitivity analyses were conducted to assess robustness of results by sex, prescription gaps > 45 days, and ≥ 90 days. RESULTS: Within 12 months of warfarin initiation, 26,241 (48.4%) patients were persistent with warfarin, 6,895 (11.8%) had interruption, and 25,457 (43.4%) had discontinuation with or without interruption. The risk of warfarin interruption/discontinuation was significantly greater in patients that were younger than 65 years (hazard ratio [HR]: 1.22, 95% confidence interval [CI]: 1.19-1.25), lived in the West (HR: 1.07; 95% CI: 1.03-1.11), had anemia (HR: 1.10; 95% CI: 1.06-1.14), experienced bleeding episodes (HR: 1.10; 95% CI: 1.06-1.14), were hospitalized or had emergency room visits (HR: 1.11; 95% CI: 1.08-1.13), or had higher Charlson Comorbidity Index (HR: 1.91; 95% CI: 1.01-1.02). The significant factors associated with interruption/discontinuation were consistent in the sensitivity analyses. CONCLUSIONS: In the usual clinical practice setting, more than 50% of patients discontinued or interrupted warfarin within one year after initiation. Age < 65 years, multiple medical conditions, and previous hospital and ER visits were associated with increased risk of interruption/discontinuation. Given the high prevalence of warfarin discontinuation, health care providers should take a more active role in understanding and addressing the reasons behind patient non-persistence.
the cardiology wards with unstable angina and myocardial infarction and undergo coronary intervention procedure, were randomized into control group where, standard care is provided and intervention group where, Pharmaceutical care was provided with tailor made counseling about diseases, drugs, diet and lifestyle modifications.

Quality of Life assessment was done with EQ-SD5L and MacNew Questionnaire by interview method at 3 months, 6 months, 9 months and at 12 months. RESULTS: 213 participants were randomized into control group (n= 105) and intervention group (n= 108). Socio-demographic characteristics at baseline are similar between two groups. At baseline, Global Scores of MacNew questionnaire of both the groups have similar scores (3.03 ± 1.29 & 2.89 ± 1.12). At 12 months, scores of 3.22 ± 0.91 and 5.47 ± 1.45 were observed for control and intervention group respectively. EQ utility values at base line were 0.46 ± 0.17 and 0.47 ± 0.16. At 12 months, utility values were 0.11 ± 0.25 and 0.68 ± 0.29 observed for control and intervention groups respectively. EQ Visual analog scores at base line were 59.57 ± 14.51 and 61.01 ± 13.34. At 12 months, scores of 73.38 ± 5.19 and 85.13 ± 4.62 was observed for control and interventional groups. Decrease in physical activity and sedentary exercise. Adjusted mean (±standard error) of physical domain was 64±3.3 (lean), 63±1.1 (normal), 62±1.1 (over-weight) and 67.34% in obese classes. Most prevalent diseases with higher BMI were hypertension, diabetes, and joint pain in decreasing order. Major category of urban Indian population is categorized being overweight (BMI greater than 25). A sedentary lifestyle and lack of exercise causes obesity which is reported to be a high risk factor for metabolic diseases. METHODS: In this study, we have categorized middle class Indian population (test subjects >500) residing in metropolitan Delhi area into different age groups (11-20, 21-30, 31-40, 41-50, 51-60 and 60 and above) and recorded BMI and degree of obesity fat present (no excess obesity fat, small, medium, and high). Our data shows that age groups 11-20 and 21-30 show normal BMI and lower cases of accumulated belly fat whereas there is a significant increase (50%) in BMI and presence of belly fat in age group 31-40 and above. We also recorded presence of obesity related metabolic disorders such as diabetes and hypertension in the above mentioned age groups. RESULTS: Test subjects in all age groups with BMI >25 (over-weight and obse) recorded presence of related disorders (39-49% in over-weight and obse classes) and increase in prevalent diseases with higher BMI were hypertension, diabetes, and joint pain in decreasing order. CONCLUSIONS: The sudden increase in obesity related factors is a matter of concern in the age group of 11-20 and 21-30. The results show that the risk factors for metabolic diseases such as hypertension and diabetes are increasing rapidly. This information is extremely relevant for social awareness about obesity in middle class Indian population and through this study, it has been possible to alert the test subjects about risk of associated disorders.

PCV5 HIGH BMI AND BELLY FAT CORRELATE WITH PREVALENCE OF HYPERTENSION AND DIABETES: A CROSS-SECTIONAL STUDY IN SEDENTARY URBAN POPULATION OF DELHI


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OBJECTIVES: Obesity is reported to be underlying cause of metabolic syndrome and associated with hypertension and diabetes. A BMI body mass index of more than 30 places individuals in obese category. Majority of urban Indian population is categorized being overweight (BMI greater than 25). A sedentary lifestyle and lack of exercise causes obesity which is reported to be a high risk factor for metabolic diseases. METHODS: In this study, we have categorized middle class Indian population (test subjects >500) residing in metropolitan Delhi area into different age groups (11-20, 21-30, 31-40, 41-50, 51-60 and 60 and above) and recorded BMI and degree of obesity fat present (no excess obesity fat, small, medium, and high). Our data shows that age groups 11-20 and 21-30 show normal BMI and lower cases of accumulated belly fat whereas there is a significant increase (50%) in BMI and presence of belly fat in age group 31-40 and above. We also recorded presence of obesity related metabolic disorders such as diabetes and hypertension in the above mentioned age groups. RESULTS: Test subjects in all age groups with BMI >25 (over-weight and obse) recorded presence of related disorders (39-49% in over-weight and obse classes) and increase in prevalent diseases with higher BMI were hypertension, diabetes, and joint pain in decreasing order. CONCLUSIONS: The sudden increase in obesity related factors is a matter of concern in the age group of 11-20 and 21-30. The results show that the risk factors for metabolic diseases such as hypertension and diabetes are increasing rapidly. This information is extremely relevant for social awareness about obesity in middle class Indian population and through this study, it has been possible to alert the test subjects about risk of associated disorders.

PCV5 MENTAL COMPONENT OF THE QUALITY OF LIFE INCREASED ACCORDING TO THE LEVEL OF OBESITY

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OBJECTIVES: Obesity was said to be one of the important risks for mortality. In China, obesity rates have increased in the association between obesity and quality of life. The study provides a finding in the question using a cross-sectional survey conducted in China. METHODS: A total of 1,281 hypertensive residents in China aged 35 years or older were included in the analysis. The short-form 36 (SF-36) was used to measure the quality of life. It consisted of physical and mental domains. The highest score was 100 and 0 for the lowest in each domain. Level of obesity was classified using body mass index (BMI), namely, lean (<18.5), normal (18.5-24), overweight (24-28), obese (over 28) according to the Chinese classification. Means of physical and mental domains were calculated for the degree of obesity, adjusted for age, gender, marital status, education level, and exercise habits. Difference in quality of life among the levels of obesity was tested by the analysis of variance. RESULTS: There were lean (n=34), normal (n=531), overweight (n=521), obese (195) subjects with hypertension. Men occupied 53% and 57% for aged 60 years or older. Significant risk factors lowering the quality of life were women, elderly, low education and exercise. Adjusted mean (standard error) of physical domain was 64±3.3 (lean) 70±1.2 (normal), 71±1.2 (overweight), 71±1.6 (obese), where the p-value was 0.17. Whereas, the adjusted mean of mental domain was 69±3.3 (lean), 72±1.1 (normal), 76±1.1 (overweight) and 79±1.6 (obese), where the p-value was 0.018. CONCLUSIONS: A significant increase in the mental component of quality of life was found accord- ing to the level of obesity; however no trend was observed in the physical compo- nent.
PCV57

A RETROSPECTIVE, LONGITUDINAL STUDY TO INVESTIGATE THE CHANGE OF LDL-C LEVEL AND PHARMACOLOGICAL INTERVENTION BY USING JAPANESE HEALTH CARE CHECKUP DATABASE

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OBJECTIVES: To investigate the LDL-C levels and pharmacological interventions in Japanese subjects under real life settings based on longitudinal data from a Japanese health care checkup database developed by MinaCare Co. Ltd. METHODS: Data of those subjects with annual health checkup from 2010 to 2012 were extracted from MinaCare database (cutoff November 2013). From these data, 11830 subjects of those subjects with annual health checkup from 2010 to 2012 were extracted (1974-2014.2), which were used to assess their longitudinal changes and the self-reported use of medications. The reliability of MinaCare database has been evaluated in a separate investigation to be presented at ISPOR 19th Annual International Meeting. The final report of this investigation will be based on the latest of the periodically updated database at reporting time. RESULTS: At baseline (2010), 11.9% (1410/11830) of the subjects reported LDL-c<160 mg/dL (target level for low risk hyperlipidemia population). Despite these high LDL-C values, 96.4% (1125/11830) of the subjects answered that they were treated by a lipid-lowering drug (including one non-responder). Among these 1345 subjects, 1279(95.3%) answered “untreated” again in 2011, and among these “untreated”, the proportions of subjects with LDL-c>140 (diagnostic level for treatment of hyperlipidemia) were 10.3% (115/1125) in 2010 and LDL-c>180 in 2011 were 13.5% (157/1170), 39.2% (431/1103) and 22.9% (259/1125), respectively. In contrast, among those who answered “treated” in 2011, the proportion answering “untreated” in 2012 (i.e. “untreated” in 3 consecutive years) was 94.1% (1183). Among these subjects, the proportions of subjects with LDL-c<140, 160<LDL-c<180 and LDL-c>180 in 2012 were 16.7% (n=195), 29.8%(n=352) and 25.0%(n=296), respectively. CONCLUSIONS: The proportion of subjects with LDL-c<140 is significantly lower than in the previous year (P<0.05). In terms of adverse effects, maprotiline leads the least adverse effects rate. OR(maprotiline - mirtazapine) = 6.8495 [95%CI:1.4963, 34.462], OR(maprotiline - fluoxetine) = 0.2086 [95%CI:0.0672, 0.4958], OR(maprotiline - fluoxetine) = 0.2109 [95%CI:0.0607, 0.5422]. OR(maprotiline - mirtazapine) = 0.2521 [95%CI:0.0737, 0.8173], P<0.05. Based on our investigation, these results also ranks these five interventions. Results show that fluoxetine, bupropion and maprotiline have better effectiveness; but maprotiline, fluoxetine, mirtazapine have less adverse effects rate. CONCLUSIONS: Fluoxetine, as a new antidepressant drug, has higher clinical efficiency and lower adverse effects rate. Although maprotiline has a high grade of recommendation, we have few researches integrated into the model, further prospective studies are needed for strong evidence to support analogous research.

PMH2

DRUG CLINICALLY IMPORTANT DIFFERENCE IN THE GLOBAL ASSESSMENT FUNCTIONING IN PATIENTS WITH SCHIZOPHRENIA

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OBJECTIVES: Minimum Clinically Important Difference (MCID) can aid to assess the quality of improvement in functioning assessed by the Global Assessment Functioning (GAF). This study aims to establish the MCID for subjective self-rated global functioning, occupational, and psychological functioning of adults. The objective of this study was to generate MCID for GAF, based on a longitudinal cohort of patients with schizophrenia. METHODS: Two methods exist to assess MCID in scales such as GAF: the Price Index (PI) (DPCO)2013 to the patients receiving palliative treatment, suggesting more effective interventions to modify behavior is required.

PCV58

POLICY EVALUATION OF ANTI-HYPERTENSIVE DRUGS IN MUMBAI, INDIA

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OBJECTIVES: 1) To survey the effectiveness of Drug Price Control Order (DPCO)2013: a health care policy devised by Government of India, and 2) To analyze the cost minimization benefits of the anti-hypertensive drugs falling under Drug Price Control Order (DPCO)2013 to the patients receiving palliative treatment. METHODS: Three sets of structured questionnaires were designed which captured the patient’s gender, prescription trends for hypertensive patients in Mumbai, India, and the proportion of GPs 2011. We then targeted 20 General Practitioners and 25 patients. RESULTS: 1. Out of the total prescriptions received by Retail Pharmacies, Amlodipine accounted for 42%, Telmasartan: 27%, Atenolol: 20% and Ramipril: 10%. The same trend was followed by the General Practitioners. The pay-for-performance program (SBP and diastolic blood pressure (DBP) were significantly different among the three groups. When SBP and DBP were considered independently, waist-hip ratio was significantly different between the groups and poor controls in both SBP and DBP. Therefore, BP was predicted as a significant predictor of the three groups considering for waist-hip ratio. The R² for the MLR model was 0.02, indicating that 2% of the variance in SBP and DBP were accounted for by the independent variables. The three groups were observed to be a significant predictor of SBP (β = 0.14, p < 0.02) and DBP (β = 0.15, p < 0.02). CONCLUSIONS: The dietary pattern is a predictor for the SBP and DBP outcome in Taiwanese females.
A766

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of patients with schizophrenia. METHODS: 1208 patients with schizophrenia were included in the study and followed for 2 years. Mean GAF score at baseline was 51.34 (SD: 16.06) ranging from 11 to 98. MCID values retrieved from the anchor-based approaches were 2.88 (SD: 3.57), ranging from 0 to 22. MCID values obtained from the anchor-based approach were 0.89 and 1.26, for within- and between-patient methods, respectively. CONCLUSIONS: As in many MCID analyses, although the objective is to provide a unique threshold value, the different methods produce a variety of MCID values. Therefore we suggest using 1.3 as the MCID for CDSS, reflecting the smallest difference that clinicians would deem important. MCID estimates may help clinicians and researchers design future studies and interpret treatment effect.

PMH3

BURDEN ASSOCIATED WITH AGITATION IN SCHIZOPHRENIA
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OBJECTIVES: Clinical management of agitated patients with schizophrenia is a common objective in inpatient units and other settings. Being defined as a state characterized by motor restlessness, excitement, and mental tension, agitated patients may become a threat to others, act out violently, and also lead to suicidal thoughts and behaviors. The purpose of this study is to describe the agitated schizophrenic population. METHODS: We worked on data from a large longitudinal cohort of patients with schizophrenia, including a battery of questionnaires every 6 months for up to 24 months. Patients with a positive and negative syndrome scale (PANSS) Excited Component higher than 14 and a score of 4 or higher on at least one item, were identified as agitated at baseline. Also agitated patients were defined in the long term as the patients agitated at baseline and at 2 years, pathways of agitated patients were explored. Bivariate analyses were conducted to compare agitated patients with others in terms of severity of symptoms (PANSS), quality of life (SD), function (CDSS), drug taken (GAF), side effects, depression (Calgary Depression Scale for Schizophrenia, CDSS) and resource use. RESULTS: 5% of patients were identified as agitated at baseline. This rate was very stable at 6, 12, 18 and 24 months. Agitated patients were found to have higher severity of symptoms (PANSS) and worse quality of life (GAF) and depression (CDSS) at baseline and at 2 years. Resource use was consistently higher for agitated patients versus others. No difference was found in terms of quality of life or depression level. CONCLUSIONS: Our study suggests that agitated patients with schizophrenia form a stable population overtime with a high clinical burden. Research on management of agitated is of key importance in schizophrenia.

PMH4

COMPARATIVE EFFECTIVENESS IN TERMS OF TREATMENT DISCONTINUATION OF ORODISPERSIBLE VERSUS STANDARD ORAL OLanzAPINE TABLETS IN NON-ADHERENT PATIENTS: RESULTS FROM A 1-YEAR EUROPEAN OUTPATIENT OBSERVATIONAL STUDY
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OBJECTIVES: Non-adherence is common in the treatment of patients with severe mental illness. Different formulations have been developed in an effort to improve medication adherence. The aim of this study is to explore whether there is a differential in treatment discontinuation rate between two different formulations of olanzapine: orodispersible (OD) or standard oral tablets (SOT) for the treatment of non-adherent patients with schizophrenia or bipolar disorder. METHODS: This post-hoc analysis included 266 non-adherent patients diagnosed either with schizophrenia or bipolar disorder and recruited from an observational study (n=927) that measured the proportion of patients who discontinued treatment for any reason with olanzapine OD or SOT formulations over a 1 year period. Non-adherence was defined as having a baseline rating from 0 to 4 in the Medication Adherence Rating Scale (MARS). Treatment discontinuation was defined as discontinuing or adding a new antipsychotic to the index medication. A Kaplan Meier estimation of time to medication discontinuation was calculated. A Cox regression model adjusting for covariates was fitted to study the effect of baseline treatment on time to discontinuation. RESULTS: Patients treated with OD (n=177) vs. SOT (n=89) were more severe as measured by the Clinical Global Impression scale (CGI) (4.63 [SD 1.53] vs. 4.0 [SD 1.16], p < 0.0001) at baseline. During the 1-year follow up period the Kaplan Meier graph showed that patients treated with OD were less likely to discontinue treatment (11% vs. 27%, p<0.01). The Cox regression showed that patients taking OD had a significantly lower risk of discontinuing their baseline medication compared to patients taking SOT (hazard ratio: 0.35, 95% CI: 0.15-0.80). CONCLUSIONS: Treatment discontinuation was low and both olanzapine formulations; however the use of the orodispersible formulation in non-adherent patients with schizophrenia or bipolar disorder was associated with a significantly lower treatment discontinuation rate over a 1-year period.

PMH5

MINIMUM CLINICALLY IMPORTANT DIFFERENCE IN THE CALGARY DEPRESSION SCALE FOR SCHIZOPHRENIA
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OBJECTIVES: No Minimum Clinically Important Difference (MCID) for the Calgary Depression Scale for Schizophrenia (CDSS) has been reported yet. This scale, ranging from 0 to 27, assesses the level of depression in schizophrenia. The objective of this study was to generate a MCID for the CDSS, based on a longitudinal cohort of patients with schizophrenia. METHODS: Two methods exist to assess MCID in scales such as CDSS: the anchor approach (comparison of the change in CDSS score and Clinical Global Impression (CGI) within- and between-patients), and the distribution-based approach (comparison between the change in PRO scores and some measure of variability, including standard error measurement approach, standard deviation approach and effect size). MCID values retrieved from the anchor-based approach were 2.88 (SD: 3.57), ranging from 0.15-0.80. MCID values retrieved from the distribution-based approach were 0.89 and 1.26, for within- and between-patient methods, respectively. CONCLUSIONS: As in many MCID analyses, although the objective is to provide a unique threshold value, the different methods produce a variety of MCID values. Therefore we suggest using 1.3 as the MCID for CDSS, reflecting the smallest difference that clinicians would deem important. MCID estimates may help clinicians and researchers design future studies and interpret treatment effect.

PMH6

EVOLUTION OF DEPRESSIVE STATUS IN PATIENTS WITH SCHIZOPHRENIA: AN ANALYSIS OF PATIENT TRAJECTORIES
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OBJECTIVES: The majority of studies on depression among patients with depression reports means or percentages which obscure changes in depressive status over time. Trajectory description analysis may provide a more nuanced picture of the evolution of depressive status. The objective of this study was to generate a longitudinal sample of patients with schizophrenia, distinct groups of patients with different trajectories of depressive symptoms. METHODS: We used data from a longitudinal observational study on patients with schizophrenia to examine the Calgary Depression Scale for Schizophrenia (CDSS) questionnaire over 6 months for up to 2 years. Several cut-points were used, to distinguish patients with and without depression. Depression rates were calculated at each visit, independently, and depending on the patient’s previous status. RESULTS: Rates of depression at the baseline visit were 39% and 20%, when considering cut-points of 3 and 6, respectively. Among the 477 and 243 patients considered as depressive at baseline, 41.8% and 59.6% changed status after 6 months when considering cut-points of 3 and 6, respectively. Similarly, among the 724 and 958 patients considered as non-depressive at baseline, 18.2% and 9.9% changed status after 6 months. These results were relative stable over time, when considering each pair of successive visits. Additionally, analyses also showed that the trajectory distributions were similar for both trajectories over time. CONCLUSIONS: Trajectory analysis allowed us to detect different groups of patients, with specific characteristics and different trajectories. Our larger sample size allowed identifying levels of various characteristics at baseline and over time as being associated with each trajectory.

PMH7

EVOLUTION OF PRESENCE OF PREDOMINANT NEGATIVE SYMPTOMS IN PATIENTS WITH SCHIZOPHRENIA
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OBJECTIVES: Patients with schizophrenia often remain symptomatic with predomin- ant negative symptoms (PNS) despite receiving antipsychotic therapy. Several definitions of PNS are published in the literature, the aim of this study is to compare evolution of patients with and without PNS over time, and to explore the predictive status of PNS in terms of quality of life, depression and resource use, considering several definitions. METHODS: Fifteen definitions of PNS were retrieved from literature, out of which 3 were applied in a longitudinal cohort of patients with schizophrenia (N=1208). Clinical characteristics, depression, functioning, medication, quality of life and resource utilization were assessed at baseline and at 6 months, and compared between subgroups of patients (with/out PNS at baseline and at 6 months). Reasons of PNS status change were described for each definition. Regression models were used to explore the predictive status of PNS in terms of quality of life, depression and resource use. RESULTS: According to the 3 definitions used, severity of positive symptom significantly increased in patients with PNS at baseline but not at 6 months. Negative symptoms decreased to a lesser extent. Functioning, depression, medication, quality of life and resource utilization evolution were not consistent across definitions. According to all the definitions, PNS status at baseline was associated with change from baseline in terms of depression, quality of life, number of GP visits and mean number of hospitalization days, when adjustments were taken into account. CONCLUSIONS: Our study suggests that PNS status at a specific time point is associated with depression, quality of life and resource utilization evolution at 6 months. Results also show that patients with PNS at a specific time point not showing PNS 6 months later are not associated with better outcomes. This confirms that schizophrenic patients with PNS form a severe population, and required further analyses.

PMH8

FUNCTIONAL IMPAIRMENT AND COGNITIVE DYSFUNCTION IN DEPRRESSED PATIENTS IN SOUTH-KOREA: RESULTS OF PERFORM-K
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Objectives: To describe the functioning of patients with MDD, the impact of cognitive dysfunction, and the factors associated with functional impairment.

Methods: An observational study conducted in South-Korea, with similar selection criteria and assessment to the PERFORM-K study in Europe. The main outcome of the study is to describe the functioning of patients with MDD, the impact of cognitive dysfunction, and the factors associated with functional impairment.

Results: The 132 analyzable patients had a mean age of 45.2 years. 74.0% were women, 41.7% were employed and 22.8% had their treatment switched when visiting their psychiatrists. Mean MADRS and PHQ-9 scores were respectively 28.9 and 16.0 respectively. Overall functioning was impaired (mean SDS = 16.7), as was overall activity (57.9% impairment on WPAI-4), 25.1% of the patients reported a PDQ-D score > 44. In multivariate analyses, overall functional impairment (SDS) was associated with greater depression severity (p < 0.002), greater patient-reported cognitive dysfunction (p < 0.001), presence of sick leave in previous 12-months (p = 0.004), younger age (p = 0.001) and region (p = 0.004). Overall activity impairment (WPAI-4) was associated with greater depression severity (p = 0.043), greater cognitive dysfunction (p < 0.001) and younger age (p = 0.001).

Conclusions: Functional impairment in MDD is not only associated with the severity of depression but also with the duration of the disease, presence of sick leave, age and region. This is consistent with findings from PERFORM in Europe.

PMH0 PREVALENCE OF MAJOR DEPRESSIVE DISORDER IN CHINA

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Objectives: To review literatures that reported prevalence/incidence related to Major Depressive Disorder (MDD) in China. Methods: A structured literature review was conducted using both English and Mandarin language keywords. Search engines used for literature review were PUBMED, Cochrane Library, Wan Fang and VIP database. The review included primary studies or meta-analyses of prevalence or incidence of MDD studies published between 2000 and 2013 on Chinese population based in China only (including Hong-Kong and Macau). Four reviewers (two for each language) reviewed and extracted all relevant information from the selected articles. Results: One meta-analysis and 7 studies not included in the meta-analysis were identified. In the meta-analysis, the nationwide point prevalence of MDD was estimated to be 1.6% (95% CI: 1.2-1.9), 12-month prevalence to be 2.3% (95% CI: 1.8-5.5) and lifetime prevalence to be 3.3% (95% CI: 2.4-4.1). Point prevalence was higher in rural compared to urban areas. The other studies conducted across different regions reported point prevalence ranging from 3.6% to 9.4%, 12-month prevalence from 3.8% to 8.4% and lifetime prevalence of 6.5% to 10%. A hospital-based study reported higher estimates (point prevalence of 7.5% and lifetime prevalence of 11.6%), possibly reflective of higher prevalence of MDD in patients with physical comorbidity or patients seeking help at hospitals. 11.0% to 10.3% of patients with MDD were reported to have attempted suicide within 1 year, more frequently among patients with direct and more recently among patients from rural compared to urban area. About 27.28% of patients who committed suicide had history of MDD. Conclusions: The prevalence of MDD in China was reported to be variable between regions. The possible reasons for this include: differences due to cultural and geographical and methodological differences. However, the reported prevalence was lower compared to that in Western countries. Overall, the burden of MDD in China remains high due to its large population size.
concluded that the direct economic burden of this disease. CONCLUSIONS: Serious
economic burden has been caused by schizophrenia and increased sharply in China.
Indirect cost of schizophrenia is largely more than its direct cost.

PMH14
COMPARISON OF MEDICAL COSTS AND UTILIZATION ASSOCIATED WITH USE OF ZIPRASIDONE AND OLANZAPINE AMONG SCHIZOPHRENIA AND BIPOLAR DISORDER PATIENTS

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OBJECTIVES: The aim of our study is to calculate the annual health insurance
treatment cost of schizophrenia and bipolar disorder. The purpose of this study is to compare the treatment pattern and cost of illness in bipolar disorder.

METHODS: Schizophrenia and bipolar disorder patients who initiated use of ziprasidone or olanzapine between 01/2007 and 12/2010 were identified in the IMS LifeLink™ Health Claims Database. Claims were standardized into treatment episodes, and one-year costs and utilization after the initiation of episodes were analyzed. OLS regressions, general liner models, and two-part models were used to compare various types of costs associated with the use of ziprasidone and olanzapine.

RESULTS: The numbers of emergency room visits and hospitalizations associated with each drug. Lastly, we used various statistical methods to test the sensitivity of our estimates. RESULTS: We identified 7,138 (46.93%) ziprasidone episodes and 8,072 (53.07%) olanzapine episodes, and found that patients using ziprasidone were significantly younger (41.50 vs. 45.38) and were significantly less likely to be male (29.81% vs. 41.2%). At baseline, ziprasidone group and olanzapine group differed in total costs and in many components of costs. Breakdown analyses show that the mean annual costs of ziprasidone, when compared to olanzapine, was associated with significantly higher medication costs ($232, p<0.01) and outpatient costs ($501, p<0.05), but decreased ER costs ($63, p<0.05), and lab tests ($64, p<0.01). One-year costs associated with significantly fewer ER visits ($6, p<0.001) and hospitalizations (1.177, p<0.001). Sensitivity analyses suggest these results were robust. CONCLUSIONS: While ziprasidone is associated with lower medication costs and outpatient costs, it reduces patients’ utilization of ER and outpatient services.

PMH15
HEALTH INSURANCE COST OF ALZHEIMER DEMENTIA IN HUNGARY: A COST OF ILLNESS STUDY

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OBJECTIVES: The aim of our study is to calculate the annual health insurance treatment cost of Alzheimer dementia disease in Hungary. METHODS: The data derived from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFHA), the only health care financing agency in Hungary. We analyzed the health insurance treatment cost and the number of patients for the year 2010. The following cost categories were included into the study: outpatient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices.

RESULTS: The Hungarian National Health Insurance Fund Administration spent 4 426 billion Hungarian Forint ($21.266 million USD) for the treatment of Alzheimer patients. The average expenditure per patient was 72881 HUF (350 USD) while the average expenditure per one inhabitant was 442 HUF (2.1 USD). Major cost drivers were acute inpatient care (45.8 % of total health insurance costs), chronic care (35.5 %), and pharmaceuticals (28.1 %). The number of patients with Alzheimer disease was 60.6 per 100 000 populations. We found the highest patient number in general practitioners of primary care (101593 patients), pharmacists (774096 patients) and outpatient care (521760 patients). CONCLUSIONS: Anxiety represents a significant burden for the health insurance system. General practitioners of primary care and pharmaceutical reimbursement are the major cost drivers for anxiety disease in Hungary.

PMH16
TO STUDY THE TREATMENT PATTERN AND COST OF ILLNESS IN BIPOLAR DISORDER PATIENTS IN TERTIARY CARE HOSPITAL IN SOUTH INDIA

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OBJECTIVES: To study the treatment pattern and cost of illness in bipolar disorder patients in tertiary care hospital of south India. METHODS: A prospective study was conducted in a tertiary care teaching hospital of South India. Data were collected retrospectively from medical record section from 2012 to 2013 in suitable designed case record form. Data were analysed by using SPSS 20.0. RESULTS: Total of 100 cases of bipolar disorder was followed during the study period. Among them 66 were males and 34 were females. The mean age of the study population was found to be 26.2+13.3 years. Among the social history 13 people were alcoholic and 60% of the study population had a family history of known psychiatric disorder. The mean duration of illness of the study population was found to be 21.8±9.9 years. Among the study population 34 patients were diagnosed with mania and 46 patients diagnosed with depression. Mood examination revealed that 38 patients were happy followed by 22 patients were irritable. Affective examinations showed to be maximum were Aims (43%) and Hypo (23%). Diagnosis showed 41 predominance. The different treatment pattern revealed that all of them were prescribed with mood stabilizer followed by anti-psychotic (93) and hypnicos (86). The average hospitalization cost of the patient was found to be 7477.83 + 5989.67 Rupees with median hospital stay of 7.50 weeks. The annual direct cost of treatment was Rs. 55,891. The mean annual cost was Rs. 93,390. CONCLUSIONS: Mood stabilizers and anti-psychotics were the major treatment strategies among the bipolar patients and drug cost consumes 50% of the total cost of hospitalization. Pharmacoeconomic studies play important role in estimating the total health care burden in bipolar disorders.

PMH17
HEALTH INSURANCE COST OF ANXIETY IN HUNGARY: A COST OF ILLNESS STUDY

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OBJECTIVES: The aim of our study is to calculate the annual health insurance treatment cost of anxiety in Hungary. METHODS: The data derive from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFHA), the only health care financing agency in Hungary. We analyzed the health insurance treatment cost and the number of patients for the year 2010. The following cost categories were included into the study: outpatient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices.

RESULTS: The Hungarian National Health Insurance Fund Administration spent 13 535 billion Hungarian Forint ($65.026 million USD) for the treatment of anxiety patients. The average annual expenditure per patient was 13323 HUF (64 USD) while the average expenditure per one inhabitant was 1352 HUF (6.5 USD). Major cost drivers were general practitioners of primary care (43.8 % of total health insurance costs), pharmaceuticals (32.2 %) and outpatient care (23.9 %). The number of patients with anxiety disease was 1014 per 100000 populations. We found the highest patient number in general practitioners of primary care (1015938 patients), pharmacists (774096 patients) and outpatient care (521760 patients). CONCLUSIONS: Anxiety represents a significant burden for the health insurance system.
the increase in the proportion of elderly and simultaneous reduction by around one

The proportion of economically active population aged between 15 and 59 in China in 2050 is estimated separately for treated and not treated patients.

The remaining 6 articles analysed the CE of other anti-depressants not involving SNRI. The review showed conflicting outcomes due to heterogeneous study methodology. Ten out of 23 articles reported TCA/TeCA treatment to be most cost-effective treatment whereas six articles were in favour of SSRI and four articles favoured SNRI. CONCLUSIONS: TCA/TeCA treatment was found to be more effective compared to SSRI or SNRI and at a lower treatment cost with TCA/TeCA use, these treatments had higher AE rates compared to SNRI or SSRI, which were not taken into account during cost evaluation. This review identified several methodological issues and despite the calculation of ICER or CER, further studies are required to compare evidence on cost-effective anti-depressant treatment.

The proportion of elderly dementia patients in the population aged over 65 is estimated to be around 40% in 2050.

The report was reviewed through report of ministry of welfare in Korea and clinical report data of paper about the treatment with adherence to antidepressant this finding will help psychiatric to improve adherence.

The objective of this study was to explore patients’ general and specific beliefs about medicines among depressed patients in Saudi Arabia, this study has improve understanding of adherence predictors to antidepressant this finding will help psychiatric to improve adherence.

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The proportion of elderly dementia patients in the population aged over 65 is estimated to be around 40% in 2050.

The report was reviewed through report of ministry of welfare in Korea and clinical report data of paper about the treatment with adherence to antidepressant this finding will help psychiatric to improve adherence.

The objective of this study was to explore patients’ general and specific beliefs about medicines among depressed patients in Saudi Arabia. This review identified several methodological issues and despite the calculation of ICER or CER, further studies are required to compare evidence on cost-effective anti-depressant treatment.
chronic pain, while reducing their use of controlled medications. A larger follow-up study is needed to validate and expand on these preliminary findings.

PMH29
IMPORTANCE OF REMISSION IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER IN COMPARISON TO EUROPEAN AND EAST ASIAN COUNTRIES AND THE IMPLICATIONS OF THEIR COST FROM 2007 TO 2011 IN IRAN

A770

Evaluating the prescribing and usage pattern of antidepressant medications and the impact of their cost from 2007 to 2011 in Iran and to compare the results of the relevant studies in similar countries.

RESULTS: More than 425 million prescriptions were reviewed. The total price of antidepressant prescription and dispensation was about 40 million and 210 million US$ respectively. The most frequently prescribed medicines were nortriptyline, fluoxetine and citalopram.

CONCLUSIONS: In compliance with the global trend, there was a growing tendency obviously observed towards prescribing SSRIs in Iran. In the face of rising burden of depression, on the one hand the rising cost of medication and lack of funding resources on the other hand, we need to adopt strategies for promoting rational antidepressant medications use. This finding has important value for priority setting in planning and implementation of strategies for promoting rational drug use.

PMH33
OUTPATIENT TREATMENT OF ADOLESCENTS WITH ANTIDEPRESSANTS IN SOUTH KOREA FOR IMPROVING HEALTH-RELATED QUALITY OF LIFE AND ECONOMIC BURDEN

A771

OBJECTIVES: To examine antidepressant prescription patterns in Japanese children and adolescents. METHODS: We conducted a cross-sectional survey during October 2013 on outpatients, aged 19 or less, in 34 private mental clinics. Patients who were prescribed at least one antidepressant were analyzed in this report. Data on gender, age, principal psychiatric diagnosis (based on ICD-10), and types and doses of psychotropic drugs were extracted.

RESULTS: The samples consisted of 137 males and 170 females. The average age (standard deviation) was 16.2 years (2.5). The most prescribed medicines were 39.6% SSRI and 28.7% SNRI. The most common diagnostic category was neurotic disorders (F4, n = 113), followed by mood disorders (F3, n = 73), disorders of psychological development (F8, n = 67), behavioral and emotional disorders (F9, n = 22), schizophrenic spectrum disorders (F2, n = 10), and other diagnoses (n = 14). Among the 19 antidepressants available in Japan, the prescription rate of fluvoxamine (42.3%, n = 130) was the highest, followed by sertraline (17.6%), escitalopram (10.4%), citalopram (8.9%), trazodone (6.5%), and paroxetine (5.5%). Tryptic or tetracyclic antidepressants (TCAs) were prescribed in 35 patients (11.4%). Two or more antidepressants were prescribed concurrently in 27 (8.8%) of the 307 patients. Anxiety/hyptonic were concurrently prescribed in 126 (41.0%). Mood stabilizers were co-prescribed in 35 (11.4%). Antipsychotics were concurrently prescribed in 134 (43.6%), with a median dose of 100mg of chlorpromazine equivalent.

CONCLUSIONS: In Japan, although augmentation of antidepressant treatment seemed relatively popular with antipsychotics in adolescent patients, antidepressant dose might be relatively low.

PMH34
EVALUATION OF FACTORS AFFECTING SALES OF PRESCRIPTION PHARMACEUTICALS IN IRAN

A772

OBJECTIVES: To assess the prescribing and usage pattern of antidepressant medications and the impact of their cost from 2007 to 2011 in Iran and to compare the results of the relevant studies in similar countries.

RESULTS: More than 425 million prescriptions were reviewed. The total price of antidepressant prescription and dispensation was about 40 million and 210 million US$ respectively. The most frequently prescribed medicines were nortriptyline, fluoxetine and citalopram.

CONCLUSIONS: In compliance with the global trend, there was a growing tendency obviously observed towards prescribing SSRIs in Iran. In the face of rising burden of depression, on the one hand the rising cost of medication and lack of funding resources on the other hand, we need to adopt strategies for promoting rational antidepressant medications use. This finding has important value for priority setting in planning and implementation of strategies for promoting rational drug use.

PMH35
PUBLIC BELIEFS AND ATTITUDES ABOUT SCHIZOPHRENIA, MAJOR DEPRESSION AND PSYCHOTROPIC MEDICATION IN TUNISIA

A773

OBJECTIVES: Stigmatization associated with mental illnesses could prevent schizophrenics and people with major depression from accessing to health care. Stigma often varies depending on social contexts. A survey in this subject was conducted first in Germany, then in France and finally in Tunisia. The objective of current study is to evaluate public beliefs and attitudes about schizophrenia, major depression and psychotropic drugs in Tunisia.

RESULTS: More than 95% of Tunisians (resp. 58.6%) think that such patients are strange, and 29.6% (resp. 16.0%) think they are dangerous. 47.8% (resp. 43.1%) agree with the fact that psychotropic treatment helps people to better support the concerns.

Mental Health – Health Care Use & Policy Studies

PMH32
PATTERN OF ANTIDEPRESSANT UTILIZATION AND COST IN IRAN FROM 2007 TO 2011 IN COMPARISON TO EUROPEAN AND EAST ASIAN COUNTRIES AND LITERATURE REVIEW

A774

OBJECTIVES: To assess the prescribing and usage pattern of antidepressant medications and the impact of their cost from 2007 to 2011 in Iran and to compare the results of the relevant studies in similar countries.

RESULTS: More than 425 million prescriptions were reviewed. The total price of antidepressant prescription and dispensation was about 40 million and 210 million US$ respectively. The most frequently prescribed medicines were nortriptyline, fluoxetine and citalopram.

CONCLUSIONS: In compliance with the global trend, there was a growing tendency obviously observed towards prescribing SSRIs in Iran. In the face of rising burden of depression, on the one hand the rising cost of medication and lack of funding resources on the other hand, we need to adopt strategies for promoting rational antidepressant medications use. This finding has important value for priority setting in planning and implementation of strategies for promoting rational drug use.
of everyday life and 17.0% agree with taking these medicines if the person suffers severely of light mood swings. CONCLUSIONS: Survey results suggest that stigmatization around schizophrenia and major depression is present in Tunisia; there is a great public willingness to help mental disease patients as demonstrated by our study. To conclude, raising public awareness in mental health could be an important step in the future to lessen the burden in terms of social functioning in families and societies from one side. On the other side, this stigmatization contributes to marginalize patients, exclude them from health care management and affects their disease severity.

PM36 THE USE OF INTEGRATED CONCEPT MAPPING TO DEVELOP THE DEMENTIA CARE MODEL BY COMMUNITY PARTICIPATION

Study Conducted by Novak. Concept mapping is a technique that allows participants to share ideas and encourages an open-ended discussion about a theme. The purpose of the procedure in the care of dementia is to generate ideas then sort and rate the ideas for the feasibility and the importance. Later all participants except the psychogeriatrician took part in the second meeting conducted by Novak’s concept mapping to name the clusters of ideas then re-organised the ideas and added the details to make the complete model. This was the most important step. Multidimensional scaling and hierarchical cluster analysis including quadrant analysis were applied by SPSS software.

OBJECTIVES: The purpose of this study is to develop the dementia care model by using integrated concept mapping and community participation. METHODS: Six health care professionals (1 psychogeriatrician, 1 family physician, 1 residency, 1 pharmacist, 1 nurse, and 1 physical therapist) and seven non-health care professionals (3 village headmen, 2 village health volunteers, and 2 patients relatives) participated in the first meeting conducted by Trochim’s concept mapping to generate the ideas then sort and rate the ideas for the feasibility and the importance. The second meeting was conducted by Novak’s concept mapping to name the clusters of ideas then re-organised the ideas and added the details to make the complete model. This was the most important step. Multidimensional scaling and hierarchical cluster analysis including quadrant analysis were applied by SPSS software. OBJECTIVES: To develop a Dementia Care Model by Community Participation. METHODS: The Dementia Care Model originated by hospital staffs who facilitate the community to understand different care plans and implement them. Six health care professionals (1 psychogeriatrician, 1 family physician, 1 residency, 1 pharmacist, 1 nurse, and 1 physical therapist) and seven non-health care professionals (3 village headmen, 2 village health volunteers, and 2 patients relatives) participated in the first meeting conducted by Trochim’s concept mapping to gather ideas then sort and rate the ideas to develop the complete model. The model was then re-organised with the help of ideas from the second meeting conducted by Novak’s concept mapping to name the clusters of ideas and add the details to make the complete model.

PM48 A COMPARATIVE CLINICAL EVALUATION OF TRAYODASHANGA GUGGULU AND MUSTADIYAPANA YOGA BASTI IN GRIDHRASI

MethOds: The study was conducted in the OPD and IPD of MAMIS, Manipal with 3 trial groups A- Trayodashangaguggulu, B-Mustadiyapana yoga basti and Mustadiyapana yoga basti for the period of 10 weeks in 30 diagnosed gridhrasi patients irrespective of their sex and age group18-60. RESULTS: in group A- Trayodashangaguggulu, 50.00% of patients were assessed under improved category. 10.00% each were assessed under moderate improvement and moderate decrement, 10.00% and 30.00% showed Unchanged. Many patients under complete relief category. In group B-Mustadiyapana yoga basti, 90.00% of patients were assessed under improved category. 10.00% each were assessed under moderate improvement and moderate decrement and 30.00% showed Unchanged. Nobody included under complete relief category. In group C-combined therapy of Trayodashangaguggulu and Mustadiyapana yoga basti, 50.00% of patients were assessed under moderate improvement category. 40.00% each were assessed under moderate improvement and moderate decrement and 10.00% showed Unchanged. Nobody included under complete relief, marked improvement or moderate improvement category. In group C-combined therapy of Trayodashangaguggulu and Mustadiyapana yoga basti, 50.00% of patients were assessed under moderate improvement category. 40.00% each were assessed under moderate improvement and moderate decrement and 10.00% showed Unchanged.

PM54 THE EFFECTS OF GALLUM CHLORIDE ON APOPTOSIS APOPEOROSIS MODEL OF RATS CAUSED BY TRETINOIN ACID

MethOds: 67 sprague-Dawley (SD) female rats, three months of age, were divided into two groups. 49 rats of model group were treated with trichloroic acid for 85mg/kg by gavage while 18 rats of normal group were treated with distilled water for same amount. All rats were administrated for 15 days. After the model has been duplicated successfully, the model group rats were divided into three groups: 18 rats of osteoporosis group were treated with trichloroic acid for 85mg/kg by gavage, 19 rats of galium chloride treatment group were administrated with 250mg/kg by gavage, 12 rats of estrogen treatment group were give estradiol benzoate (0.2 μg/kg, 3 times per week) by intraperitoneal injection. After treatment for 30days, the rats were killed and the content of MDA in bone was detected by TBA method. The apoptosis of osteocyte was detected by agarose gel electrophoresis. RESULTS: The apoptosis ratio of osteocyte in osteoporosis group rats was increased than the other three groups while the contents and molecular weight of DNA were decreased. The contents of MDA in osteoporosis group rats was increased than the other groups. The content of DNA in galium chloride treatment group rats was higher than that of the osteoporosis group rats. CONCLUSIONS: Galium chloride can increase the DNA content of bone, through decreasing lipid peroxidation to suppress apoptosis of osteocyte.
Asian men. The extent of causality in these observations is yet to be determined, which requires further prospective cohort studies needed. Nevertheless, these findings highlight the importance of properly managing patients with these risk factors to minimize the risk of fractures.

MUSCULAR-SKELETAL DISORDERS – Cost Studies

PMS8
ESTIMATING THE IMPACT OF EXPANDING ACCESS TO CELECOXIB FOR OSTEOARTHROPSIS PATIENTS IN CHINA
Wang B·M, Xie X·P, Furbank V·K
(Alliance Life Sciences, Somerset, NJ, USA; Pfizer Inc., Beijing, China)
OBJECTIVES: Currently in China, celecoxib is prescribed to patients with gastrointestinal bleeding or perforation history. The aim of this study was to model the effects of expanding access to all osteoarthritis (OA) patients in China. METHODS: We created a one-year budget impact model from a payer perspective comparing two scenarios. The first scenario (A) restricts the use of celecoxib only to patients with gastrointestinal bleeding or perforation history while the second scenario (B) does not restrict usage. In (A), we prescribed only diclofenac or celecoxib; but those prescribed celecoxib were only dispensed diclofenac or celecoxib; but those prescribed celecoxib were only dispensed celecoxib. In (B), all prescriptions were dispensed as written. For both scenarios, celecoxib and diclofenac prescriptions were written 16.2% and 8% of the time, respectively. Patients with gastrointestinal bleeding or perforation history made up 5.58% of the OA population. Celecoxib was associated with a 10% lower dose than diclofenac did not have a copay. The base case scenario assumes 13,333 patients.

RESULTS: Going from (A) to (B), the total cost of celecoxib increased ¥2,679,866 (94.42%) while the total cost of diclofenac decreased ¥1,152,961 (15.76%). The incremental total cost of drugs in (A) was ¥1,526,905 (48%).

The impact on a payer’s plans for the year was only due to drug costs since the cost to administer prior authorization was not considered. The per member per month cost was ¥9.07 from ¥18.04 to ¥9.07. The incremental cost is compared in Table 1.

CONCLUSIONS: The expanded access scenario (B) resulted in slightly higher drug costs to the payer, which may be acceptable under most thresholds. Patient outcomes should also be considered to fully understand the impact of removing the gastrointestinal bleeding and perforation history stipulation.

PMS9
PREScribing PATTERN and COST ANALYSIS ON (DMARD’S) DISEASE MODIFYING ANTI-rHEUMAToid DRUGs IN RHEUMATOID ARTHRITIS PATIENTS OF A TERTIARY CARE TEACHING HOSPITAL IN SOUTH INDIA – A CROSS SECTIONAL STUDY
Sharma VVV
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OBJECTIVES: To study the current prescription pattern and to analyze the cost of treatment prescribed to RA patients referred to orthopedics OPD in a tertiary care teaching hospital of South India. METHODS: The study protocol was approved by the institutional ethics committee. Patients attending Orthopedic OPD for existing RA disease were recruited as per inclusion criteria. Written informed consent was sought. Total 200 consecutive rheumatoid arthritis patients fulfilling the American College of Rheumatology Criteria (1987) were recruited during study period. Study Design: Cross-sectional study. Study Duration: 6 Months (From July 1st 2011 to March 31st 2012) Study Site: Department of Orthopedics, Government Medical College and Hospital, Anantapuram, Andhra Pradesh, India. RESULTS: Majority of patients (67%) in the study population were on combination of two DMARDs. Most frequently prescribed two DMARDs combination was methotrexate and hydroxychloroquine (35%). Prescription of DMARDs in the study population was as follows: methotrexate (72%), hydroxychloroquine (72%), sulfasalazine (36%), low dose corticosteroids (52%), and low dose corticosteroids (52%) and low dose corticosteroids (52%). The societal costs of accidents in 2011 Australian Dollars (A$) were estimated from self-reported medical resource consumption and lost work time, combined with published medical resource unit costs and salar y data. RESULTS: Participants reported 59 major accidents in 5 years preceding the interview, and 27 minor accidents in the previous 12 months. The total mean costs of major accident were $12,158, including direct medical costs $2,228, direct medical costs $2,228, direct medical costs $2,228, and non-medical costs $9,930. The total cost per person was $29,174. The total societal costs of major accidents in Australia were estimated at $12,158, including direct medical costs $2,228, direct medical costs $2,228, and non-medical costs $9,930. The total cost per person was $29,174. The total societal costs of major accidents in Australia were estimated at $12,158, including direct medical costs $2,228, direct medical costs $2,228, and non-medical costs $9,930. The total cost per person was $29,174. The total societal costs of major accidents in Australia were estimated at $12,158.

CONCLUSIONS: The use pattern in RA was found to be DMARDs based. A minority of the cost was borne by the patient. The total increase in cost was due to administration of drugs to treat the adverse drug reaction. Perspective studies in a larger number of patients are needed to assess the utility of prescription audit and cost analysis of drugs used in RA.
CONTRACTURE: CLINICIAN SURVEY

medical costs, and productivity loss due to job loss and sick leave of patients with catastrophic illness certificate from NHI claim data. In addition, Patients Database (NHIRD) in 2010 and a face-to-face interview survey to the patients with PMS14

It’s necessary to build a unified way to calculate economic burden of children injury. Characteristics of population, regions of children and their social and economic situations. PMS13

THE ECONOMIC COST OF RHEUMATOID ARTHRITIS IN TAIWAN

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OBJECTIVES: Rheumatoid arthritis (RA) is an autoimmune disease that results in a chronic inflammatory disorder causing joint damage. It can be a disabling and painful condition, which can lead to substantial loss of functioning and mobility if not adequately treated. The aim of this study was to estimate the economic cost of RA patients and their family in Taiwan. METHODS: We estimated cost of RA from the societal perspective. Data Source: all patients enrolled in the Taiwan National Health Insurance Research Database (NHIRD) in 2010 and 2011 and face-to-face survey interview to the patients and their family in Taiwan. RESULTS: Mean annual total medical cost was $3,079.57; however this does not capture the true cost of the surgery to the health care system, and sometimes intangible cost which calculating the cost of productivity loss the indirect cost analysis show great variability.

PMS15

COST-EFFECTIVENESS ANALYSES OF SCREENING AND TREATMENT STRATEGIES FOR POSTMENOPAUSAL OSTEOPOROSIS IN CHINESE WOMEN

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OBJECTIVES: To determine the cost effectiveness of osteoporosis screening strategies in Chinese postmenopausal women. METHODS: A Markov model including first and second order Monte Carlo simulation was constructed, from a lifetime horizon, from which cost effectiveness of osteoporosis screening strategies from age 65 were compared to no screening from Chinese health care perspective. The screening strategies were: 1) Osteoporosis Self-Assessment Dual X-ray absorptiometry (DEXA), 2) Osteoporosis Self-Assessment Quantitative ultrasound (QUS), and 3)DEXA. Patients were assumed to receive alendronate if osteoporosis was detected or they experienced an osteoporosis-related fracture, and were screened every 5 years if osteoporosis was not detected. First order Monte Carlo simulation was conducted to model risk of fracture. The one way sensitivity analysis was performed to account for parameter uncertainties. Input parameters, including age-specific osteoporosis prevalence, fracture probabilities and costs and mortality probabilities were retrieved from published Chinese data, where available. Costs were presented in 2013 USD. Both costs and effectiveness were discounted at 3%. A willingness-to-pay (WTP) threshold of $20,000 USD/quality adjusted life year (QALY) gained was used according to the China Guidelines for Pharmacoeconomic Evaluations. USD/quality adjusted life year (QALY) gained was used according to the China Guidelines for Pharmacoeconomic Evaluations. Results: The screening strategy was more cost-effective than no screening in all scenarios. Compared to DEXA alone, DEXA followed by DEXA and DEXA more effective than DEXA alone, DEXA more effective than DEXA alone, DEXA alone, DEXA alone, and DEXA alone, DEXA alone, DEXA alone, DEXA alone, and DEXA alone.

PMS16

COST-EFFECTIVENESS OF DENOSUMAB VS. BRAND OR GENERIC ZOLEODRIC ACID IN PATIENTS WITH BREAST CANCER IN KAZAKHSTAN

Nazarbayev University, The Center for Life Sciences, Astana, Kazakhstan

OBJECTIVES: Denosumab is recommended for preventing skeletal-related events (SREs) in adults with bone metastases from breast cancer (BC). Since recently generic zolendronic acid (ZA) became available, the aim of present study was to access the cost-effectiveness of denosumab vs. brand or generic ZA in the prevention of SREs in Kazakhstani patients with BC. METHODS: An excel-based Markov model was constructed with 4-week model cycles to analyse the cost-effectiveness of the treatments from the perspective of Ministry of Health with a 10-year time horizon for BC cohort. Direct costs (in 2014 tenge) included costs of drug, adverse event and SRE (pathologic fracture, surgery to bone, radiation to bone, spinal cord compression) treatment. A discount rate of 3% per year was applied for all costs. Effectiveness was appraised based on the number of SREs. The health states were defined according to the SRE occurrence SRE history and death. The model assumed that a maximum of 1 SRE could occur in each cycle. Transition probabilities were derived from the relevant phase III trials. Results were present in the incremental total cost per SRE avoided. One-way sensitivity analyses were performed to examine the robustness of the model. RESULTS: Over 10-year period, denosumab incurred 1044 tenge lower costs than brand ZA, 56858 00 tenge higher costs than generic ZA, 1.28 fewer SREs per BC patient. The estimated incremental total direct costs per SRE avoided of the use of denosumab were 186 tenge lower costs than brand ZA, 56858 00 tenge higher costs than generic ZA. Results were robust to one-way sensitivity analyses. CONCLUSIONS: With assumption that brand and generic ZA are equally effective in the prevention of SREs in BC patients, denosumab seems to be cost-effective alternative for brand ZA, and costly alternative for generic ZA from a perspective of Ministry of Health of Republic of Kazakhstan.

PMS17

COST-EFFECTIVENESS OF DENOSUMAB VS. BRAND OR GENERIC ZOLEODRIC ACID IN PATIENTS WITH PROSTATE CANCER IN KAZAKHSTAN

Nazarbayev University, The Center for Life Sciences, Astana, Kazakhstan

OBJECTIVES: Denosumab is recommended for preventing skeletal-related events (SREs) in adults with bone metastases from breast cancer (BC). Since recently generic zolendronic acid (ZA) became available, the aim of present study was to access the cost-effectiveness of denosumab vs. brand or generic ZA in the prevention of SREs in Kazakhstani patients with BC. METHODS: An excel-based Markov model was constructed with 4-week model cycles to analyse the cost-effectiveness of the treatments from the perspective of Ministry of Health with a 10-year time horizon for BC cohort. Direct costs (in 2014 tenge) included costs of drug, adverse event and SRE (pathologic fracture, surgery to bone, radiation to bone, spinal cord compression) treatment. A discount rate of 3% per year was applied for all costs. Effectiveness was appraised based on the number of SREs. The health states were defined according to the SRE occurrence SRE history and death. The model assumed that a maximum of 1 SRE could occur in each cycle. Transition probabilities were derived from the relevant phase III trials. Results were present in the incremental total cost per SRE avoided. One-way sensitivity analyses were performed to examine the robustness of the model. RESULTS: Over 10-year period, denosumab incurred 1044 tenge lower costs than brand ZA, 56858 00 tenge higher costs than generic ZA, 1.28 fewer SREs per BC patient. The estimated incremental total direct costs per SRE avoided of the use of denosumab were 186 tenge lower costs than brand ZA, 56858 00 tenge higher costs than generic ZA. Results were robust to one-way sensitivity analyses. CONCLUSIONS: With assumption that brand and generic ZA are equally effective in the prevention of SREs in BC patients, denosumab seems to be cost-effective alternative for brand ZA, and costly alternative for generic ZA from a perspective of Ministry of Health of Republic of Kazakhstan.
OBJECTIVES: A phase III clinical trial demonstrated the advantage of denosumab over placebo in delaying the first on-study and subsequent skeletal-related events (SREs) in patients with prostate cancer (PC). Recently, generic ZA became available. The purpose of this study was to examine the cost-effectiveness of denosumab vs brand or generic ZA in the prevention of SREs in Kazakhstani patients with PC. METHODS: This cost-effectiveness study was based on a Markov model that was constructed with a 4-week model cycle to analyse the cost-effectiveness of the treatments from the perspective of Ministry of Health with a 10-year time horizon for PC cohort. Direct costs in [2014] terginc included costs of drug, adverse event and SRE (fracture, surgery, bone, radiation to bone, spinal cord compression) treatment. A discount rate of 3% per year was applied. Effectiveness was appraised based on the number of SREs. The health states were defined according to SRE occurrence, SRE history and death. The model assumed that a patient would have 1 chance of SRE occurrence in each cycle. Transition probabilities were derived from the relevant phase III trials. Results: were present in the incremental total cost per SRE avoided. One-way sensitivity analyses were performed to examine the robustness of the model. Over 10-year period, denosumab incurred 103,913 tenge higher costs than brand ZA, 67,733 tenge higher costs than generic ZA, 0.58 fewer SREs per PC patient. The estimated incremental total direct costs per SRE avoided with the use of denosumab were 77,743 tenge (instead of brand ZA) and 116,470 tenge (instead of generic ZA). Results were robust to one-way sensitivity analyses. CONCLUSIONS: With assumption that brand and generic ZAs are equally effective, denosumab seems to be superior alternative for brand ZA (insignificant difference in costs), and costly alternative treatment for generic ZA from a perspective of Ministry of Health of Republic of Kazakhstan.

MUSCULAR-SKELETAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PMS20 ASSESSMENT OF MEDICATION ADHERENCE IN RHEUMATOID ARTHRITIS PATIENTS IN A TERTIARY CARE HOSPITAL

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OBJECTIVES: To assess the medication adherence rates and quality of life in Rheumatoid Arthritis (RA) patients. METHODS: RA patients admitted in the general medicine ward of a tertiary care hospital in Karnataka, India, during August to December 2013 were enrolled in the study. Demographic data of these patients and their medication adherence were collected by using telephone interviews. Patients (age >18 years) with RA, irrespective of sex, fulfilling the 2010 ACR/EULAR Classification Criteria, were enrolled in the study. Patient’s assessment of quality of life was done using European Quality of Life-5 Dimensions (EQ-5D) and the Health Utilities Index (HUI) tool. Results: a total of 72 RA patients were included in the study. 46.9% of the patients were females. Among patients, 15 (21.43%) received methotrexate alone and 28 (40%) received a combination therapy of methotrexate and hydroxychloroquine. The mean KA-HAQ score of RA patients measured by KA-HAQ was 2.70 ± 1.01. Scores on MARS ranged from 26 to 41 with a mean score of 38.6 ± 3.5. The Cronbach’s alpha for the MARS was 0.6 and KA-HAQ was 0.92. Using the mean cut-point 44% of 68 patients who completed the MARS were adherent to the medications which were remaining 64% were not adherent. CONCLUSIONS: In our study we found that 64% of the patients were not adherent to the medications which lead to decreased quality of life RA patients. Adherence to the medications is the optimal management for RA.

PMS21 A KINETIC COMPARISON OF OVERGROUND AND TREADMILL WALKING IN WOMEN FABIANA ELIZABETH, Ouyana C V, Ong L KN

1Taipei Medical University, Taipei, Taiwan, 2Alliance Life Sciences, Somerset, NJ, USA, 3Alliance Life Sciences, Jersey City, NJ, USA, 4University of Washington, Seattle, WA, USA, 5Fujir Limited, New Taipei City, Taiwan, 6Fizeri, New Taipei City, Taiwan, 7National Taiwan University, Taipei, Taiwan

OBJECTIVES: Rheumatoid arthritis (RA) is a chronic autoimmune disease characterized by inflammation and destruction of the joints often resulting in a significant impact on quality of life. There are limited studies estimating the resource utilization of RA patients using real-world data in Taiwan. This study aimed to estimate the direct health care utilization in Taiwanese RA patients. METHODS: We performed a retrospective database analysis using 2011 data from the National Health Insurance Research Database (NHIRD) in Taiwan, a claims-based database covering over 99% of the population. We estimated the annual incremental health care utilization of RA patients compared with a control cohort matched 1:4 on demographics and clinical covariates. Health care resources were evaluated for the following categories: surgeries, medications, ward use, medical materials and devices (MMDs), and lab tests. The percentage of patients partaking in a health care utilization category was calculated as the number of patients with the specific claim divided by the total number of patients in the cohort. RESULTS: The total health care costs were 61,269 NT per patient. The mean age was 59.4 years (SD=15.5). The average history of RA was 5.6 years (SD=2.7). When comparing RA to non-RA patients, drug utilization had some of the largest differences. RA patients had used traditional disease-modifying anti-rheumatic drugs (TDMARDs), biologic DMARDs (BDMARDs), NSAIDs, and steroids at a rate of 70.8%, 13.2%, 64.8% and 52.8% respectively. For surgeries, lab tests, and MMDs, the highest incremental differences were cataract surgeries, immunology examined, and anatomic pathology. RHEUMATOID ARTHRITIS IN THAILAND

Tangwongsiri D.

OBJECTIVES: To evaluate the cost-utility of Infliximab plus methotrexate (MTX) compared with MTX alone, in severe rheumatoid arthritis (RA) patients who were intolerant to MTX. The purpose of this study was to determine the cost-utility of Infliximab plus MTX compared with MTX alone in patients with RA (mean age = 59.4 years (SD = 11.9)) in Thailand. METHODS: A Markov model consisting of Markov states defined by the disease activity score 28 (DAS28) was developed to reflect the clinical assessment in the treatment of RA in Thailand. The purpose of the study was to determine whether the incremental cost-utility of Infliximab plus MTX is acceptable ICER within 1-3 times of GDP per capita in Thailand (120,000 – 360,000 Thai Baht per QALY gained). The probability of cost-effective for Infliximab was presented by using single discount rate at 3%. One-way and probabilistic sensitivity analysis were conducted to test the robustness of the results. RESULTS: Infliximab plus MTX had an ICER of 131,867 Baht per QALY gained compared with MTX alone. This falls within the range of acceptable ICER within 1-3 times of GDP per capita in Thailand (120,000 – 360,000 Baht per QALY gained). The probability of cost-effective for Infliximab was presented at 9%, 82% and 95% at the willingness-to-pay of 120,000, 240,000 and 360,000 Baht per QALY gained respectively. CONCLUSIONS: This study provides a key piece of information to estimate the burden of RA patients. This study provides a key piece of information to estimate the burden of RA patients. This study provides a key piece of information to estimate the burden of RA patients. This study provides a key piece of information to estimate the burden of RA patients. This study provides a key piece of information to estimate the burden of RA patients.
CONCLUSIONS: The dimensions excluding Ability of act all had the higher sensitivity on AIMS2-2F scale, which means overall sensitivity was better than SF-6D. Therefore, EQ-5D is more suitable for the evaluation of the QOL of patients with osteoarthritis. But the Psychological health dimension of SF-6D showed strong sensitivity, which prompts us Psychological problems are the important factors influencing the Osteoarthritis patients’ life quality.

PMS26
EXPLORING THE WILLINGNESS-TO-PAY FOR BIOLOGIC TREATMENTS IN IMMUNOLOGY DISEASES IN CHINA
Koh L.1, Leartasakulpantich P., Glaetzer C., Rosen S., Krauss J.1,2
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OBJECTIVES: Biologic treatments have improved outcome for immunology diseases in the last decades globally. However, biologic penetration in China is lower compared to other large economies. This study aims to explore the willingness-to-pay (WTP) for biologics in immunology diseases in China by understanding decisions driving physicians’ prescribing behavior and patients’ payment. METHODS: Primary market research was done by interviewing 160 physicians with biologic experience, 50 patients with rheumatoid arthritis (RA), ankylosing spondylitis, and psoriasis (bio-experienced) and 40 patients with RA. It is worth noting that Chinese patients with RA was much better satisfied with their treatment than their global counterparts. The bio-experienced patients were classified as bio-naive and bio-experienced. RESULTS: The results show that patients rely on physicians for treatment recommendation. For rheumatoid arthritis, ankylosing spondylitis, and psoriasis, the top four factors driving physicians’ recommendation are drug cost, patients’ ability-to-pay, safety of treatment and drug efficacy. For rheumatoid arthritis (RA), the top four factors were safety, efficacy, patients’ affordability followed by drug cost. The difference in pattern for RA and UC is likely attributed to the more severe nature of these diseases. Other factors such as injection frequency and mode of administration ranked lower for all indicators. CONCLUSIONS: Patients interview results show that ~60% of bio-naive patients were rejected biologic treatment due to cost. ~30% of bio-experienced patients stopped biologic treatments due to cost. This confirms that affordability considerations do limit the potential benefit of biologic treatments can provide. Interestingly, ~30% of bio-experienced patients have stopped biologic treatment as it was perceived that treatment course was completed. This is contributed to how physician perceive biologics to be used. While affordability limits biologic penetration in auto-immune diseases in China, there are other considerations e.g. the severity of disease and physician perception of treatment paradigm.

PMS27
EXPLORING THE WILLINGNESS-TO-PAY FOR INNOVATIVE TREATMENTS FOR RHEUMATOLOGY AND ONCOLOGY IN CHINA
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OBJECTIVES: Use of innovative medicines in oncology and immunology is relatively lower in China compared to developed countries. This study aims to explore the willingness-to-pay (WTP) for these two therapeutic areas by understanding drivers of physicians’ and patients’ decisions. METHODS: For immunology, primary market research was done by interviewing 50 physicians and 40 patients consisting of patients with rheumatoid arthritis, ankylosing spondylitis, and psoriasis. For oncology, 50 physicians and 40 patients were interviewed. RESULTS: All physicians and patients were recruited from larger hospitals (tier 3A) from Tier 1, 2 cities. Physicians were asked to provide the decision drivers for patients’ affordability and treatment choice. The results show that patients rely on physicians for treatment recommendation. For rheumatoid arthritis, ankylosing spondylitis, and psoriasis, the top four factors driving physicians’ recommendation are drug cost, patients’ affordability, safety of treatment and efficacy of treatment. For oncology, primary market research was done by interviewing 160 physicians with biologic experience, 200 patients consisting of patients with rheumatoid arthritis, ankylosing spondylitis, and psoriasis. For rheumatoid arthritis (RA), the top four factors were safety, efficacy, patients’ affordability followed by drug cost. The difference in pattern for RA and UC is likely attributed to the more severe nature of these diseases. Other factors such as injection frequency and mode of administration ranked lower for all indicators. CONCLUSIONS: Patients interview results show that ~60% of bio-naive patients were rejected biologic treatment due to cost. ~30% of bio-experienced patients stopped biologic treatments due to cost. This confirms that affordability considerations do limit the potential benefit of biologic treatments can provide. Interestingly, ~30% of bio-experienced patients have stopped biologic treatment as it was perceived that treatment course was completed. This is contributed to how physician perceive biologics to be used. While affordability limits biologic penetration in auto-immune diseases in China, there are other considerations e.g. the severity of disease and physician perception of treatment paradigm.

PMS28
STAKEHOLDER EVIDENCE REQUIREMENTS AND PRICE EXPECTATIONS FOR BIOSIMILARS IN THREE ASIAN MARKETS
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OBJECTIVES: This study aims to explore the evidence requirements and price expectations for biosimilars in three Asian markets: China, India, and South Korea. METHODS: A mixed-methods research design was used to explore the evidence requirements and price expectations for biosimilars in three Asian markets. A structural equation model was adopted to model the evidence requirements and price expectations. RESULTS: The evidence requirements for biosimilars in China, India, and South Korea were 3.6, 2.6, and 2.0, respectively. The price expectations for biosimilars in China, India, and South Korea were 0.7, 1.1, and 1.0, respectively. CONCLUSIONS: The evidence requirements and price expectations for biosimilars in China, India, and South Korea are lower than those in Western countries. However, the evidence requirements and price expectations for biosimilars in China, India, and South Korea are higher than those in emerging markets such as Brazil, Russia, India, and China (BRIC). This indicates that the evidence requirements and price expectations for biosimilars in China, India, and South Korea are important factors influencing the market access and pricing of biosimilars. Further research is needed to explore the evidence requirements and price expectations for biosimilars in these three Asian markets.
and humanitarian) requirements to support reimbursement and prescription of biosimilar drugs. In three Asian markets (Japan, South Korea and China), we conducted secondary research to review the macroeconomic factors impacting biosimilar entry (regulatory policy, intellectual property protection etc.). Payer/physician guidance and positions on biosimilar use across markets and diseases were also reviewed. Following this, primary research was conducted with a mix of payers and physician stakeholders to understand: 1. The therapy areas that payers/physicians consider most attractive for biosimilars; 2. Payer/physician value drivers and evidence generation/support requirements; 3. Cross-market comparison of accreditation, reimbursement and uptake; and 4. The likelihood of payers and physicians considering biosimilars in the absence of comparative data vs. the branded biologic, recognizing the complexity of the biologic. Overall, efficacy/safety data and price are key value drivers for biosimilar reimbursement and uptake. In the absence of comparative data vs. the branded biologic, concerns around safety/efficacy may impact uptake but the promise of significant budget savings supports positive reimbursement/access decisions.

CONCLUSIONS: The access environments for biosimilars in the five markets vary, with Japan and South Korea being fairly consistent while China having lower thresholds. Evidence requirements also tend to vary by therapy area and complexity of the biologic. Overall, efficacy/safety data and price are key value drivers for biosimilar reimbursement and uptake. In the absence of comparative data vs. the branded biologic, concerns around safety/efficacy may impact uptake but the promise of significant budget savings supports positive reimbursement/access decisions.

OBJECTIVES: To investigate the mental health of rheumatic diseases patients and how psychological treatment of rheumatism inpatients improves the mental health status in rheumatism inpatients.

METHODS: 1. To compare the mental health status in rheumatism inpatients with normal by SCL-90 score. 2. 66 inpatients with rheumatism were recruited in the study and randomly divided into study group (n=33) and control group (n=33). The patients in the study group accepted psychotherapy and pharmacotherapy, and control group only accepted pharmacotherapy. 3. Six weeks later, the effect of psychotherapy to rheumatism inpatients were assessed by comparing the score of SCL-90 between the two groups. RESULTS: SCL-90 score in the study group decreased significantly in rheumatism inpatients group compared with normal group: rheumatism inpatients group (152.8±35.8) and normal group (129.9±38.7), (P<0.05). 6 weeks later, the SCL-90 sore of study group was lower than that of control group. 3. The SCL-90 score significantly improved after psychological treatment. CONCLUSIONS: The mental health status of rheumatism patients can not be ignored, because the patients have varying degrees of mental psychic symptoms. The psychotherapy can improve the mental health status in rheumatism patients and can help the recovery of the patients.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PRS1

THE EFFECTIVENESS AND SAFETY OF FEBUXOSTAT: AN EXPERIENCE IN MEDICAL CENTER IN TAIWAN
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OBJECTIVES: The aim of this study was to assess the effectiveness and safety of febuxostat for chronic gout.

METHODS: We retrospectively review patients with diagnosis of gout (ICD-9 275.8) concomitant with febuxostat during Jun 2012 to Dec 2013 in Changhua Christian Hospital. Patients with prescription of febuxostat less than 30 days were excluded. The date of first prescription of febuxostat and the date of first prescription of gout medication and the date of first AUR were collected from the clinic database. The correlation between the date of first approval and the delay (p=0.001). There was an overall strong negative correlation between the date of first approval and the delay for both T2DM and RA, and there was an overall strong negative correlation between the date of first approval and the delay (p<0.001). There was an overall strong negative correlation between the date of first approval and the delay (p<0.001).

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PRS2

INHALED ANTICHOLINERGICS AND RISK FOR ACUTE URINARY RETENTION: A CASE-CROSSOVER AND CASE-TIME-CONTROL STUDY
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OBJECTIVES: Recent nested case-control studies have raised concerns of the risk for acute urinary retention (AUR) among patients receiving tiotropium, a long-acting inhaled anticholinergic. In this study, we examined the effect of inhaled anticholinergics on the occurrence of AUR using self-controlled methods, case-crossover and case-time-control designs, which adjust for all time-invariant confounders and reduce threat of control-selection bias.

METHODS: Patients aged ≥45 years with chronic obstructive pulmonary disease (COPD) were included from the IMS LifeLink Health Plan Claims Databases. Cases with AUR in both inpatient and outpatient settings during 2006-2009 were identified. In the case-time-control approach, ten controls were randomly selected for each case after matching age, gender, geographic location, and the secular trend of use. Exposure to tiotropium, ipratropium, and metolonium with significant anticholinergic effects was determined in the 30-day period prior to the event and in a 30-day reference period which was 180 days prior. Multivariate conditional logistic regression was used to evaluate the association between anticholinergic exposure and AUR, with sensitivity analyses and subgroup analyses based on age, gender, and related comorbidities.

RESULTS: A total of 6,608 cases and 60,080 controls were identified. The mean age was 74 years and 78% were male. In the case-crossover analysis, adjusted odds ratio (OR) of AUR was 1.34 (95%CI 1.13-1.60) for tiotropium and 1.19 (1.00-1.43) for ipratropium. In the case-time-control analysis, the risk of AUR OR was 1.24 (1.03-1.50) for tiotropium and 1.26 (1.05-1.51) for ipratropium. The risk of AUR related to tiotropium and ipratropium was similar among patients aged >75 years, males, and those with benign prostate hyperplasia, prostate cancer, and diabetes.

CONCLUSIONS: Our results support current evidence that use of inhaled anticholinergics with high risk for AUR (odds increased by 20-35%) is COPD patients. Providers should be aware of the potential risk for AUR when making treatment decisions.
COPD hospitalization is higher in the winter. However, the busy period tends to
and its minimum on Aug. 23. The distribution is symmetric around the year. There
were fitted. Admission date was converted into an angle called
persons 30 years of age or older were included if there was a principal ICD-9-CM
compactly for any underlying more serious respiratory disorders to help
These data suggest that patients presenting with cough should be investigated

**Prs4**

**Pollen morphology and total protein of taraxacum officinale and aster alpinus**

**OBJECTIVES:** To investigate the seasonal variation in hospitalization for COPD in a Midwestern US State

**RESULTS:** A total of 13,902 participants were screened, of which 7,030 were eligible and 5,250 enrolled. The highest percentage of participants receiving care for a respiratory disorder had primary diagnosis of AR 14.0%, (95%CI: 13.4%, 14.6%), followed by Asthma 13.5% (12.9%, 14.1%), Rhinosinusitis 5.4% (4.6%, 5.3%) and COPD 4.9% (5.0%, 5.7%). Cough or coughing up phlegm was reported as symptom by more than half the participants. Cough or coughing up phlegm was reported as the main reason for medical visit by more than 20% of participants. Among all symptoms reported, cough was most frequently reported by patients with a primary diagnosis of COPD (73%), followed by Asthma (61%), Rhinosinusitis (59%), and AR (47%). In addition, cough was the most frequently reported main reason for seeking medical care among participants with a primary diagnosis of COPD (43%), for Asthma (33%), for Rhinosinusitis (33%), and for AR (11%).

**Conclusions:** Cough is a prominent symptom and major driver of medical care for patients with Asthma, Allergic Rhinitis, COPD or Rhinosinusitis. These data suggest that cough and other symptoms should be investigated comprehensively for any underlying more serious respiratory disorders to help with appropriate disease management.

**PSr8**

**Analysis of factors causing chronic obstructive pulmonary disease in Eastern region of China**

**OBJECTIVES:** Chronic Obstructive Pulmonary Disease (COPD) has become increasingly a major public health problem. This study aimed to evaluate the risk factors for COPD based on data from several cities in eastern region of China.

**METHODS:** Data were extracted from China Health Statistics for six cities and provinces (Liaoning, Beijing, Tianjin, Shanghai and Guangdong) in the eastern region of China where rates of COPD were available. Descriptive statistics and multivariate analysis using logistic regression: mechanical ventilation (OR: 9.81; CI: 4.98-19.35; p < 0.001), immunosuppression (OR: 4.31; CI: 1.65-11.27; p < 0.003), liver insufficiency (OR: 3.69; CI: 1.43-9.55; p < 0.007), APACHE II score > 20 (OR: 2.72; CI: 1.56-4.76; p < 0.001) and male sex (OR: 1.28; CI: 1.14-1.48; p < 0.001) were predictors of mortality (17.4%). Mechanical ventilation, immunosuppression, Liver insufficiency, APACHE II score > 20 and male sex were found to be independent predictors of mortality in HAP patients.

**Prs8**

**Analysis of factors associated with the outcome of hospital acquired pneumonia**

**OBJECTIVES:** To analyze risk factors associated with the outcome of hospital acquired pneumonia (HAP). **METHODS:** A prospective observational study, carried out in a tertiary care teaching hospital. HAP patients who fulfill the inclusion criteria were identified and enrolled into the study after taking informed consent. Patients were followed from the day of diagnosis of HAP to the day of discharge/death.

The patient data like demographic, social habits, co-morbid diseases, interventions (mechanical ventilation), severity assessment (APACHE II score) and clinical outcome (discharge or death) were recorded in the case record forms. Univariate and Multivariate analysis were used to determine the association of the studied risk factors with clinic outcome. **RESULTS:** Total of 505 patients were enrolled in the study, of which 196 were improved and discharged, remaining 88 patients were expired. The mean age of study patient population was 55 ± 16.2 years and 38.4% patients were more than 60 years of age. The majority of patients were males (n=338 (66.9%)). 230 (45.5%) patients were ventilated during their stay in the hospital. Twelve variables (age, sex, mechanical ventilation, APACHE II>20, cardiac, pulmonary, renal, immunosuppression, diabetes mellitus, liver insufficiency, smoking and alcohol intake) were analyzed for possible association with the clinical outcome of HAP in Univariate analysis. Variables with statistical significance during the Univariate analysis were entered into the multivariate analysis. The following five variables were found statistically significant independent predictors of outcome (mortality) in these patient population in multivariate analysis using logistic regression: mechanical ventilation (OR: 9.81; CI: 4.98-19.35; p < 0.001), immunosuppression (OR: 4.31; CI: 1.65-11.27; p < 0.003), liver insufficiency (OR: 3.69; CI: 1.43-9.55; p < 0.007), APACHE II score > 20 (OR: 2.72; CI: 1.56-4.76; p < 0.001) and male sex (OR: 1.28; CI: 1.14-1.48; p < 0.001) were predictors of mortality (17.4%). Mechanical ventilation, immunosuppression, Liver insufficiency, APACHE II score > 20 and male sex were found to be independent predictors of mortality in HAP patients.

**RsP8**

**Incidenc-based cost of asthma in Vietnam**

**OBJECTIVES:** Nowadays, health care costs of asthma are under pressure in all countries due to high prevalence, incidence and the chronic nature of disease. Hence, the aim of the study is to evaluate the lifetime cost of asthma for every new case and the incidence-based economic burden of asthma in Vietnam. **METHODS:** A Markov model with 5 states, including mild, intermittent, moderate and severe, has been built. The model has a cycle length of 1 year with the time horizon of life time. The population incidence-based economic burden of asthma in Vietnam.

**RESULTS:** The incidence-based cost of every new case of asthma in Vietnam accounts for 70,019,897 VND, in which costs for drugs and medical services account for 60.55% and 39.45%, respectively. The cost for diagnosis and management of asthma within life-time per capita is $1,459,674 VND, which is around 2.77 times higher than for the costs of asthma exacerbation treatment (18,560,224 VND). With nearly 231,260 new cases of asthma annually, Vietnam has
the incidence-based economic burden of asthma within lifetime horizon of around 16,193 billion VND should be considered to conduct the health care policies in Vietnam.

**PRS10**

**ECONOMIC BURDEN OF PEDIATRIC ATOPIC DERMATITIS IN ASIA-PACIFIC: A REVIEW OF THE LITERATURE**

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**OBJECTIVE:** Atopic dermatitis (AD) is a chronic skin disease typically presenting in infancy. A literature review was conducted to identify pediatric AD cost estimates in Asia-Pacific (AP) countries.

**METHODS:** An electronic literature search was conducted in PubMed, Google Scholar and other Asian electronic databases to identify and conduct a quantitative summary of studies reporting on pediatric AD cost estimates in AP countries. Open text searches were used to maximize the sensitivity of the search strategy. These searches were supplemented by manual reviews of bibliographies of the articles reporting cost estimates.

**RESULTS:** Annual AD costs per patient were identified in Australia (cross-sectional survey of 48 parents of AD children, age 4 months-15 years; total costs for all, mild, moderate, and severe cases: $2,745; $925; $3,301; $4,907, respectively), Indonesia (model-based; age 0-6; urban; total: $1,097; direct: $957), and Thailand (model and chart review of 3,502 patients, all, mild, moderate, and severe cases: $2,745; $925; $3,301; $4,907, respectively).

**CONCLUSIONS:** The economics of pediatric AD in AP has not been extensively studied. Based on available evidence, annual pediatric AD costs are generally high. Variations in cost estimates are due to between-study differences in country of analysis, types of costs included, severity of AD, and costing methodological considerations. Further evaluations of the AD costs and the cost-effectiveness of pediatric AD prevention strategies in AP countries are warranted.

**PRS11**

**BURDEN OF ATOPIC DERMATITIS IN INDONESIA, MALAYSIA, AND SINGAPORE: ESTIMATES FROM A MATHEMATICAL MODEL**

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**OBJECTIVES:** Children with a family history of atopic disease receiving cow's milk formula (CMF) are at high risk of atopic dermatitis (AD). Modeling techniques were used to estimate the economic impact of AD among urban high-risk children in Malaysia, Indonesia, and Singapore.

**METHODS:** A cohort Markov model was developed to simulate the cumulative incidence and costs of AD in 3 cohorts (one per country) of urban, high-risk infants partially fed with CMF in early infancy (months 0-4). AD incidence was from the GINI study, the largest/prospective experimental study of infant formula and AD in this population. AD treatment patterns and resource use assumptions were derived from expert opinion (n=8). Costing of resource use was based on the respective countries’ prices. Key model outputs included the cumulative incidence and costs (dollars) of AD (converted to 2013 USD) from diagnosis to age 6. Multivariate probabilistic sensitivity analysis was used to generate 95% confidence intervals (CI) around study outcomes.

**RESULTS:** The 6-year cumulative risk of AD was 38% (95% CI: 22%, 57%) in Malaysia, 40% (95% CI: 30%, 53%) in Indonesia, and 26% (95% CI: 18%, 36%) in Singapore. Expressed on an annual basis, the cost of AD per child was $2,742 (95% CI: $2,033, $3,503) in Malaysia, $2,536 (95% CI: $2,015, $3,157) in Indonesia, and $2,536 (95% CI: $2,015, $3,157) in Singapore.

**CONCLUSIONS:** The cumulative incidence of AD was significantly higher in Malaysia than Indonesia and Singapore. These results have important implications for the public health and economic burden of AD in the region and can be used to support national planning and policy making efforts.

**PRS14**

**HEALTH CARE UTILITY AND COST OF MANAGEMENT IN PATIENTS WITH STEVENS-JOHNSON SYNDROME AND TOXIC EPIDERMAL NECROLYSIS IN THAILAND**

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**OBJECTIVES:** To compare the health utilities and the costs of managing Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) in Thailand.

**METHODS:** A retrospective study using an electronic health database from a 1000 bed university-affiliated hospital in Thailand was undertaken. Patients who were admitted with SJS/TEN from 2002 to 2007 were included. The cost was determined using the ratio of cost-to-charge of the hospital for each year. The cost was converted to 2013 value by consumer price index. The cost was converted to US$ using $2.97 Thai-baht per 1 US$. A total of 157 patients were included with 56.1% of male. Average age of the patients was 45.3±23.0 years. Of those patients, 118 patients were primarily diagnosed as SJS/TEN, while 39 patients were secondarily diagnosed as SJS/TEN. About 146 patients (93.0%) were diagnosed as SJS and the rest of them were diagnosed as TEN. The length of stay (LOS) was 10.1±3.2 days for all patients. The LOS for primarily diagnosed patients was 6.8±4.8 days, while the LOS for secondarily diagnosed patients was 20.2±22.5 days. Most of patients (93.0%) were treated with systemic corticosteroids. Prednisolone was commonly used as an oral medication, while dexamethasone was usually used as an inject medication. The average cost of managing SJS/TEN for all patients was $1,012±563. The median cost was $342 (min-max: $11–$26,345). The average cost for primarily diagnosed patients was $515±724, while that for secondarily diagnosed patients was $2,536±1,713.

**CONCLUSIONS:** Health care utility and cost of managing SJS/TEN in Thailand were substantial. Policy makers may consider allocating resources to support the development of strategies to minimize preventable SJS/TEN.
OBJECTIVES: Bacterial lysates reduce acute exacerbations for patients with chronic obstructive pulmonary disease. The purpose of this study was to conduct a cost-effectiveness analysis of bacterial lysates from a payer perspective through the results from a Meta analysis and a Delphi panel survey in China.

METHODS: A cost-effectiveness analysis was to project the 12-month health benefits and costs associated with bronchitis and rhinosinusitis treatments included in the 2017 Chinese National guideline for chronic obstructive pulmonary disease in China. A one-way sensitivity analysis was used to explore each parameter’s impacts on the uncertainty of the results.

RESULTS: The group receiving routine care only was dominated by the group with bacterial lysates plus routine care. Sensitivity analysis showed the robustness of the results. For a COPD patient, compared to the routine care as control group, the alternative treatment with bacterial lysates could reduce 1.9 exacerbations in 12 months (WMD, -1.865; 95% CI, -2.128 to -1.603, P < 0.0001). The projected QALYs were more than those receiving routine care in the clinical efficacy and effects of OM-85. Incremental cost-effectiveness ratio (ICER) was calculated based on the above efficacy and cost information.

RESULTS: The results indicate that, when compared with best supported care therapy, OM-85 is a dominant therapy (with better clinical efficacy and lower overall costs) in Chinese population for the clinical management of chronic bronchitis and rhinosinusitis.

One way sensitivity analyses were performed and the ICER result was demonstrated to be robust. CONCLUSIONS: Based on its clinical efficacy in preventing acute exacerbations of chronic bronchitis and rhinosinusitis, OM-85, when compared with standard care therapy, proved to be a dominant therapy (better clinical efficacy and lower overall costs) in Chinese population for the clinical management of chronic bronchitis and rhinosinusitis.

PSR19

RESOURCE UTILIZED IN A RANDOMIZED CLINICAL TRIAL TO CURE PATIENTS WITH LOW MOTIVATION TO QUIT

Baski E1, Thelen J2, Agbor Bawa W2, Goggins K1, Harris K5, Richter K1, Williams K1, Pattin J1, Hong K1, Choe W1, Yang H1, Ku S1

Objectives: Unmotivated smokers are a unique population and have rarely been specifically targeted for recruitment into smoking cessation trials. While accurate cost data are essential to estimate resource utilization in replicating an intervention, currently the costs of recruiting unmotivated smokers are not reported in the literature. We aim to describe the costs and recruitment methods associated with successful enrollment of smokers who are unmotivated to quit smoking.

Methods: To determine the most cost effective option to recruit patients for the trial one-way sensitivity analysis using a tornado diagram was conducted. All costs are reported in 2012 dollar values. RESULTS: A total of 774 persons were screened for participation, and 155 were ultimately enrolled in the study. Overall rate of cost recruitment totaled $16,931.94 (direct costs $12,252.50; activity-based costs $4,679.43), translating to $21.88 per recruitment contact and $66.40 per newly enrolled participant. The most successful recruitment methods were newspaper advertisements and word-of-mouth. Financial incentives also motivated many to participate. CONCLUSIONS: We are the first to report the cost of recruiting smokers with low motivation to quit and shed light on this unique challenge. Study results may aid future researchers, recruitment makers, and clinicians seeking to enroll for unmotivated smokers. This economic analysis can serve as a guide to determine the budget for actively enrolling these patients in future trials and suggests the most efficient means to do so.

RESPIRATORY-RELATED DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSR20

HEALTH STATUS IN ADULT PATIENTS WITH COPD IN KOREA

Kim ES, Lee BJ, Lee CW, Jung AR, Hwang HS

Objectives: The purpose of this study is to assess health status of Korean adults with COPD using EQ-5D and the association between health status and disease severity using spirometry as a lung function measure. METHODS: A stratified multistage clustered probability design was used to select a nationally representative sample. The mean overall and annualized (uncounted) cost per patient developing AD was $5,814 and $1,392, respectively. CONCLUSIONS: This mathematical model suggests that the burden of AD in childhood is high and that feeding high-risk infants with pHF-W instead of CMF should reduce this burden.
wide (Stage (n=858): 0.906(0.006), Stage II (n=1,091): 0.912(0.005), Stage II (n=119): 0.857(0.18), Stage I (n=110): 0.780(0.07)). CD-QS was not significantly different by 4-stage disease severity but showed a trend of deterioration in Stage III and IV. In the post-hoc analysis, COPD patients were divided into two-stage groups [group 1: Stage I and II; group 2: Stage III and IV]. In this analysis, 2-stage severity had no negative association with utility (p<0.0001). Our results demonstrated that COPD impairs utility and shows a relationship between utility and COPD disease severity in Korea.

**PRS21**

**FACTORS CONTRIBUTING TO QUALITY OF LIFE IN COPD IN SOUTH KOREA**

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**OBJECTIVES:** The burden of COPD is increasing in Korea. Health-related quality of life of COPD patients should be improved. The main objective of this study is to investigate the factors associated with COPD patients’ quality of life.

**METHODOLOGY:** Data of Korean National Health and Nutrition Examination Survey(KNHANES) 2007-2012 were used. According to the GOLD criteria, we classified COPD patients into I-IV grades. EQ-5D index score were analysed by the severity of COPD and Comorbidities. Wilcoxon rank-sum test were used to compare quality of life in COPD patients with the factors associated with COPD patients’ quality of life. After controlling these factors, severe and depressive COPD patients reported their quality of life was significantly worsened. Strategies for COPD prevention and management should be developed and implemented. Improvement of health-related quality of life in COPD can be considered as an index of goals to achieve.

**PRS22**

**HEALTH-RELATED QUALITY OF LIFE FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN SOUTH KOREA**

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**OBJECTIVES:** COPD is known as a disease with irreversible progress but preventable and manageable. In Korea, COPD was ranked 12 with 242 DALYs (per 100,000) following diarrhea (960 DALYs), respiratory infection (858) and asthma(970 DALYs). Health-related quality of life in COPD patients has not been evaluated. **METHODOLOGY:** This cross-sectional study was conducted in chest clinic of the Data of Korean National Health and Nutrition Examination Survey(KNHANES) 2007-2012 were used. According to the GOLD criteria, we classified COPD patients into IV grades. EQ-5D index score was used to measure the severity of COPD and Comorbidities. Wilcoxon rank-sum test were used to test the difference of quality of life in COPD patients with that of the general population. **RESULTS:** Data of Korean National Health and Nutrition Examination Survey(KNHANES) 2007-2012 were used. According to the GOLD criteria, we classified COPD patients into IV grades. EQ-5D index score was used to measure the severity of COPD and Comorbidities. Wilcoxon rank-sum test were used to test the difference of quality of life in COPD patients with that of the general population. **CONCLUSIONS:** People of all socio-demographic categories practice self-medication. The level of inappropriate drug use denotes self-medication among the factors associated with self-medication. The primary outcome of attack frequency of respiratory infection using the DerSimonian and Laird random effects model. **RESULTS:** A total of 76.8% of the respondents indulged in self-medication practices. Of which, 33.0% used the medication inappropriately. The most frequently self-diagnosed illness or symptoms of illnesses were: GI illnesses, cough/cold and headache/fever. Of the illnesses, more than 35% were less than 24 hours duration and nearly 80% less than seven days duration of illness. The reasons given by respondents for self-diagnosis and self-medication were non-seriousness of the illnesses, for emergency use of medications, for personal experience about similar symptoms (39.7%) and even advice of non-physician health professional (33.5%). Whatever the duration of illness and reasons for self-diagnosis and self-medication were non-seriousness of the illnesses, for emergency use of medications, for personal experience about similar symptoms (39.7%) and even advice of non-physician health professional (33.5%). Whatever the duration of illness and reasons for self-diagnosis and self-medication were non-seriousness of the illnesses, for emergency use of medications, for personal experience about similar symptoms (39.7%) and even advice of non-physician health professional (33.5%). 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Whatever the duration of illness and reasons for self-diagnosis and self-medication were non-seriousness of the illnesses, for emergency use of medications, for personal experience about similar symptoms (39.7%) and even advice of non-physician health professional (33.5%).
OBJECTIVES: Tobacco smoke is a strong risk factor for chronic obstructive pulmonary disease (COPD), and over 300 million people are estimated to smoke in China. This study examined characteristics and treatment patterns of COPD-diagnosed patients attempting to quit smoking in urban China. METHODS: National Health and Wellness Survey (NHWS) 2010 and 2012 China data were analyzed. NHWS is a mixed-mode, computer-assisted telephone-based, national probability sample of adults aged 18-64 years stratified by gender and age to represent the demographic composition of urban China. Inclusion criteria comprised self-reported diagnosis with COPD and current smokers “trying to quit” or non-smokers “in the process of quitting.” Sociodemographic, health behaviors, Charlson comorbidity index (CCI) scores (indicating degree of mortality risk), and smoking treatment utilization patterns were assessed. Descriptive statistics included percentages/frequencies for categorical variables and means/standard deviations for continuous variables. RESULTS: Among 1,421 respondents diagnosed with COPD, 35.5% (n=505) were smokers, among which 43.8% (n=221) were currently attempting to quit. Quit attempters were on average 41.1 years old (SD=12.7), employed (76.5%), employed (66.9%), 34.8% were overweight/obese, and they had been diagnosed with COPD an average 6.9 years (SD=7.7), with 25.3% reporting moderate/severe COPD. Mean CCI was 2.53, 57.5% drank alcohol regularly, and 30.3% exercised frequently. Many reported smoking as the main cause of their COPD (57.5%). There were no significant differences in smoking treatment utilization by cigarette type. CONCLUSIONS: Among COPD patients attempting to quit smoking in urban China, few utilized prescription cessation treatments. Given the significant unmet need for these treatments, the proportion of smokers with COPD, effective smoking cessation programs are needed.

PS27
ACCESS TO ASTHMA MEDICINES IN THERAN; IRAN
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OBJECTIVES: Asthma is a chronic disease affecting more than 300 million people throughout the world. Our aim was to examine the availability, pricing and affordability of asthma medicines in Tehran. METHODS: A retrospective cohort study was conducted among asthmatic patients aged 2-64 years old who prescribed in this situation.RESULTS: A total of 9,370 asthma patients were included in the cohort (levalbuterol: 1,652; albuterol: $4041.7 vs. albuterol: $3903.1, p<.41). This nonsignificant difference remained when using the propensity score matching method.

PS28
ECONOMIC IMPACT OF LEVALBUTEROL VERSUS ALBUTEROL IN LOW-INCOME POPULATION
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OBJECTIVES: Short-acting (β2-agonists - albuterol and levalbuterol) - are widely prescribed to prevent asthma exacerbations. However, there are significant cost differences between the two medications. The objective of this study is, therefore, to examine the economic impact of levalbuterol versus albuterol on total health care expenditure in a high-risk, low income asthma population. METHODS: A retrospective cohort study was conducted among asthmatic patients aged 2-64 years old who received levalbuterol or albuterol in the South Carolina Medicaid database between January 2001 and December 2012. Expenditures were inflated to 2011 dollars using the gross domestic product deflator, and adjusted using linearized models with a gamma distribution and log-link function. Propensity score matching was performed to minimize the possible relationship related to unbalanced groups. RESULTS: A total of 9,370 asthma patients were included in the cohort (levalbuterol: 1,652; albuterol: 7,718). The annual spending on levalbuterol was approximately 5 times more than albuterol ($272.6 vs $56.0, p<.001). After adjustment for age, sex, race, year of index date, length of asthma, and proportions of days covered by asthma care ($386.3 vs. $488.1, p<.001). However, there were no statistically significant differences between levalbuterol and albuterol on total health care expenditures (levalbuterol: $4041.7 vs. albuterol: $3903.1, p= .41). This nonsignificant difference remained when using the propensity score matching method. CONCLUSIONS: More than an 8% decrease in health care costs. Fun asthma patients were associated with lower asthma-related costs on ED visits, hospitalizations or outpa- tents facilities. These cost savings, however, failed to offset the high cost of acquiring levalbuterol, suggesting that levalbuterol did not generate greater economic impact than albuterol on low-income asthma population.

SENSORY SYSTEMS DISORDERS – Clinical Outcomes Studies

PS33
THE ECONOMIC BURDEN AND THEIR PREDICTORS IN PRESCHOOL CHILDREN WITH DENTAL CARIES IN URBAN BEIJING
Zhang Y1, Yang L2
1Peking University, Beijing, Beijing, China, 2Peking University, Beijing, China
OBJECTIVES: Dental caries is associated with poor quality of life and higher health care cost. This study aimed to assess the cost of treatment of dental caries of preschool children (3 to 6 years old) and to characterize predictors of these costs. METHODS: 194 preschool children were selected by random sampling from the 1205 children of urban Beijing. All children were examined in a dental clinic of Peking University. The Truven 2003-2007 MarketScan™ Medicaid Database was used. Women with psoriasis were identified by inpatient and outpatient records. The investigators created an algorithm to identify eligible pregnant women and their gestational age claims database to identify drug use during pregnancies. The prevalence of drug use was determined by the proportion of prescriptions. The top 10 most popular prescriptions as well as metformin were identified based on the proportion overall and by trimester of pregnancy. Use of topical corticosteroids were revealed by drug potency. RESULTS: Based on the algorithm created by the investigators, 974 pregnant women with psoriasis were identified, and 386 (39.6%) of them filled psoriasis drugs and saw a physician for psoriasis before pregnancy. The most common medications prescribed most patients were topical corticosteroids (n=122, 31.6%). Of those patients given topical corticosteroids, the majority were low to medium potency drugs (94%, 32.8%). The second most common drugs used was (or other) products such as topical vitamin-D analogues and pimecrolimus. This was followed by biologics (n=2, 0.5%) and other systemic treatments (n=2, 0.5%). Two antibiotic treated methotrexate had overall the lowest cost required for the entire gestational period. CONCLUSIONS: This study revealed the prevalence of psoriasis medications used in pregnant women with psoriasis, which could provide information on how risks and benefits of psoriasis treatment in pregnant women were weighed. In general, the use of common drugs was in line with treatment recommendations for pregnant women. However, there were some treatments prescribed that were not suitable for pregnant women. Care should be needed to ensure safe treatments for pregnant women.

SENSORY SYSTEMS DISORDERS – Cost Studies

PS33
THE ECONOMIC BURDEN AND THEIR PREDICTORS IN PRESCHOOL CHILDREN WITH DENTAL CARIES IN URBAN BEIJING
Zhang Y1, Yang L2
1Peking University, Beijing, Beijing, China, 2Peking University, Beijing, China
OBJECTIVES: Dental caries is associated with poor quality of life and higher health care cost. This study aimed to assess the cost of treatment of dental caries of preschool children (3 to 6 years old) and to characterize predictors of these costs. METHODS: 194 preschool children were selected by random sampling from the 1205 children of urban Beijing. All children were examined in a dental clinic of Peking University. The Truven 2003-2007 MarketScan™ Medicaid Database was used. Women with psoriasis were identified by inpatient and outpatient records. The investigators created an algorithm to identify eligible pregnant women and their gestational age claims database to identify drug use during pregnancies. The prevalence of drug use was determined by the proportion of prescriptions. The top 10 most popular prescriptions as well as metformin were identified based on the proportion overall and by trimester of pregnancy. Use of topical corticosteroids were revealed by drug potency. RESULTS: Based on the algorithm created by the investigators, 974 pregnant women with psoriasis were identified, and 386 (39.6%) of them filled psoriasis drugs and saw a physician for psoriasis before pregnancy. The most common medications prescribed most patients were topical corticosteroids (n=122, 31.6%). Of those patients given topical corticosteroids, the majority were low to medium potency drugs (94%, 32.8%). The second most common drugs used was (or other) products such as topical vitamin-D analogues and pimecrolimus. This was followed by biologics (n=2, 0.5%) and other systemic treatments (n=2, 0.5%). Two antibiotic treated methotrexate had overall the lowest cost required for the entire gestational period. CONCLUSIONS: This study revealed the prevalence of psoriasis medications used in pregnant women with psoriasis, which could provide information on how risks and benefits of psoriasis treatment in pregnant women were weighed. In general, the use of common drugs was in line with treatment recommendations for pregnant women. However, there were some treatments prescribed that were not suitable for pregnant women. Care should be needed to ensure safe treatments for pregnant women.
**Preschool children with dental caries is associated with high treatment costs and the number of caries plays an important role in determination of costs. Therefore, preschool children should pay attention to oral hygiene and form good habits to prevent dental caries.**

**PS44**

**BURDEN OF WET AGE-RELATED MACULAR DEGENERATION IN CHINA**

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**OBJECTIVES:** To explore the burden of wet age-related macular degeneration (WAMD) in China. **METHODS:** Multi-center, retrospective and cross-sectional investigational study. Fifty-one cities were selected as sample cities, and several hospitals were involved in each city. Patients were selected according to inclusion and exclusive criteria, and they were divided into 5 groups: Long-term proper therapy (LPT), poorly controlled therapy (PCT), medical therapy (MT), no medical therapy (NMT), and controls. **RESULTS:** The final analysis sample comprised 21,346 patients who were randomly divided into 5 groups. After treatment, the visual acuity (VA) change model was used to evaluate the quality of life (QOL). The mean annual cost of 35,768 RMB and 35,576 RMB was calculated. The amount of resource consumption was estimated by experts' assessment. **CONCLUSIONS:** The visual acuity (VA) change model was used to evaluate the quality of life (QOL). The mean annual cost of 35,768 RMB and 35,576 RMB was calculated. The amount of resource consumption was estimated by experts' assessment.

**PS45**

**COST-EFFECTIVENESS ANALYSIS OF LATANOPROST COMPARED WITH DORZOLAMIDE/TIMOLOL FIXED COMBINATION FOR THE TREATMENT OF OPEN-ANGLE GLAUCOMA AND OCULAR HYPERTENSION PATIENTS IN KOREA**

**Lee Y.**, **Park D.J.**, **Ko S.K.**

Pfizer Pharmaceuticals Korea Ltd, Seoul, South Korea

**OBJECTIVES:** Glaucoma is a major cause of visual impairment and a chronic disease affecting millions for lifetime. Management of intraocular pressure (IOP) is the main focus of treatment, and many pharmacological treatment agents are recommended and available in Korea. This study was conducted to facilitate efficient allocation of limited resources amongst various pharmacological agents. The objective of this study was to evaluate costs and effectiveness of two most commonly used drugs in Korea which are latanoprost and dorzolamide/timolol fixed combination. **METHODS:** A decision analytic model was developed from a payer perspective. The base case model was based on a quarter analysis. The model was constructed based on a one-month cycle with a time horizon of one year. The treatment success to measure effectiveness was defined as achieving a ≥20% reduction IOP from baseline. Costs of medication, diagnostic fees, physician and pharmacy visitation fees, and surgery fees were included in the study. Utility values according to the severity of glaucoma were also incorporated in the model. Treatment success and failure rates as well as utility for each health state were obtained from previously published literature and local market analysis data. Cost information was obtained from Korea-specific data sources. The result of this study was expressed in an incremental cost-effectiveness ratio (ICER). One-way sensitivity analysis was conducted to evaluate different clinical parameters. **RESULTS:** The final effectiveness values for latanoprost and dorzolamide/timolol fixed combination were 0.9098 and 0.9098 in quality-adjusted life year (QALY) in China. **CONCLUSIONS:** The current study used an economic model to compare cost and effectiveness of the two drugs. The results demonstrated that the effectiveness of latanoprost was similar to dorzolamide/timolol fixed combination.

**PS46**

**A PROSPECTIVE PHARMACOECONOMIC STUDY OF BILATERAL PROSTAGLANDIN/PROSTATELIDE THERAPY FOR LOWERING INTRAOCULAR PRESSURE (IOP) IN THE PATIENTS IN SOUTH INDIA**

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Adda, Phagwara, Punjab, India

**OBJECTIVES:** To determine monthly cost and cost effectiveness of bilateral prostaglandin/prostamide therapy for lowering intraocular pressure (IOP) in patients taking bimatoprost (0.03%), latanoprost (0.005%), or travoprost (0.004%). **METHODS:** This prospective pharmacoeconomic study evaluated the direct cost and cost effectiveness of prostaglandin/prostamide therapy for reduction of IOP in patients with glaucoma or ocular hypertension. Drops in five new 2.5-mL bottles were counted and then averaged for each drug. Average retail price was determined by surveys of pharmacies. Drop count, average retail price, average wholesale price, and IOP reduction were used to estimate treatment costs using the time horizon of one month. **RESULTS:** The mean annual cost of 507,502 baht followed by etanercept (582,881 baht) and infliximab (548,002 baht) respectively. **CONCLUSIONS:** The treatment group followed by etanercept (582,881 baht) and infliximab (548,002 baht) respectively.

**PS47**

**A LITERATURE REVIEW ON COST-EFFECTIVENESS OF TREATMENTS FOR WET AGE-RELATED MACULAR DEGENERATION**

**Yin X.**, **Peng S.**, **Liu Q.**, **F**

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**OBJECTIVES:** To compare the cost-effectiveness for different therapies to Wet Age-Related Macular Degeneration (wAMD). **METHODS:** Literature Review: Several Database, such as Pubmed, Web of Science, Elsevier, Medline were searching using 16 codes. We applied inclusion criteria to screen the literature. Randomized controlled trials (RCTs), Guangzhou Clinical Trials, (CCTs), and controlled Before-and-After studies were selected. This study focus on four common interventions to wAMD: Best Supportive Care (BSC), Photodynamic Therapy (PDT), and Ranibizumab therapy (RA) and bevacizumab therapy (VA). Cost-effectiveness analysis model was conducted to evaluate different clinical parameters. **RESULTS:** Compared with BSC and PDT, Ranibizumab therapy was more effective in wAMD treatment in different countries. From social perspective, Ranibizumab therapy was also more cost-effectiveness than BSC and PFT, and then later in 15 years. However, from third-payer perspective, incremental cost-effectiveness ratio (ICER) between Ranibizumab and BSC, Ranibizumab and PFT, varied in different countries. Frequency and duration of Ranibizumab usage may be key determinants of ICER. **CONCLUSIONS:** Ranibizumab therapy have better clinical effect than BSC and PDT in wAMD treatment. Ranibizumab is also more cost-effectiveness than BSC and PFT from social perspective in long term. It may be related to the highly indirect cost of wAMD. However, from third-party perspective, cost-effectiveness in price and quantity of Ranibizumab in therapy influenced its cost-effectiveness. More research based on varied price and different drug usage in Ranibizumab therapy should be conducted before it were paid.

**PS48**

**ECONOMIC EVALUATION OF BEVACIZUMAB VERSUS RANIBIZUMAB IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION IN CHINA**

**Lee T.**, **Li X.**, **Zhang Y.**

China Pharmaceutical University, Nanjing, China, *People’s Hospital, Peking University, Beijing, China*, **China Can University, China**, **University Hospital Taiwan, Taiwan, China**

**OBJECTIVES:** To evaluate the cost-effectiveness of the off-label used bevacizumab versus ranibizumab for patients with neovascular age-related macular degeneration (AMD) in China. **METHODS:** Two different Markov models were used separately to compare costs per quality-adjusted life year (QALY) of four strategies defined by drug (bevacizumab or ranibizumab) and dosing regimen (monthly or as needed) in patients with neovascular AMD in China’s health care system. The VA model was based on the health status (VA) which is used to define the health status according to the degree of VA changes from the time when entering the model. Both models used a lifetime horizon with a cycle length of 3 months. Clinical data used in the models primarily came from the Comparison of Age-related Macular Degeneration Treatments and Assessment of Run-_out (CATT), while the costs came from the financial department of a tertiary hospital in Beijing. **RESULTS:** In the base-case analyses, the bevacizumab as needed strategy had slightly lower QALYs (17.479 QALYs and 15.917 QALYs in the VA Range model and the VA Change model, respectively) but at much lower costs (CN¥88,341 and CN¥79,967 in the VA Range model and the VA Change model, respectively) but at much lower costs (CN¥88,341 and CN¥79,967 in the VA Range model and the VA Change model, respectively). The probabilities of bevacizumab strategies being more cost-effective than ranibizumab strategies exceeded 99% if the willingness-to-pay (WTP) threshold for a QALY was less than CN¥120,000. When the threshold was less than CN¥90,000 per QALY, bevacizumab as needed was the most cost-effective alternative. **CONCLUSIONS:** The bevacizumab as needed strategy was the most cost-effective strategy compared with the ranibizumab strategies in treating patients with neovascular AMD, if the WTP threshold is below CN¥90,000 per QALY in China. This much cheaper treatment can substantially reduce the burden to the Chinese aging society.

**PS49**

**COST UTILITY ANALYSIS OF USTEKINUMAB FOR THE TREATMENT OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS IN THAILAND**

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**OBJECTIVES:** To evaluate the cost-utility of ustekinumab versus infliximab and etanercept, the only biologic agents available for psoriasis in Thailand, among adults with moderate-to-severe plaque psoriasis who fail to respond to systemic therapies and meet criteria based on the biologic guideline for psoriasis in Thailand. **METHODS:** The published ‘York psoriasis model’ was modified based on the current treatment algorithm and criteria of biologics use in Thai psoriasis guideline. Short-term trial efficacy data (PASI response) from a published network meta-analysis of RCT was used to model the response of patients to initial treatment. Beyond the initial period, the model extrapolated results up to 10 years with annual PASI responses estimated by treatment withdrawal. The DUG scores from ustekinumab trials were transposed into utility gain (EQSD) and applied to PASI response level regardless of the treatment received. Both direct medical cost and non-medical cost including burden of illness were included. **RESULTS:** The lowest mean annual cost of 507,502 baht followed by etanercept (582,881 baht) and infliximab (585,426 baht) respectively. **CONCLUSIONS:** The mean QALY gain of ustekinumab was higher than etanercept (0.1468 vs. 0.1392) but lower than infliximab (0.1468 vs. 0.1564). Considering the cost-utility ratio, ustekinumab was dominant compared to etanercept.
cept and infliximab showed the ICER of $6,719.775 bht/QALY compared to ustekinumab. The probability of cost-effectiveness threshold of 120,000 bht/QALY remained in favor of ustekinumab at 72.60% and presented at 13.60% for both etanercept and infliximab. CONCLUSIONS: Ustekinumab seems to be more cost-effective than etanercept and infliximab for patients with moderate-to-severe plaque psoriasis following biologic treatment guideline for psoriasis in Thailand.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSS10 ADHERENCE, PREDICTING FACTORS AND SATISFACTION OF PATIENTS ON GLAUCOMA THERAPY: FINDINGS FROM A CROSS-SECTIONAL STUDY IN KOREA

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OBJECTIVES: The aim of the study was to identify adherence and predicting factors for non-adherence and to assess the association of adherence with patient satisfaction of glaucoma therapy. METHODS: The study population included 1,046 glaucoma outpatients with less than two years of drug use recruited at 11 eye clinics from March to November 2013. All patients completed a self-administered questionnaire asking about their daily use of glaucoma medications to estimate adherence and patients’ baseline characteristics to examine predicting factors for non-adherence. Adherence was defined as patients administering the drug for ≥90% of prescribed days. Patient satisfaction was also measured using the 14-item Treatment Satisfaction Questionnaire (TSQM) questionnaire which provided scores on four sub-scales: medication effectiveness, side effects, convenience and global satisfaction. The scores on TSQM are ranged 0 to 100 where higher scores indicate better satisfaction. RESULTS: Of 1,046 patients, 71.5% showed to be adherent to their glaucoma therapy while 28.9% accounting for 298 of patients remained non-adherent. The predicting factors for non-adherence were found to be patients’ age above 65 years, and unemployed (p < 0.05). Non-adherent patients showed less satisfactory to treatment than adherent patients as displayed by relatively lower scores in PSS12 and PSS13 compared to PSS11 patients. Patient satisfaction was significantly associated with adherence and was reduced for adherent patients in the study population were non-adherent, and age and employment status were shown to influence non-adherence. Global satisfaction of glaucoma therapy.

PSS12 UTILITY VALUES AMONG MYOPIC PATIENTS IN MAINLAND CHINA

Li S, Shandong University, Jinan, China

OBJECTIVES: To elicit utility values of adult myopic patients in mainland China. METHODS: A valid sample of 442 myopia patients (spherical equivalent at least -0.5 D) aged 17-44 years, who were scheduled to undergo refractive surgery, were recruited. Information on time trade-off (TTO, years of life willing to sacrifice for treatment of myopia) and standard gamble (SG) for blindness (risk of blindness from losing the ability to sacrifice for treatment of myopia) utility values, sociodemographic and clinical data were obtained. RESULTS: The mean utility values based on TTO and SG were 0.96±0.05 (95% confidence interval (CI) 0.95–0.96, median 0.98) and 0.93±0.05 (95% CI 0.92–0.94, median 0.97), respectively. Myopic patients using contact lens had significantly higher TTO utility values than those wearing glasses (p < 0.001). There was no significant difference in the TTO and SG utility values by age, gender, occupation, educational levels, residence, reasons for refractive surgery, severity and duration of myopia [P > 0.05]. CONCLUSIONS: The TTO and SG produce similar mean utility values, but there is poor agreement between results for the two methods. Utility values associated with myopic patients obtained in this study or reported in the literature appear to be higher than those obtained for other ophthalmic conditions.

SENSORY SYSTEMS DISORDERS – Health Care Use & Policy Studies

PSS11 PRESCRIBING PATTERNS AND EXPENDITURES FOR OTTIS MEDIA-RELATED ANTIBIOTICS FOR CHILDREN IN THE TEXAS MEDICAID PROGRAM

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OBJECTIVES: To determine the prescribing patterns and expenditures for otitis media (OM)-related antibiotics in the Texas Medicaid pediatric population, and identify the demographic and antibiotic-related factors associated with expensive prescribing patterns of OM antibiotics. METHODS: This retrospective study used Texas Medicaid outpatient medical and prescription claims data for children younger than 13 years old with a diagnosis of OM (ICD-9: 381.0-382.0) and claims for OM-related antibiotics from January 2008 to December 2011. OM-related antibiotics were selected based on the guidelines proposed by the American Academy of Pediatrics and the American Academy of Family Physicians in 2004, and were classified into three categories: cephalospirins, macrolides and penicillins (amoxicillin/other penicillins). The total number (proportion) of prescriptions and costs were compared across selected antibiotics and categories. Generalized linear model was used to evaluate potential factors associated with expensive prescriptions. RESULTS: 355,638 children, with a mean age of 3.9 (SD 3.2) years were included. The majority were boys (52.1%), younger than 3 years old (53.0%), Hispanic (55.0%), enrolled in fee-for-service program (83.1%) and from an urban region. OM-related antibiotic prescription claims decreased from 137,557 in 2008 ($5,281,040) to 65,697 in 2011 ($2,010,391). The mean cost per prescription decreased significantly from $38.39 in 2008 to $30.60 in 2011 (p < 0.01). The most frequently used category of OM-related antibiotics was penicillins (215,654 claims). Amongst penicillins, the most frequently prescribed OM-related antibiotic (48.2%), followed by cefdinir (21.5%). However, the total outpatient prescription cost was highest for cefdinir ($1,736,640), followed by amoxicillin-clavulanate ($2,798,234), azithromycin ($1,914,929), azithromycin ($1,298,427), cefuroxime ($49,191), clarithromycin ($42,959), cefpodoxime ($19,685) and ceftriaxone ($5,792). Higher age, Asian race/ ethnicity, female gender, fee-for-service program enrollment, Texas region, acute OM, amoxicillin-clavulanate, and cephalosporins were significant predictors (p < 0.05). CONCLUSIONS: Prescribing evidence including cost-effectiveness of selected OM-related antibiotics declined between 2008 and 2011 in the Texas Medicaid pediatric population.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1 SECOND GENERATION AZOLES FOR PROPHYLAXIS AGAINST INVASIVE FUNGAL INFECTION: IS VORICONAZOLE EQUIVALENT TO POSACONAZOLE IN HAEMATOLOGY PATIENTS?

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OBJECTIVES: No randomised controlled trial has compared voriconazole and posaconazole for prophylaxis against invasive fungal infections (IFI) in high risk haematology patients. We performed a systematic review and indirect comparison of voriconazole versus posaconazole using itraconazole/fluconazole as the common comparator and our recently published review of full body antifungal prophylaxis for all haematology patients. The indirect estimates of risk differences (RD) were not statistically significantly different from 0.0, therefore indicating that voriconazole is not worse than posaconazole in terms of the incidence of proven or probable IFI [RD (95% CI): 0.00 (-0.06, 0.14) in HSCT/GVHD; 0.04 (-0.06, 0.14) in AMI(MDS); and all-cause mortality rates [RD (95% CI): 0.00 (-0.07, 0.06) in HSCT/GVHD; 0.03 (-0.09, 0.16) in AMI(MDS)]. Results should be interpreted with caution due to heterogeneity between the risk levels of patient populations. However, the robustness of the indirect comparisons can be supported by the four direct non-randomised studies which consistently demonstrated similar efficacy of voriconazole and posaconazole and superior efficacy of voriconazole over itraconazole and fluconazole based on the incidence of breakthrough IFI. CONCLUSIONS: The clinical evidence presented in the direct and indirect comparisons consistently demonstrate that there are no statistically significant differences between voriconazole and posaconazole in terms of efficacy outcomes. Voriconazole offers an alternative to posaconazole for prophylaxis against invasive fungal infections for haematology patients.

PSY2 INTERCHANGEABILITY STUDY OF MULTISOURCE PARACETAMOL 500MG TABLETS, PRODUCED IN MONGOLIA

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OBJECTIVES: To define interchangeability of locally produced Paracetamol (Acetaminophen INN) 500mg tablets. METHODS: For this purpose Paracetamol 500mg tablets produced by 7 local manufacturers were tested. As a comparator product was used Panadol 500mg, produced by GlaxoSmithKline. Bioequivalence testing was done according to the WHO guideline, Multisource (generic) pharmaceuticals: guidelines on registration requirements to establish interchangeability, WHO Technical Report Series, No.937, 2006. Based on Biopharmaceutics Classification System Paracetamol tablets bioequivalency testing was done in vitro through determination of dissolution. RESULTS: In each media of pH 1.2, 4.5 and 6.8 were tested 12 unit samples. All samples were dissolved in three media in not less than 85% of the labelled amount of the paracetamol in 15 minutes. According to the questionnaire, all manufacturers producing Paracetamol tablets answered that the formulation of dosage form was considered the attribute of active pharmaceutical ingredient and excipients and used machinery's specification. As criteria for choosing the formulation, manufacturers were used pharmacopoeial monograph, stability study data and dissolution results. Mongolian manufacturers Paracetamol formulations not contain excipients such as sodium bicarbonate, which is fastening the drug absorption. Three manufacturers use Povidone as a binder, same like comparator product. Most formulations contain Talc and Magnesium stearate as a lubricant and contain Searc drug actions which contain starch and cellulose, their derivatives. CONCLUSIONS: Paracetamol 500mg tablets produced by all 7 local manufacturers: LM1, LM2, LM3, LM4, LM5, LM6 and LM7 are bioequivalent in terms of bioavailability and could be interchangeable with comparator pharmaceutical product.

PSY3 CLINICAL EFFICACY OF THE POLYHERALD CYURVIEC MEDICINE IN THE MANAGEMENT OF OVERWEIGHT

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OBJECTIVES: To evaluate the clinical efficacy of the polyanalyside from Curugame in the management of overweight and obesity. METHODS: A randomised, placebo-controlled trial with 2 phases. In the first phase, BMI and metabolic parameters were measured and participants were randomly assigned to control or treatment group. In the next phase, the treatment group was divided into 3 subgroups and treated for 8 weeks with 600mg of Polyanalyside. RESULTS: After 8 weeks, significant decrease in BMI and waist circumference was observed in the treatment group. CONCLUSIONS: Polyanalyside is an efficacious natural medicine for the management of obesity.
OBJECTIVES: The metabolic disorder begins with signs of overweight. If unattended it leads to metabolic syndrome with Hypertension and Diabetes. The polypharmacy and chronic disease conditions are primarily used in this study in the management of over weight. The polyherbal formulation consists of Triphala, Guduchi and Mandor basma(TGMB). METHODS: Study design is randomised single blind comparative method. Total number of patients in both arms were 40 (20 each) were administered. The control group were administered Guggulu and treatment group recived TGMB for 45 days. The parameters observed include monitoring of BMI, Lipid Profile, blood sugars. RESULTS: Before treatment (BT)Average BMI of control treatment group was 28.1/28; After treatment (AT), C 26.59/T 26.79; At baseline, 3, 6 and 12 months. Effectiveness of treatment was assessed by ODQ collected at baseline, 3, 6 and 12 months. Effectiveness of pharmacotherapy was assessed as improvement in pain score and disability at 3, 6 and 12 months. All participants were asked to rate their pain using visual analog scale (VAS) and disability assessed by Oswestry low back pain disability questionnaire (ODQ) collected at baseline, 3, 6 and 12 months. Differences were tested by way repeated analysis of variance model used to assess the change in pain and disability scores. RESULTS: Total 131 female patients of mean age 46.2(5.7) years with BMI 22.5(5.7) were included in the study. At baseline, duration of CLBP was 24 (12-60) months. At the baseline patients on monotherapy 27%, Dual 45% and, multiple 28%. Overall prescribed drugs are; Pregabalin (82%), Amiptryptiline (64%), Duloxetine (59%), Tramadol (42%), Nortriptiline (36%), topical analgesics (5%), Calcium-vitamin supplements (5%), Physical exercises and pain education (75%). During the period of follow-up switching of therapy occurred for reasons like low effectiveness and reduced pain intensity etc. When compared to baseline, there is a significant P<0.05 reduction in pain score (70 (50-90) vs 40 (25-50)) and disability (51(42-62) vs 22 (16-32)) observed at the end of 12 months of follow-up. Over the period of follow-ups, we found the significant improvement in pain (P<0.01) and disability (P<0.023). CONCLUSIONS: Our study findings indicated that pharmacological treatment, posture and physical exercises could be helpful in managing pain and improving of disability in CLBP patients.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY5 HEALTH ECONOMIC EVALUATION COMPARING IV FERRIC CARBOXYMALTSOYE, IRON SUCROSE AND BLOOD TRANSFUSION FOR TREATMENT OF PATIENTS WITH IRON DEFICIENCY ANEMIA (IDA) IN SINGAPORE

Objectives: The prevalence of anemia is higher in Asian females. The iron content in the diet is often insufficient to meet the requirements of the growing children and pregnant women. Iron deficiency anaemia (IDA) is a major cause of morbidity and mortality in developing countries including Singapore. Aims: The objectives of this study were to compare the cost-effectiveness of three different treatment regimens for iron deficiency anaemia (IDA) in Singapore.

METHODS: A decision analytic model was developed using TreeAge Pro software to compare the use of intravenous iron (IVFe), oral iron (IOFe), and blood transfusion for the treatment of IDA in Singapore. The model included the costs and outcomes associated with each treatment option, including costs for medication, laboratory tests, and any complications or adverse events. The outcomes were calculated using the Quality-Adjusted Life Years (QALYs) gained, and the costs were derived from local sources.

RESULTS: The decision analysis revealed that IVFe was the most cost-effective option, followed by IOFe and then blood transfusion. The incremental cost-effectiveness ratio (ICER) for the IVFe compared to IOFe was $1,500 per QALY gained, while the ICER for blood transfusion compared to IOFe was $4,000 per QALY gained. These results indicate the marginal efficacy of the control group over the treatment group in reducing the BMI and clinical parameters. However, the TGMB was enriched with phytomedicines and mineral from Guggulu.

PSY4 PRESCRIBING PATTERNS AND TREATMENT OUTCOMES IN NORTH INDIAN FEMALE PATIENTS WITH CHRONIC LOW BACK PAIN

Kanukula R1, Bansal D2, Ghai B 3

OBJECTIVES: This observational study was designed to determine the prescribing pattern, improvement of pain intensity, and disability in female patients with CLBP. The study also examined whether the use of topical analgesics, calcium & vitamin supplements, and physical exercises can be tolerated due to its side effects, responds relatively slowly, or cannot be used in cases with severe pain.

METHODS: This observational study included 131 female patients. The patients were administered EQ-5D and the quality of life was computed manually. Additional data on socioeconomic status was also collected in order to calculate the cost-effectiveness study. RESULTS: The data collected was compiled and the cost effectiveness of Propofol (N=32) vs Thiopental (N=19) was calculated using EQ-5d 5L crosw index calculator. The EQ-5D score for Propofol was 0.22±0.08 and for thiopental was 0.29±0.21. The ICER was calculated using. "The average cost effectiveness = [∆Costs/∆Health Utility Benefit] and it was found to be 2535.21. CONCLUSIONS: It is found that thiopental is cost effective than propofol as ICER for the treatment is more than 2535.

SYSTEMIC DISORDERS/CONDITIONS – Patient-Reported Outcomes & Patient Preference Studies

PSY7 UNDERSTANDING THE JAPANESE GENERAL PUBLIC’S RATIONALE FOR TRADES - A THREE-TRADE-OFF ASSESSMENT FOR SYSTEMIC LUPUS ERTHEMATOUS

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OBJECTIVES: To understand the Japanese public’s rationale for the trade-offs of hospitalising systemic lupus erythematosus (SLE) patients. METHODS: Utility and demographic data were collected from 101 subjects from the general public in Tokyo. Subjects responded to six hypothetical system lupus erythematosus health states described by six levels of severity. Subjects provided their valuation of their utility through a visual analog scale and time-trade-off. One health state was randomly selected (excluding the anchor state) for each respondent to provide their rationale for their trade-offs. RESULTS: Respondents were comprised of 54 men and 47 women. Subjects provided a range of responses from concerns of family burden to self-preservation (“Prefer to live as long as possible”) and needing to finish personal ethical missions and “Dignity” / “Pride” by not wanting to ask others for any assistance. “Unable to bear symptoms / Prefer to die” was the most frequently provided response (~30%) followed by “Burden on family / others” (~20%). Subjects who responded to the mild health state had a tendency to respond “Able to tolerate symptoms” over other responses. Subjects were more likely to respond with “Hope for a cure” CONCLUSIONS: Our study found that subjects were able to provide valid utility estimates from the time-trade-off. The rationale for trade-offs provide insights into how responses are formulated within an Asian country. Additional research will need to be conducted to compare these results to other Asian and Western cultures.

PSY8 PREVALENCE OF NEUROPATHIC PAIN IN KOREAN PATIENTS SCHEDULED FOR LUMBAR SPINE SURGERY AND THEIR HEALTH RELATED QUALITY OF LIFE: NATIONALWIDE, MULTICENTER, PROSPECTIVE, CROSS-SECTIONAL, OBSERVATIONAL STUDY

Cho Y1, Kim KH1, Kim H2

OBJECTIVES: The objectives of this study were to investigate the prevalence of neuropathic pain (NP) in patients scheduled for lumbar spinal surgery and the relationship between health-related quality of life (HRQoL) and NP. The study also aimed to identify the risk factors related to NP and outcomes for surgical treatment between patients with and without NP.

METHODS: This study was a nationwide, multicenter, cross-sectional, observational study. It was conducted from September 2011 to May 2013, and included a total of 1,109 patients who were scheduled for lumbar spinal surgery from 44 spinal centers (both orthopaedics and neurosurgeons). Patients were diagnosed of having NP if the intensity of the pain was ≥ 5 on a 0-10 point numerical rating scale (NRS) and the pain had a characteristic type of burning or electric shock type of pain. NP was assessed using the ShortForm-36 Health Survey (SF-36) and the Brief Pain Inventory (BPI). The SF-36 was used to measure the patients’ health-related quality of life. The BPI was used to measure the intensity of pain and the interference of pain in daily activities. The patients were asked to describe what they considered when making their trade-offs. Additional data was collected from 101 subjects in Tokyo. Subjects responded to six hypothetical system lupus erythematosus health states described by six levels of severity. Subjects provided their valuation of their utility through a visual analog scale and time-trade-off. One health state was randomly selected (excluding the anchor state) for each respondent to provide their rationale for their trade-offs. RESULTS: Respondents were comprised of 54 men and 47 women. Subjects provided a range of responses from concerns of family burden to self-preservation (“Prefer to live as long as possible”) and needing to finish personal ethical missions and “Dignity” / “Pride” by not wanting to ask others for any assistance. “Unable to bear symptoms / Prefer to die” was the most frequently provided response (~30%) followed by “Burden on family / others” (~20%). Subjects who responded to the mild health state had a tendency to respond “Able to tolerate symptoms” over other responses. Subjects were more likely to respond with “Hope for a cure” CONCLUSIONS: Our study found that subjects were able to provide valid utility estimates from the time-trade-off. The rationale for trade-offs provide insights into how responses are formulated within an Asian country. Additional research will need to be conducted to compare these results to other Asian and Western cultures.

PSY6 COST EFFECTIVENESS OF PROPOFOL VERSUS THIOPENTAL IN ICU WARDS

Reddy K1, Prabhu N1, Gonneppanavar U1, Nagappa AN1

OBJECTIVES: To study the cost effectiveness of Profofol and Thiopental Sodium in ICU wards as Induction Anesthetic; when performing major surgery , anesthe-thesia is provided by the anesthetist agent. The primary treatment strategies in the operating room are alternative as induction anesthetic agents. The efficacy and safety of both agents are considered almost equal. However propofol costs 248 INR (approx 4 $) whereas thiopental is 689 INR (approx 1.2 $). The variation in the price indicates that thiopental is a natural choice due to price advantage. However propofol is more popular choice of anesthetia as it is rigorously marketed and in order to establish the value of thiopental the following study was carried out. METHODS: The study was a comparative prospective observational study. The ICU patients who were going on anesthetia procedure were included in the study. The patients who were on the age; the choice of the anesthetic to be used is at the discretion of the anesthesiologist. RESULTS: There was no significant difference between the efficacy of Propofol (N=32) vs Thiopental (N=19) was calculated using EQ-5d 5L crosswalk index calculator. The EQ-5D score for Propofol was 0.22±0.08 and for thiopental was 0.29±0.21. The ICER was calculated using. "The average cost effectiveness = [∆Costs/∆Health Utility Benefit] and it was found to be 2535.21. CONCLUSIONS: It is found that thiopental is cost effective than propofol as ICER for the treatment is more than 2535.

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these patients suffered greater pain and lower HRQoL than nociceptive pain patients. The more remarkable improvement NP patients showed after treatment highlights the importance of appropriate diagnosis and treatment of NP.

SYSTEMIC DISORDERS/CONDITIONS – Patient-Reported Outcomes & Patient Preference Studies

PSY9 PRICING AND MARKET ACCESS OF ORPHAN DRUGS IN ASIA: A COMPARATIVE STUDY ACROSS GROWTH MARKETS

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OBJECTIVES: With the majority of the world’s population and considerably higher GDP growth rates, Asia represents a significant opportunity for commercialization of orphan drugs (OD) for rare diseases. However, despite some countries implementing policies to facilitate this process, funding for ODs remains challenging due to conflicting priorities with coverage of essential medicines. We aimed to understand the current coverage policies for ODs in China, Taiwan, Singapore and South Korea, and considered the influence of any identified policies on the results.

RESULTS: National legislation for OD coverage was identified in Taiwan, Singapore and South Korea, however, the degree to which policy influences coverage varies considerably between these countries. Additionally, in the absence of national legislation in China, provincial policies do exist, albeit infrequently and with considerable disparity. Scores for access drivers were minimally correlated with pricing and reimbursement status (r = 0.24, p < 0.05). High scores were not necessarily indicative of positive coverage; rather, affordability is the primary driver for access.

CONCLUSIONS: Our results demonstrate that, although there is considerable market opportunity supported by variable legislation to facilitate OD coverage, pricing and market access remains challenging and is not necessarily related to individual product value. Therefore, pharmaceutical companies seeking access for ODs should consider selective programs, designed to improve affordability and patient access.

PSY10 THE SOCIOECONOMIC COSTS OF THE UNDERTREATMENT OF PAIN

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OBJECTIVES: To investigate the scale and socioeconomic cost of untreated/uncon- trolled chronic pain. METHODS: We performed a systematic literature search in PubMed to identify studies reporting the economic cost of pain globally and in Asia Pacific.

RESULTS: Prevalence estimates for chronic pain among adults range from 2-40% in the US and 12-30% in Europe, with similar rates reported in Hong Kong (10.8%) and Singapore (8.7%). Chronic pain is costly not only because it requires controlled chronic pain.

To investigate the scale and socioeconomic cost of untreated/uncontrolled chronic pain.

OBJECTIVES: The aim of this research was finding the factors affect the decision of customer in drug stores for selecting the sore throat lozenges. METHODS: Survey research had been conducted since October to November 2012. The data was collected by using questionnaires from 410 buyers age over 15 years who request the sore throat lozenges in drugstores for themselves. RESULTS: Most of respondents were 30-40 years old (30.49%), hold bachelor degree (40.73%), students (25.12%), no monthly income (27.80%) and had no income (27.80%). Most of them used to buy modern medicine types of sore throat lozenges (68.78%) more than traditional medicine types. Their objectives were for reducing sore throat (36.35%) follow by reducing throat irritation (23.97%), reducing cough (19.95%) and expectorant (9.98%) respectively. Most of them would buy the modern medicine in the next time (69.27%). The level of decision making using available factor and information sources were in high priority, the other factor was in medium level. The relationship between gender and gender and former using on selecting the types of sore throat lozenges were statistical significance of 0.05 level. The factors influenced the selection of sore throat lozenges were (1) Place factor (r=0.21±1.81) especially selecting from availability and convenience was in the high level, (2) Information factor (r=3.60±0.33) especially selecting by using their information and receiving the information from health professionals were in the high level, receiving the information from various mediums and the intimate persons were in the medium level, (3) Price factor (r=3.44±0.18) especially selecting from appropriateness was in the high level, (4) Product factor (r=3.18±0.50) especially selecting from taste was in the high level (r=4.02±1.81). CONCLUSIONS: The results could be applied by community pharmacists in advising the customers for sore throat lozenges selection and the manufacturers or marketing managers in producing and distributing their products.

PHP2 ASSESSING THE IMPACT OF PATENT LOSS ON OVERALL REVENUES AND STOCK PRICES OF PHARMACEUTICAL COMPANIES

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OBJECTIVES: With the pre-tax R&D cost of bringing a biopharmaceutical product to market estimated at $1.2 billion, revenues from blockbuster drugs may need to cover the development cost of multiple new drugs. We analyzed four major blockbuster products that lost patent protection between 2011 and 2012 and the associated change in sales it had on the company. METHODS: We identified four major products (atorvastatin, clopidogrel, quetiapine, and montelukast) that lost patent protection between 2011 and 2012. Then, we retrieved sales data for the drug, total revenue, and stock price for the company from Q1 2011 to Q4 2013. Results: The sales of the four drugs were down an average of 78.8% by Q3 2013 while total revenues for the companies were only down on average 11.9%. Stock prices over the same period increased an average of 72.5%.

During the time the drugs were under patent, they made up an average of 16.8% of gross domestic product. Investors seem to appropriately price in patent expiration with the pre-tax R&D cost of bringing a biopharmaceutical product to market estimated at $1.2 billion, revenues from blockbuster drugs may need to cover the development cost of multiple new drugs. We analyzed four major blockbuster products that lost patent protection between 2011 and 2012 and the associated change in sales it had on the company. METHODS: We identified four major products (atorvastatin, clopidogrel, quetiapine, and montelukast) that lost patent protection between 2011 and 2012. Then, we retrieved sales data for the drug, total revenue, and stock price for the company from Q1 2011 to Q4 2013. Sales data was from IMS Health via drugs.com. Total company revenue per quarter was provided by Charles Schwab & Co. and historical stock data was taken from Yahoo! Finance. RESULTS: During the time the drugs were under patent, they made up an average of 16.8% of total revenues per quarter. Total sales for the four drugs were down an average of 78.8% by Q3 2013 while total revenues for the companies were only down on average 11.9%. Stock prices over the same period increased an average of 72.5%. During the time the product had patent protection, the stock prices of those four companies increased at an average of 5.7% per quarter, as opposed to the 5.8% increase per quarter when the patent expired. During patent protection, average company revenue grew at an average of 1.52% per quarter; when the patent expired, revenue declined at an average of 1.9%. CONCLUSIONS: Overall these blockbuster drugs do not seem to significantly decrease revenues and do not influence stock prices when their patent protection is up. Large pharmaceuticals may reinvest profits to bolster their pipelines and find replacements for these large-revenue drugs. Investors seem to appropriately price in patent expiration with the pre-tax R&D cost of bringing a biopharmaceutical product to market estimated at $1.2 billion, revenues from blockbuster drugs may need to cover the development cost of multiple new drugs. We analyzed four major blockbuster products that lost patent protection between 2011 and 2012 and the associated change in sales it had on the company. METHODS: We identified four major products (atorvastatin, clopidogrel, quetiapine, and montelukast) that lost patent protection between 2011 and 2012. Then, we retrieved sales data for the drug, total revenue, and stock price for the company from Q1 2011 to Q4 2013. Sales data was from IMS Health via drugs.com. Total company revenue per quarter was provided by Charles Schwab & Co. and historical stock data was taken from Yahoo! Finance. RESULTS: During the time the drugs were under patent, they made up an average of 16.8% of total revenues per quarter. Total sales for the four drugs were down an average of 78.8% by Q3 2013 while total revenues for the companies were only down on average 11.9%. Stock prices over the same period increased an average of 72.5%.
OBJECTIVES: Diagnosis related groups (DRG) like financing method was introduced in Hungary in 1993 for acute care hospital activity. Due to the increased activity of the hospitals, an upper ceiling, the so called performance volume limit (PVL) was introduced in acute care hospital financing in 2004. The aim of our study was to analyze the effect of performance volume limit on DRG based hospital financing on the example of a Hungarian tertiary teaching hospital, the Clinical Centre of the University of Pécs. METHODS: Data derived from the financial database of the National Health Insurance Fund Administration, the only health care financing agency in Hungary. We analyzed the three of hospital activities over the performance volume limit ceiling. We calculated the proportion of hospital activity over that ceiling measured by DRG cost-weights. The period 2004-2013 was involved into the study. RESULTS: The annual number of patients varied between 72671 (2007) and 82509 (2009) at the Clinical Centre of the University of Pécs. During the same period the actual performance volume limit for DRG costweights varied between 97784 and 116970. However due to the regulation of the upper ceiling of hospitals’ activity, 3.0 % (2007) to 14.9 % (2009) of that activity found the cost-weights reimbursed to the hospitals. The average loss of reimbursement due to performance volume limit was 7.2 % of annual revenues between 2004-2013. CONCLUSIONS: The introduction of performance volume limit into the DRG based hospital financing resulted in a partial loss of hospitals’ revenues. Despite of in PVL, the number of patients produced its output, thus the annual number of patients did not declined in this hospital.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP4 CO-ADMINISTRATION OF TURMERIC POTENTIATES PREVENTIVE EFFECT OF BLACK SEEDS IN METABOLIC SYNDROME
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OBJECTIVES: The metabolic syndrome (MS), a combination of metabolic abnormalities including obesity, diabetes, dyslipidemia and hypertension is associated with an increased risk of cardiovascular disease and stroke. Complementary medicines including herbs like Turmeric and Black seeds (Nigella sativa) can be used to prevent or as an adjuvant to control MS with fewer side-effects, better acceptability and cost-effectiveness. This study determines if the co-administration of Turmeric potentiates the beneficial effects of black seeds on MS in rats. METHODS: Black seeds and Turmeric alone and in combination at different dosages were administered to fructose-fed rats. Blood pressure, fasting sugar and lipid profile were measured before an after 3 and 6 weeks of treatment. The serum and endothelial functions were determined at 6 weeks of intervention. RESULTS: Black seeds at the dose of 0.6 g/kg prevented hypertension at week 3 of intervention, while at 6 weeks it prevented hypertension, hyperglycemia, dyslipidemia and endothelial dysfunction. Turmeric at a dose of 20 mg/kg prevented the anti-infective medicines in Tianjin, China using index method. METHODS: Data were extracted from inpatient claims in Urban Employee Basic Medical Insurance database of Tianjin, China, from 2006 to 2010. Price indices were measured by Fisher and Chained Fisher index formulas by quarter. The quantity weight unit was defined daily dose (DDD) and the price unit was the price per DDD. Price indices were calculated both at molecule level (defined by active ingredient) and product level (defined by molecule, strength, preparation, and manufacturer). RESULTS: The data contained 41 molecules and 786 products among the essential anti-infective medicines, and 81 molecules and 636 products among the non-essential anti-infective medicines. For the non-essential anti-infective medicines, the price index decreased to 0.90 (in chained Fisher index at molecule level) from 2006 Q1 to 2010 Q4, and the price index for the non-essential anti-infective medicines decreased to 0.73 (in chained Fisher index at molecule level) during the same period. For the essential and non-essential anti-infective, the results of chained Fisher and unchained counterparts were similar (10% vs. 9% for the essential and 28% vs. 27% for the non-essential at molecule level). The price index at molecule level decreased slower than the counterparts at product level (10% vs. 24% for the essential and 27% vs. 40% for the non-essential). CONCLUSIONS: The price of the essential and non-essential anti-infective medicines among national reimbursement drug list had decreased in Tianjin, China, but the price of the essential anti-infective medicines decreased slower than the non-essential anti-infective medicines.

PHP5 IMPACT OF DRUG POLICY ON IMPROVING ACCESS TO MEDICINES IN DELHI
Bhat N
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OBJECTIVES: To assess the impact of drug policy on improving access to essential medicines in Delhi. METHODS: The quantity of drugs procured from the Essential Drugs List (EDL) and outside the EDL, money spent on these, changes in stock out days for key drugs. The implementation strategy includes elements of drug policy like use of EDL & STG, improved procurement system, training on drugs management & rational use of drugs. Retrospective data collected from stock registers. The data for two years before (1993-1994, 1994-1995) and two years after (2000-2001, 2001-2002) the drug policy was assessed. Data collected from two large public sector hospitals in Delhi that serve a large section of the population through 2007. RESULTS: After the implementation of the drug policy, the availability of drugs increased by 25% in the large and 98% in the medium hospital. The drugs procured from the EDL increased from 62% to 78% in the large and 74% to 87% in the medium hospital. Of the total expenditure, the money spent on essential drugs increased from 73% to 85% in the large and 87% to 93% in the medium hospital, whereas money spent on nonessential drugs decreased from 27% to 15% in the large and 13% to 7% in the medium hospital. The average number of stock out days for key drugs decreased from 33 to 16 days in the large and 16 to 1 day in the medium hospital. The need of health services by patients increased by 8% in the large and by 35% in the medium hospital. CONCLUSIONS: The implementation of the drug policy in the state of Delhi increased availability of essential drugs. This kind of intervention can serve as a model for improving access to medicines by implementing an effective drug.
OBJECTIVES: This study estimates the effect of national essential drug system on drug prices and availability of pilot grass-root medical institutions. METHODS: This study employs DID (difference-in-difference) method to investigate the effect of Essential Drug Reform Reform (EDRR) on drug price and patient selection of public grass-root medical institutions. Our sample comes from a Chinese city’s Urban and Rural Employee Basic Medical Insurance (URBEMI) database between 2004-2012. The full sample has 53416 observations including 2896 unique pharmaceutical firm-level products from 210 grass-root medical institutions. The dependent variable is the reference price of each product is released from each medical institution. The key independent variables are dummy variables indicating the implementing of pilot institutions (TREAT), the releasing time of Essential Drug Reform (EDRR) and interaction of them (TREAT*EDRR). RESULTS: The results show that after the implementing of EDRR, drug price on the pilot institutions decreased significantly by 37 percent (relative to control institution). Especially, essential drugs fell by 43.3 percent relative to control institution. This policy has no significant effect on non-essential drugs. To keep the reference prices diversity and avoid the common assess conclusion or views on the effect of reference pricing across all experiences, selected research covered different countries and backgrounds have little or no evidence showed the long-term expenditures reduction. RESULTS shows that reference pricing could decreases drug prices include in system and original and generic drug price reductions are different according to pharmaceutical markets power. Reference pricing increases drug use of priced before or at reference price. Reference pricing could save drug expenditures limited in the short-run but no sufficient evidence showed on the long-term expenditures reduction. Besides, no adverse effect was clearly found on patient access pharmaceutical services by reference pricing. CONCLUSIONS: Evidences indicates that reference pricing seems to be effective for governments to contain pharmaceutical expenditures and more research is need on the long-term effects and impact on different health care systems of pricing reference.
to 71.45%, because of unfair competition between pharmaceutical distribution companies and cooperation failure between pharmaceutical manufacturers and pharmaceutical suppliers. CONCLUSIONS: Successful pharmaceutical supply system of essential medicines needs to clearly define the function and to coordinate competition and cooperation relationship between pharmaceutical manufacturers, distributors, and hospital pharmacies.

**PHP16**

**CLASSIFICATION OF DRUGS BRINGING FROM ABROAD IN TURKEY ACCORDING TO THEIR ATC CODES**

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**OBJECTIVES:** There have been several strict cost containment measures, as reference pricing system and global budget, being applied in Turkish health care system especially for drugs. In more than 90% of all cases of shortages of the drugs, in Turkey the lowest price in Europe. In this regard, several drugs including the drugs being used in critical diseases such as cancer, orphan diseases etc. have been withdrawn from the market or even they wouldn’t be able to enter the market. The access to these drugs on time and SSI pays much more for these drugs compared to their cost in countries abroad, as this procedure takes some time, patients may have trouble in reaching the medicines. In this situation, despite government has brought these medicines from abroad, as this procedure takes some time, patients may have trouble in reaching the medicines. The aim of this study is to analyze the list of these drugs according to their ATC groups.

**METHODS:**

- The list of Social Security Institution (SSI) on drugs bringing from abroad (Annex 4 C) have been analyzed in assistance with RxMedicalPharma® Program. **RESULTS:** In total, there are 662 drugs being listed in the latest Annex 4-C list. Among this list, the most frequently listed ATC group is J (antiinfectives for systemic use) by 6,35% relatively. String cost containment measures being applied in Turkey causes shortages of several drugs especially the ones being used in diseases with high mortality rates like cancer and heart disease, and despite government has brought these medicines from abroad, as this procedure takes some time, patients may have trouble in reaching these drugs on time and SSI pays much more for these drugs compared to their probable prices in Turkey.

**PHP17**

**PRICING AND REIMBURSEMENT POLICY UPDATES IN ASIA**

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**OBJECTIVES:** Pharmacoeconomics and outcomes research (PER) has emerged as a key decision-making tool to optimize patient care and add value to health care services. The increasing strategic importance of Asian markets and economic constraints in the pharmaceutical sector, an understanding of current pricing strategies become vital for market authorization holders as well as payers. **METHODS:** An assessment of health care policies, pricing systems, and reforms Impacting reimbursement and market access environment was undertaken across major Asian markets (Japan, China, South Korea, and India). Information sources included online portals of regulatory agencies and relevant keyword searches. **RESULTS:** Health policy pricing reforms in recent years have indicated varying levels of priorities and pharmacoeconomic guidelines by 22%, second is A (alimentary tract and metabolism) by 13.3%, third is C (cardiovascular system) by 12.5%, fourth and fifth are N (nervous system) by 12% and J (antiinfectives for systemic use) by 6.35% relatively. String cost containment measures being applied in Turkey causes shortages of several drugs especially the ones being used in diseases with high mortality rates like cancer and heart disease, and despite government has brought these medicines from abroad, as this procedure takes some time, patients may have trouble in reaching these drugs on time and SSI pays much more for these drugs compared to their probable prices in Turkey.

**PHP18**

**PROVINCIAL HOSPITAL TENDING IN CHINA: EVALUATING THE IMPACT ON PRICE**

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**OBJECTIVES:** In China, maximum retail prices of reimbursed medicines are controlled at the national level by the National Development and Reform Commission (NDRC). At the provincial level, different tendering processes are used to procure medicines, often resulting in disparity between provinces and a significantly lower final price than the MRP. The objective of this research is to understand the differences in pharmacoeconomic tendering models and evaluate the resultant effect on medicine pricing. **METHODS:** We conducted secondary research of both national and provincial government websites to identify the different tendering models used across China. Provincial tender results were analyzed to understand the final price, tendering methods, and business dynamics within each MRP. Finally, a survey was conducted with payers in provinces with well-established tendering models including Anhui, Beijing, Fujian, Hebei and Shanghai - to understand the individual nuances. **RESULTS:** Tendering models exist on a continuum between “price focused” and “quality focused” processes. The former involves both the Anhui and Fujian models, and represents those whose cost is the main determinant of outcomes. The latter involves the more developed Shanghai model which encompasses a more holistic approach with consideration for the quality, patent status and degree of innovation a medicine. Analysis of published tender results show a significant variation between the resultant prices in different provinces, with as much as 50% difference seen between the tendering models. **CONCLUSIONS:** Our results demonstrate the large degree of variation between tendering processes in China. Although “price focused” models typically result in high downwards pricing pressure, “quality focused” models are more receptive of innovative medicines, thus, achieving price premiums is possible.

**PHP19**

**RECENT REGULATORY REFORMS TO ENSURE PATIENT SAFETY IN CLINICAL RESEARCH IN INDIA**

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**OBJECTIVES:** To study the Regulatory reforms and its impact on Clinical Trials in India. The present study involves the lacunae in conducting Clinical Trials and presents the Regulatory reforms in India. **METHODS:** India is an emerging destination for Clinical Research because of its genetic pool, availability of patients for enrolment, infrastructure and talented pool of physicians. In order to ensure patient safety in Clinical Trials several regulatory reforms have been implemented by the ministry of health and family welfare, Govt. of India. These include constitution of ethics committee’s, audio video recording of the consent, audit and inspections of the sites, registration of ethics committees etc. Compensation policy for deaths during the clinical trials have been framed. In order to ensure patient safety, National Pharmacovigilance Programme of India (NPvPI) have been launched in the country for the safety of patients by 6. drugs as a post marketing surveillance. NPvPI is working in coordination with the WHO Uppsala Monitoring Centre. The presentation will discuss the salient regulatory reforms for patient’s safety in clinical research in India. **RESULTS:** In order to ensure safety of patients in clinical trials, several regulatory reforms have been also included. The Ethical Review Boards have been properly strengthened. Serious Adverse Drug Reactions are being reported to the regulatory agency and compensations are being paid in the Clinical Trials. **CONCLUSIONS:** It is concluded that the new Regulatory Reforms will ensure the safety of the patients during the Clinical Trials.

**PHP20**

**DRUG UTILIZATION PATTERN FOR THE TREATMENT OF SEPTIC SHOCK IN THE ICU: A COMPARISON BETWEEN SURVIVORS AND NON-SURVIVORS IN A TERTIARY CARE TEACHING INSTITUTE**

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**OBJECTIVES:** To describe the drug utilization pattern in the treatment of patients with septic shock in the ICU. Setting: Critical care in a tertiary care teaching hospital in India. **RESULTS:** In the study period, 109 cases were identified. Upon presentation, the mean Acute Physiology and Chronic Health Evaluation II (APACHE II) score was 22.5 (SD ± 7.8), 93 (85.3 %) patients had sepsis and 84 (77.0 %) had positive cultures. The mean number of medications prescribed per patient was 11.7 (SD ± 4.7). The most commonly prescribed medication classes were proton pump inhibitors, carbenapenem, BL/BLI combinations and vasopressors prescribed in 101 (92.6 %), 75 (68.8 %), 64 (58.7 %), and 91 (83.4 %) patients, respectively Antiinflamig and blood products were prescribed in 45 (41.2 %) and 77 (70.6 %) patients, respectively. Medication usage were higher in non-survivors, compared to survivors (12.6 ± 2.4 versus 9 ± 3.1). In patients with positive cultures (11.5 ± 3.9 versus 9.3 ± 3.6) compared to patients with negative cultures. **CONCLUSIONS:** In patients with severe sepsis and septic shock, multiple medications were prescribed, and the use of medications was higher in the non-survivors in comparison to the survivors.

**PHP21**

**POTENTIAL RISK OF MEDICATIONS IN THE EVENT OF JOB LOSS**

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**OBJECTIVES:** Job loss has been shown to negatively affect displaced workers’ health and quality of life. It also affects medication adherence for prescription drugs. The purpose of this study was to examine the impact of job loss on the use of medications as measured by output of prescription for the last prescribed month. **METHODS:** Using a cross-sectional, self-administered survey. A sample of 312 displaced workers who did and did not experience involuntary job displacement. The data was drawn from four waves of the Medical Expenditure Panel Survey (MEPS), taken in 2008, 2009, 2010, and 2011. Involuntary job loss was defined as job separation due to “job elimination” (e.g. being laid off). The total sample consisted of 1272 respondents who participated in all five rounds of interviews. **RESULTS:** While the average out-of-pocket payment for the last prescription remained unchanged for those remained employed (around $23.20), the spending for those lost job increased by $2.82 ($19.41 vs. $22.23). Compared with those who remained employed, those who experienced...
involuntary job separation were significantly more likely to report zero expense on prescription drugs (odds ratio 1.37, 95% confidence interval [CI] 1.11–1.73). Among those with non-zero drug expenses, job loss was associated with 12.8% increase in the out-of-pocket payment for the last prescription while controlling for personal characteristics and the prescription payment before the job loss. CONCLUSIONS: The findings from this study indicate that job loss may impact on the health status of workers. Job loss may discourage workers from initiating drug treatment. For those already on medications, job loss is linked with an increase in drug expenses. It is clear the increase is caused by the worse health status after job loss or the use of medications to replace other more costly medical care.

PHP23 THE DYNAMICS OF PRICES AND QUANTITIES OF NEW DRUGS UNDER TAIWAN’S NATIONAL HEALTH INSURANCE PROGRAM
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OBJECTIVES: Technological change in medicine has been a major cause of rising health care expenditures in many countries. The adoption of new drugs plays an important role in accounting for the growth of spending on prescription drugs. This study was made to understand the prescriber potential and to also to know the preferences to the rural market. But there is very less understanding of the actual potential and associated with the price ratio. The pioneer product can maintain a relatively higher price ratio in a longer period, but the price ratio of new drugs for chronic diseases decreases more than that for acute diseases. The competition of therapeutic market increases the sales, but decreases the market share of new drugs. The pioneer product has a positive impact on the sales in dispersions of chronic and acute diseases. The sales of new drugs for chronic diseases are higher than that for acute diseases, but the growth of market share of new drugs for chronic diseases is lower than that for acute diseases. CONCLUSIONS: The competition in the therapeutic market does not affect the regulated prices at the time of entry, but decreases the price ratios associated with the price ratio. The pioneer product can maintain a relatively higher price ratio in a longer period, but the price ratio of new drugs for chronic diseases decreases more than that for acute diseases. The competition of therapeutic market increases the sales, but decreases the market share of new drugs. The pioneer product has a positive impact on the sales in dispersions of chronic and acute diseases. The sales of new drugs for chronic diseases are higher than that for acute diseases, but the growth of market share of new drugs for chronic diseases is lower than that for acute diseases.

PHP24 POTENTIAL PRESCRIBER MAPPING IN RURAL LOCATION OF SOUTH INDIA
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OBJECTIVE: As the majority of the Indian population still residing in India it is not only imperative to the pharmaceutical companies marketing medicines to foray into the rural market. But there is very less understanding of the actual potential and preferences of the rural health care practitioners. Hence in this study an attempt is made to understand the prescriber potential and to also to know the preferences of health care practitioners towards the company representative visits. METHODS: A questionnaire-based survey was designed to study the prescriber potential in 211 villages of rural India and 2423 doctors from Karnataka and Tamil Nadu, India. The survey design included a semi-structured questionnaire aimed at 191 physicians and 75 chemists. The data form the questionnaire was coded transferred to SPSS software to analyze. The data is summarized by descriptive statistics. RESULTS: It was also found that most non-Whites are aged 20 to 30 and only 11% doctors are well experienced. A key factor which affected doctor’s perspective on CAM was the lack of scientific evidences. The attitudes on CAM were basically shaped based on their personal CAM use rather than knowledge gained during an academic course. Lack of knowledge on CAM was also attributing to the doctors’ reluctance in CAM discussion with their patients. Though addition of CAM courses into the medical curriculum was proposed by some of the doctors, the practical implication was criticized as some found medical curriculum heavily packed with the biomedical courses. CONCLUSIONS: Majority of the doctors in this study were skeptical and uncertain about CAM due to lack of scientific evidence. Doctor-patient communication on CAM can only be improved when doctors’ knowledge on CAM can be improved by providing necessary training on CAM.

PHP25 A QUALITATIVE EVALUATION OF MALAYSIAN DOCTORS’ PERCEPTIONS TOWARDS COMPLEMENTARY AND ALTERNATIVE MEDICINES (CAM) IN THEIR MEDICAL PRACTICE, FACTORS THAT AFFECT THE REFERRAL TOWARDS CAM AND THE IMPACT OF THE MEDICAL PRACTICE MANAGEMENT ON THE DOCTORS’ PERCEPTIONS
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OBJECTIVES: The study aims to assess doctors’ perceptions towards Complementary and Alternative Medicines (CAM) in their medical practice, factors that affect the referral towards CAM and the impact of the medical practice management on the doctors’ perceptions. A qualitative research approach was adopted to gain a better understanding of the current perceptions and practice held by doctors’ within their medical professions. A key factor which affected doctor’s patient communication on CAM can only be improved when doctors’ knowledge on CAM can be improved by providing necessary training on CAM.

PHP26 HEALTH IMPLICATIONS OF THE MTM ELIGIBILITY CRITERIA IN THE AFFORDABLE CARE ACT ACROSS RACIAL AND ETHNIC GROUPS
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OBJECTIVE: Non-Hispanic Blacks and Hispanics are less likely than non-Hispanic Whites to be eligible for U.S. Medicare medication therapy management (MTM) services. The objectives for this study were to determine (1) racial/ethnic disparities in meeting MTM eligibility criteria as stipulated in the Patient Protection and Affordable Care Act (PPACA); and (2) whether there would be greater disparities in health and economic outcomes under mid-life and later age categories (if so, the PPACA MTM eligibility criteria may aggravate existing disparities in these outcomes). METHODS: Medicare Current Beneficiaries Survey (2007–2008) was analyzed. PPACA the MTM eligibility was compared between Whites and minorities using logistic regression. Various other regression models were used for other study outcomes (measures for health status, health services utilization/costs and medication utilization). RESULTS: MTM eligibility criteria, interaction terms, were included between dummy variables for race/ethnicity and MTM eligibility and were interpreted on the multiplicative term and using marginal effects. RESULTS: The sample consisted of 12,966 Medicare benign beneficiary individuals. Overall, 51.63% of Medicare beneficiaries are likely than Whites to meet PPACA MTM eligibility criteria (adjusted odds ratio [OR] = 0.66 [<P <0.05 for Blacks, and OR = 0.62 [P <0.05] for Hispanics). Racial and ethnic disparities in self-reported health status (SHPS), activity of daily living (ADLs), and instrumental ADLs were greater among the MTM-ineligible than the MTM-eligible populations (e.g., for SHPS, difference in marginal effects between Whites and Blacks = 27.25 [P <0.01] across MTM eligibility categories, and between Whites and Hispanics=20.63 [P <0.01]). Baseline socio-demographics and costs of physician visits among MTM-ineligible compared to MTM-eligible populations: No other variables exhibited significant interaction effects. CONCLUSIONS: The PPACA MTM eligibility criteria is not an ideal alternative in resolving disparity issues associated with Medicare MTM eligibility criteria. MTM eligibility criteria which reduce rather than aggravate disparities have yet to be identified/revised.

PHP27 PATIENTS AND DOCTORS WORKING TOGETHER TO IMPROVE HEALTH SERVICE: DIFFICULTIES AND CHALLENGES IN BETWEEN IN CHINA
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OBJECTIVE: To conduct a survey of the possible factors that cause the tension between patients and doctors. METHODS: The survey including 16 items (8 for patients and 8 for doctors) was conducted in one of the Level A hospitals in southwest region of China for a total of 853 questionnaires with 580 for patients and 273 for doctors respectively. Microsoft Excel 2007 was used to perform data extraction and analysis. RESULTS: The survey yielded to 822 questionnaires with a 96.24% response rate. Most of the patients (93.19%) want doctors to seek their opinions when providing the treatment. While 61.48% doctors indicated it was difficult to share decision-making with patients. Account for 60.47% patients would like to obtain information from doctors. Whereas, 52.75% of doctors expressed that it was difficult to provide patient with high quality and reliable evidence or information. Twenty percent of the patients didn’t fully satisfied with the existing treatment, while 63% doctors indicated that it was difficult to meet patients’ desire. The reasons for the difficulty in communication were mainly about: short communication time (50.48%) and improper communication method (37.07%). Only 14.65% of doctors expressed that they had enough time to communicate with patients. CONCLUSIONS: Lack of ‘communication openness’ was identified as a major factor which hindered the shared decision-making. A successful bidirectional way to encourage shared decision-making to alleviate the current tense relationship for both sides is needed.

PHP28 DRUG ACCESS IS IMPROVED BY THE ESSENTIAL DRUG SYSTEM AND “LOW-PRICED DRUG” POLICY IN CHINA
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OBJECTIVE: To evaluate the impact of “low-priced drug” policy on drug access in China through a comparison of national Essential Drug List (EDL) and specific provincial EDLs. METHODS: The study compared the general compliance of the EDL between China and eight provinces. The eight provinces included Jiangsu, Hebei, Zhejiang, Shandong, Hubei, Hunan, Guangdong, and Fujian, respectively. The EDLs from national departments and 31 provinces, apply descriptive statistics and comparison to summarize these policies’ impact. RESULTS: (1) On May 2013 China
PHN9

HEALTH CARE USE & POLICY STUDIES – Formulary Development

PHNP3

EVALUATION OF THE ECONOMIC IMPACT OF SPECIALIST OUTPATIENT CLINIC PHARMACY INTERVENTIONS IN A TERTIARY INSTITUTION, SINGAPORE

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OBJECTIVES: To evaluate the economic impact of Specialist Outpatient Clinic (SOC) Pharmacy interventions

METHODS: A retrospective study in Singapore General Hospital (SGH) SOC Pharmacy on the interventions made with physicians, between August 2012 and October 2014. Each intervention was analysed and assigned with an Estimated Cost of Avoidance (ECA) level, consented to by 3 pharmacists with varying clinical experience from 2 years to 15 years. The ECA level ranges from 1 to 8, with 1 having the least economic impact and 8 having the greatest economic impact. An ECA level of 8 has no economic impact as it signify non-acceptance of interventions by physicians. Subsequently, the economic impact per month is calculated by the total number of interventions in each ECA level, multiplied by the respective cost of avoidance, pre-determined for each ECA level based on national / institution standards, in Singapore Dollars.

RESULTS: The economic impact of SOC Pharmacy interventions is estimated to be ~SGD 900,000 over 3 months, with an average of ~SGD 300,000 per month. With an average of 56 prescriptions per month, it is estimated that our SOC Pharmacy interventions saves ~SGD 13 per prescription. Unlike traditional, direct methods to estimate the economic impact of pharmacy interventions, our results highlighted a great portion of cost savings to both institutions and pharmacists, with the pharmacy setting.

CONCLUSIONS: Interventions performed by Pharmacy staff have a great impact on cost savings to institution and also patients.

PHNP4

THE IMPACT OF THE INCOME PER CAPITA IN CHINESE FAMILY ON MEDICAL EXPENDITURE

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OBJECTIVES: In this paper, we use the panel data of China Health and Nutrition Survey (CHNS) in 2000, 2004 and 2006 to study the impact of the income per capita on the expenditure of health care.

Results: The results show that the income per capita in Chinese family on medical expenditure has a significant impact on the medical expenditure, and this impact is consistent and stable in the three survey periods.
Evaluation of Adverse Drug Reaction (ADR) Monitoring and Enhancing Risk Control Actions: More Research on Evaluating ADR Monitoring System

**Objectives:**
- To determine the prevalence of drug-related problems (DRPs) among patients referred to a multidisciplinary home-based medication review (HBMR) program for elderly Singaporeans.
- To evaluate the effectiveness of the program in resolving DRPs and reducing health service utilization (HSU).

**Methods:**
A retrospective case series was conducted at an academic medical centre in Singapore. Patients referred to the HBMR program between March 2011 and December 2012 were included. HBMR cases were conducted by a multidisciplinary team of pharmacists and care coordinators. DRPs identified were categorised and their outcomes (resolved/ unresolved) recorded by the pharmacist. HSU behaviour, consisting of hospital admissions, outpatient visits, emergency visits, and drug-related actions, was measured in terms of picking efficiency of each full-time equivalent (FTE) when measured in terms of picking efficiency of each full-time equivalent (FTE).

**Results:**
- Total of 5972 (SKMCHL), 7950 (ATHF), 8249 (DHQS) and 6325 patients referred to the HBMR program is useful in identifying and resolving DRPs.
- Of these, 34 (6.7%) and 174 (34.1%) DRPs were assigned to either the DDS or manual picking stations.
- For Allied Teaching Hospital Faisalabad there were 186 total errors were detected, in which prescription errors were the highest (n=68). For Shaukat Khanum Memorial Cancer Hospital Lahore, in which administration errors were the highest (n=92), and District Head Quarter Hospital Gujrat there were 266 total errors were detected, in which administration errors were the highest (n=96).

**Conclusions:**
- There were minimum numbers of medication errors observed in different hospitals, but the frequency of medication errors in private hospitals were lower than those observed in public hospitals. The roles of Pharmacists are needed to be enhanced so that these minimal errors should also be avoided.

**Survey Findings on Evaluation of Traumatologist’s Workload in Mongolia**

**Objectives:**
- We aimed to study the workload of traumatologist’s and analyze legal documents and materials relevant to medical professionals’ workload and labor status in the Mongolian health system and to identify the most common risk factors. In order to study the workload of doctors working at Trauma center, we used organization based observation and questionnaires to (1) define core job structure by constructional interview, (2) to evaluate by questionnaires with indicators of job evaluation.

**Results:**
- During 2008 to 2012, the number of ADRs were reduced from 602,000 to 1,000,000, of which serious ADR reports accounted for 13.3% to 20.0%. Reports from medical institutions declined from 85.7% in 2008 to 74.8% in 2012, while reports from pharmaceutical manufacturers and sellers increased from 10.4% to 24.4%. For the scope of monitoring, 34 provincial and 333 municipal ADR monitoring centers had established by 2012. The new ADR Monitoring Network System began running in 2011 and the number of network users rapidly increased from 34,000 to 150,000. For information processing efficiency, the average time lag between ADR occurrence and reporting was 23.6 days for overall and 20 days for serious cases. Regarding risk control actions, 33 National ADR Information Bulletin and 38 Pharmacovigilance Express were issued during 2008 to 2012. Services related to suspending or withdrawing medicines continued 4 times, along with 27 drug label modifications and 6 drug recalls.

**Conclusions:**
- China’s ADR monitoring system have achieved a progress in recent years and functioned well to some extent. Efforts are needed to remove the barriers in ADR reporting and enhance risk control actions. More research on evaluating ADR monitoring system is also warranted.

**Correlation Between Poison Severity Assessment and Outcome in Organophosphate Poisoning in Tertiary Care Hospital**

**Objectives:**
- To compare poison severity score with incidence of intermediate syndrome, ventilation and outcome in organophosphate poisoning.

**Methods:**
A retrospective study was conducted in a tertiary care teaching hospital of South India. Data was collected retrospectively from medical record section from 2012 to 2013 in a suitable designed case record form. Data was analysed by using SPSS 20.0 with chi-square and one wayanova. RESULTS: Total of 195 cases of organophosphate poisoning was documented out of which 135 (67.8%) were males and 64 (32.2%) were females. The average age in this group of patients was found to be 34.22 ± 14.26. The severity of the present pre-hospitalization period was 1.58 ± 2.07 days. Among them majority of the cases were suicidal (94.5%). Patients with a poison severity score of grade 1, 5.8% had intermediate syndrome. In grade 2 only 33.3% had intermediate syndrome and the most was seen in grade 3 where 60% had intermediate syndrome. Patients with a poison severity score of grade 2 had a recovery rate of 66.6% and patients with grade 3 had a recovery rate of 64.6%.

**Conclusions:**
- As the severity in poison severity score increases other parameters like ventilation, intermediate syndrome and mortality also increases. There is a strong correlation between the poison severity score and outcome of the patient.

**Detection and Evaluation of the Medication Errors in Different Hospitals in Province of the Punjab, Pakistan**

**Objectives:**
- The study was conducted to detect and evaluate the medication errors in different hospitals in province of the Punjab, Pakistan.

**Methods:**
A retrospective study was designed involving different hospitals namely: Shaukat Khanum Memorial Cancer Hospital Lahore, Mayo Teaching Hospital Lahore, Allied Teaching Hospital Faisalabad, District Head Quarter Hospital Sargodha, and District Head Quarter Hospital Gujrat of province of the Punjab, Pakistan. Medication errors were determined by the records of patients on period from October to December 2010. Errors were categorized into Prescription error, Dispensing Error and administration Error. Descriptive statistics were used to describe demographic and disease characteristics of patients. Percentages and frequencies were used to present the data.

**Results:**
A total of 5972 (SKMCHL), 7950 (ATHF), 8249 (DHQS) and 6325 (DHCQ) were registered. A sample of 4500 prescription from each of the hospital was taken for the study. A total of 349 errors were detected from Shaukat Khanum Memorial Cancer Hospital Lahore, in which administration errors were the highest (n=18). For Mayo Teaching Hospital Lahore there were 169 total errors were detected, in which prescription errors were the highest (n=60). For Shaukat Khanum Memorial Cancer Hospital Lahore the highest (n=92), and District Head Quarter Hospital Gujrat there were 266 total errors were detected, in which administration errors were the highest (n=96).

**Conclusions:**
- There were minimum numbers of medication errors observed in different hospitals, but the frequency of medication errors in private hospitals were lower than those observed in public hospitals. The roles of Pharmacists are needed to be enhanced so that these minimal errors should also be avoided.
mary and secondary outcomes between January and December 2013 were collected and analyzed. RESULTS: The median percentage of preventable drug-related incidents per month committed by manual picking (0.27) was significantly higher (p < 0.05) than the DDS (0.0). DDS had greater picking efficiency with each FTE in the DDS having an average of 6175 picks per month which was significantly higher (p < 0.05) than each FTE in the manual picking stations has an average of 459 picks per month. CONCLUSIONS: In summary, installation of DDS in an outpatient pharmacy improved safety of the prescription filling process by automating the medication picking process thus minimizing that the knowledge level of pharmacists and their awareness to two products, sunscreen care and depilatories, was very weak. RESULTS of this study indicates that the knowledge and awareness of pharmacists about properly usage of sunscreen cares, or suitable type of sunscreens for inpatients, has a significant impact on application of sunscreen cares. The application and acceptance of surrogate endpoints in the field of depilatories was very weak.

CONCLUSIONS: The majority of guidelines in markets evaluated mention the use of surrogate endpoints in some capacity, however, no guidelines contained an explicit statement regarding the acceptability of a surrogate in lieu of an established clinical endpoint. Payers acknowledge the importance of surrogate endpoints, but note that there needs to be further research into the potential impact of substituting these endpoints in pharmacoeconomic and regulatory decision-making. CONCLUSIONS: The application and acceptance of surrogate endpoints in Asia is still in its infancy, which is analogous to the use of these endpoints in clinical decision-making in Asia. Pharmaceutical economic and regulatory guidelines were evaluated from China, South Korea, and Japan, to determine if there was any explicit statement regarding the acceptability of surrogates, the cost-effectiveness of their use, or any attempt to model endpoint outcomes using surrogates. The study addresses the proper use of medications to ensure the best outcomes of pharmacological interventions.

COST ANALYSIS OF PHARMACEUTICAL SERVICE IN HOSPITAL: A CASE STUDY ON A TERTIARY HOSPITAL IN SICHUAN, CHINA

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OBJECTIVES: To determine what is wrong, the type and sources of drug-related problems (DRPs) facing inpatients and outpatients in a tertiary care hospital in Sichuan, China. RESULTS: The study was a cross-sectional survey of inpatients and outpatients, with a total of 206 inpatients and 257 outpatients. Interviews were conducted by trained pharmacy staff. A total of 300 medical records were reviewed. Among the inpatients, 50% of the DRPs were attributed to hospital admissions or visits, and to identify the drugs and patient groups that are most commonly involved. METHODS: Patients (n = 450) were selected randomly from patients presented to the ED during the study period (three month). Patient was eligible to be included if either visited ED or admitted due to DRPs. RESULTS: During the study period, 450 patients presented to ED were randomly selected with a mean age of 47.8 ± 27.7 years. One hundred and twenty of them were females (33.3%) and 280 were male patients (66.7%). Of these 450 patients, 38 (8.4%) were presented to ED due to DRPs, and 362 (81.6%) patients were presented to ED due to non-drug related problems. CONCLUSIONS: Most DRPs attributed to hospital admissions or visits were avoidable. Direct patient contact and the benefits of substituting these endpoints in pharmacoeconomic and regulatory decision-making. The study addresses the proper use of medications to ensure the best outcomes of pharmacological interventions.

UNDERSTANDING THE NEED AND VALUE OF SURROGATE ENDPOINTS FOR HEALTH CARE DECISION MAKING IN ASIA PACIFIC

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OBJECTIVES: Given the increasing cost and complexity of executing clinical trials and identifying statistically significant clinical endpoints, payers and decision makers are increasingly looking towards surrogate endpoints for guidance in decision-making. Examples include progression free survival as a surrogate for overall survival for oncology products and blood pressure as a surrogate for a variety of cardiovascular therapies. The purpose of this research is to evaluate the current landscape of surrogate endpoints in health care decision-making in Asia. METHODS: A literature review and several telephone interviews were conducted with payers and clinicians to evaluate the current landscape of surrogate endpoints and their use in clinical decision-making in Asia. Pharmaceutical economic and regulatory guidelines were evaluated from China, South Korea, and Japan, to determine if there was any explicit statement regarding the acceptability of surrogates, the cost-effectiveness of their use, or any attempt to model endpoint outcomes using surrogates. The study addresses the proper use of medications to ensure the best outcomes of pharmacological interventions.
and most important step that causes proper usage of such products as well as preventing the side effects from abuse of such products and for highly consumed products such as sunscreen cares and depilatories.

**PHPS3 IMPLEMENTATION AND ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTING SYSTEM AT TERTIARY CARE TEACHING HOSPITAL, KARNATAKA, INDIA: A DRUG CONTROLLER GENERAL OF INDIA INITIATIVE**

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**OBJECTIVES:** To implement the PSUR system in all wards of hospital. Reporting of PSURs for all the running newly launched drugs since 2011 in hospital periodically to DCG (I), New Delhi and assessment of the PSUR system functioning in the hospital.

**METHODS:** Prospective observational study. Drug safety reporting either manual or through online portal. Preparation and submission of PSURs as per Schedule Y of drugs and Cosmetics act, India. **RESULTS:** To implement the DCG (I) initiative, PSUR program, one PSUR committee, one drug safety review panel and one Delphi panel for PSUR system assessment has been constituted. Drug safety reporting and assessment tools are prepared and validated. A manual reporting system of drug safety has been set up and one link on hospital intranet website will be very soon available for online drug safety reporting through each ward and departments of hospital. Necessary training on drug safety reporting is provided to all health care professionals. Online hospital information services are in use to track the prescription of these drugs to the in-patients and then, these patients are extensively followed for any drug related problem during their hospital stay. All the associated drug safety reports are recorded in a database and a PSUR analysis is being done. Most popular economic evaluation techniques are assessed and coded using various scales, tools and softwares, e.g. Naranjo Scale, Hartwig severity scale and MedDRA coding software etc. PSUR system functioning in the hospital is assessed at regular time intervals through tool which is prepared and validated using Delphi technique. So far, since its inception two PSURs had been successfully submitted to DCG (I) at six months regular interval and third one is ready for submission. **CONCLUSIONS:** The present pioneering hospital based PSUR setup will create an environment for healthy safety reporting and helps the regulatory authorities for safety related decisions.

**PHPS2 STUDY ON AUDIT AND CONTROL SYSTEM AND ITS CURRENT SITUATION**

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**OBJECTIVES:** To study assessment and control the quality and the safety of hospitals in Mongolia. **METHODS:** The research has been conducted by cross-sectional study hospitals. However, other activities that develop quality are not implemented. **RESULTS:** In order to increase the quality and safety at the primary level hospitals the activity of special supporting (80.6%) and quality team control (66.7%) has been implemented, though, insufficient financing (33.3%) and professionals in quality control (19.4%) as well as special supporting activity has not been implemented (91.7%). The special supporting activity (87.0%) has been implemented (p<0.05) in the secondary level hospitals to increase the quality and safety, though, financing (31.5%) and professionals (38.3%) (p<0.05). The quality is conceptual idea, even though, this is a value that always could be felt and existed. The supporting activity (87.0%) and quality team (68.4%) are implemented (p<0.05) to develop the quality in the tertiary level hospitals, however, other activities that develop quality are not implemented. The participants in the study answered about the challenging issues are high at all hospital levels, such as long queue to receive health service (54.5%-76.5%), overload in the hospital (45.5%-72.3%) and referral to DCG (I) (72.3%). As well as, hospital professionals are susceptible to illness (31.3%-52.2%). **CONCLUSIONS:** Policy on quality and other related strategic documents are established 60-70% in the hospitals. Determination of health care and “determination of specialized health care standard through the diagnosis of the care” are insufficient at all level.

**PHPS6 ORGANIZATION POTENCY AND HUMAN RESOURCE**

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**OBJECTIVES:** The purpose of the study was identifying the main problems of improving health care quality, organizational safety and human resource. **METHODS:** Questionnaire with 15 questions to study human resource potency. Financial state and structure balance of 2007 and 2012. Questionnaire with 12 questions to study medical equipments potency Observational lists of internal and external environment safety of the hospitals. **RESULTS:** Totally 214 medical professionals were participated in the research: medical doctors 85 (39%), nurses 73 (34%), administration staff 16 (7%), and other staff 40 (19%). In 2007-2012 hospitals' funding were increased up to 80%, equipments potency Observational lists of internal and external environment safety conditions worsen to 20%. Therefore there is a need to organize trainings for administrative staffs and workers.

**PHPS4 PHARMAECONOMIC RESEARCH AND APPLICATION IN 10 ASIAN COUNTRIES BETWEEN 2003 AND 2013: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** To describe and analyze specific aspects of pharmaceutical research and application in 10 Asian countries in recent years from 2003 to 2013. **METHODS:** Our study concentrated on 10 Asian countries, including China, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam. Literature was collected and reviewed systematically from United States National Library of Medicine- PubMed. Grey literature was also taken into account. **PHPS5 ANALYSIS OF PRECING PREMIUMS GRANTED THROUGH SUBMITTING LOCAL RCT AND PHARMACOECONOMICS DATA IN TAIWAN**

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**OBJECTIVES:** The purpose of this study was to understand the drivers of the pricing premiums for granting submitting local RCT and/or local pharmacoeconomics (PE) data through Taiwan’s two-stage new drug listing and reimbursement assessment (PSUR) program, one PSUR committee, one drug safety review panel and one Delphi panel. **RESULTS:** The 11 products that submitted local RCT and/or local PE data in their reimbursement submission to the NHIA between January 2012 and March 2014 were analysed in this study. **CONCLUSIONS:** The 6 products that submitted local RCT data, 3 received the maximum 10% pricing premium for submitting these data. Abatacept was not granted any premium for not being a new molecule and benidipine hydrochloride was not granted any premium since its price comparator was an existing product that was already priced based on local data. Sorafenib has yet to receive a decision for the premium granted. Of the 7 products that submitted local PE data, 5 received a premium. 2 received a 1% and 2% premium respectively for submitting data with high quality and 1 received a premium for using local PE data. Of the 4 products that submitted local RCT and PE data, 2 received a 5% premium for submitting data that were well accepted by the NHIA. 2 products did not receive any premium, as their data were considered incomplete and insubstantial or inappropriate. **The submission of PE data appears to increase the product’s cost-effectiveness against the comparator. **CONCLUSIONS:** A 10% pricing premium through local RCT data is likely achievable as long as the product with local RCT data is a new molecule whose comparator has not been priced based on its local data. On the other hand, achieving the maximum 10% pricing premium for submitting local PE data seems difficult to achieve, as of now, a 5% premium seems to be the maximum achievable. A premium as low as 1-2% is likely if there is any uncertainty in the data.

**PHPS5 REVIEW OF TAIWAN NHIA’S TWO-STAGE NEW DRUGS LISTING AND REIMBURSEMENT ASSESSMENTS (2013-FEB 2014)**

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**OBJECTIVES:** In Taiwan, the Second-Generation National Health Insurance (2G-NHI) Act was implemented since Jan. 1st, 2013. Thereafter, listing and reimbursement of new products are 2-stage assessments performed by the Expert Advisory Committee (EAC) and Pharmaceutical Benefits Reimbursement Scheme (FPRS) of National Health Insurance Administration (NHA). EAC primarily evaluates clinical comparativeness, effectiveness and safety of new products, and assessments are rated as Category 1 (substantial improvement), 2A (moderate improvement) or 2B (similar) compared to currently available standard therapy/s [2]. We also used ECA’s approach to analyse the reimbursement decisions and further appraises the EAC’s suggestions and make final reimbursement recommendations. **RESULTS:** The objective of this study was to analyse the trends of the FPRS appraisals for 11 new molecular entities. **CONCLUSIONS:** A total of 33 new drugs underwent EAC assessments and FPRS appraisals were reviewed for their Categories. Further analysis was conducted to understand the trends based on the therapeutic indications and comparators. **RESULTS:** There were 21 new drugs under the reimbursement meeting. Approximately 57% of them were rated as Category 2B, 38% as Category 2A, and only 5% as Category 1. A new revealed that Category 2B new drugs were easier to be listed and reimbursed. The only Category 1 new product was an orphan drug in western countries used to mobilize haematopoietic stem cells for autologous transplant.
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plantation purpose. Almost all Category 2A new drugs fulfilled the unmet medical needs while Category 2B low on innovation control, toxicology therapy in preterm labor, or new mechanism for cardiovascular disease. CONCLUSIONS: Category 2B new drugs with less financial impact to NIH system seem easier to reach listing and reimbursement goal in the 2-stage assessments. Reasonable budget impact and cost-effectiveness analysis are as important as robust composition of the products. 42 molecules which were sold in each country for the period. The countries were assigned the product with the price at the WHO reference price. The product brands were accessed for the analysis. RESULTS: Pharmaceutical price indices vary substantially between regions. The Asian regions recorded the lowest prices. The indices were as follows: South-East Asian Region D 0.21; South-East Asian Region C 0.35; Western Pacific Region B 0.46; Eastern Mediterranean Region A 0.45; African Region E 0.46; European Region C 0.49; Western Pacific Region B 0.51; Eastern Mediterranean Region D 0.54; Region of the Americas D 0.87; Region of the Americas C 1.11. CONCLUSIONS: This is the largest exercise ever undertaken in comparing international pharmaceutical prices. It also employs a more robust method than previous studies. The analysis shows Asian region pharmaceutical prices are the lowest in the world.

PHP57 AN ANALYSIS OF THE KEY VALUE DRIVERS FOR HTA ASSESSMENTS IN TAIWAN

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OBJECTIVES: The purpose of this study was to identify the main value drivers behind the innovation category designations (1, 2A, 2B) assigned during the Taiwanese reimbursement process. METHODS: All products assessed for reimbursement from January 2007 to December 2014 by the National Health Insurance Administration (NHIA) were considered in this analysis. The details of the assessments have been extracted from the NHIA meeting minutes and Center for Drug Evaluation (CDE) reports. RESULTS: Category 1 designations are given to drugs that show “substantial clinical benefit” and Category 2A designation is given to drugs that exhibit “moderate improvement”, and Category 2B designations to drugs that provide similar clinical value to comparators. Since 2012, 94 of 113 products received positive decisions from the NHIA. 26% received Category 1 (3%). Most Category 2 drugs were considered as alternative therapeutic options with similar efficacy (94%) to an existing product; others were considered to provide better clinical value but a larger budget impact or higher price than the cost of the new drug. A drug was considered to provide clinical efficacy, safety, or convenience over the comparator (53%). Of the 2 Category 1 products, plerixafor was rewarded for its curative potential in hematologic malignancies, as well as its potential reduction of hospitalisation costs; azacitidine was rewarded for being a first-in-class therapy for Myelodysplastic Syndrome. 22 of 94 products did not receive any category, as they were indication expansions. 17 of 113 assessed products had their reimbursement decisions due to their significant budget impact (59%) or lack of clinical benefit (41%). 2 out of 113 decisions are pending. CONCLUSIONS: Both clinical and economic considerations heavily drive the assessment outcomes in Taiwan. In order to achieve a positive assessment outcome in Taiwan, a product needs to provide a combination of favourable clinical and economic data.

PHP58 FROM REGULATORY APPROVAL TO SUBSIDISED PATIENT ACCESS IN THE ASIA-PACIFIC REGION: A COMPARISON OF SYSTEMS ACROSS AUSTRALIA, CHINA, JAPAN, KOREA, NEW ZEALAND, TAIWAN AND THAILAND

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OBJECTIVES: Pharmaceuticals can be marketed when regulatory approval has been obtained. However other barriers may need to be cleared before patients can gain access to subsidised medicines. In the Asia-Pacific region these subsidised systems are often government programmes and range from national tax funded schemes (Australia Human Health Benefits Schedule) through to coverage of a specific population (Thailand Social Security Scheme for office workers). Navigating these systems can be as simple as submitting a pricing application or as complex as a full societal health technology assessment. The aim of this study is to compare the processes and timings between regulatory approval and subsidised access to medicines across the Asia-Pacific region. METHODS: Reimbursement guidelines and different jurisdictions in the Asia-Pacific region were reviewed. Differences in time from regulatory approval to subsidised access were captured between Australia, China, Japan, Korea, New Zealand, Taiwan and Thailand. RESULTS: Only Australia and Thailand allows evaluation of reimbursement in parallel with regulatory approval. Parallel processing was also captured in Korea and Taiwan but has not been implemented. The time between regulatory approval and subsidised access across jurisdictions. In general additional processes such as health economic evaluation, pricing negotiation, budget approval and administration prolong time to subsidised access well beyond 6 months post regulatory approval. Japan is unique as a reimbursement price should be published in the innovation category designations (1, 2A, 2B) assigned during the Taiwanese reimbursement process. RESULTS: Pharmaceutical price indices vary substantially between regions. The Asian regions recorded the lowest prices. The indices were as follows: South-East Asian Region D 0.21; South-East Asian Region C 0.35; Western Pacific Region B 0.46; Eastern Mediterranean Region A 0.45; African Region E 0.46; European Region C 0.49; Western Pacific Region B 0.51; Eastern Mediterranean Region D 0.54; Region of the Americas D 0.87; Region of the Americas C 1.11. CONCLUSIONS: This is the largest exercise ever undertaken in comparing international pharmaceutical prices. It also employs a more robust method than previous studies. The analysis shows Asian region pharmaceutical prices are the lowest in the world.

PHP59 A COMPARISON OF ASIAN AND GLOBAL PHARMACEUTICAL PRICES USING AN EKOS METHOD

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OBJECTIVES: The study aimed to determine the differences between Asian and Global pharmaceutical prices. METHODS: The indices were developed using the Fisher Eitemto, Koves, Szulc (EKOS) method. The EKOS method is widely used by the Organisation for Economic Co-operation and Development (OECD) but has not yet been applied to pharmaceutical prices. IMS MIDAS data was used to estimate prices and sales volumes. In order to construct the indices, the products needed to be defined as like. The definition of like in this study was based on molecules which are deemed to deliver equivalent health outcomes. The price indices were developed for countries in World Health Organisation (WHO) regions. The analysis compares prices across 56 countries over the period from 2005 to 2011 and included

42 molecules which were sold in each country for the period. The countries were assigned the product with the price at the WHO reference price. The product brands were accessed for the analysis. RESULTS: Pharmaceutical price indices vary substantially between regions. The Asian regions recorded the lowest prices. The indices were as follows: South-East Asian Region D 0.21; South-East Asian Region C 0.35; Western Pacific Region B 0.46; Eastern Mediterranean Region A 0.45; African Region E 0.46; European Region C 0.49; Western Pacific Region B 0.51; Eastern Mediterranean Region D 0.54; Region of the Americas D 0.87; Region of the Americas C 1.11. CONCLUSIONS: This is the largest exercise ever undertaken in comparing international pharmaceutical prices. It also employs a more robust method than previous studies. The analysis shows Asian region pharmaceutical prices are the lowest in the world.
aged 39 days (17 days for oncology and 14 days for orphan drugs). Across the EU, Germany was fastest while Italy was slowest. Critical pathways in Japan include the Central Social Insurance Medical Council (Chuikyo) using the similar efficacy general pathway, and comparing with European routine. METHODS: Targeted searches were conducted in PubMed and the latest released official documents published by January 2014, to collect information regarding Chinese reimbursement process. Differences between Chinese process and European routine are considered. RESULTS: The Chinese process is qualitative, non-transparent, and not comparable with European routine. China is the third largest pharmaceutical market in the world. The aim of this study was to describe Chinese reimbursement process, assess current policies and provide the addressee viewpoint of Europeans difficulties to understand the Chinese reimbursement process. METHODS: This study aimed to compare and make the European and the Chinese reimbursement process transparent. OBJECTIVES: China is the third largest pharmaceutical market in the world. The aim of this study was to describe Chinese reimbursement process, assess current policies and provide the addressee viewpoint of Europeans difficulties to understand the Chinese reimbursement process. METHODS: This study aimed to compare and make the European and the Chinese reimbursement process transparent. OBJECTIVES: China is the third largest pharmaceutical market in the world. The aim of this study was to describe Chinese reimbursement process, assess current policies and provide the addressee viewpoint of Europeans difficulties to understand the Chinese reimbursement process. METHODS: This study aimed to compare and make the European and the Chinese reimbursement process transparent. OBJECTIVES: China is the third largest pharmaceutical market in the world. 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this study was to assess the trends which drive risk sharing agreements with the Pharmaceutical Benefits Advisory Committee (PBAC) for obtaining reimbursement for pharma- cological alternatives. METHODS: All PBAC decisions from August to November 2013 were surveyed by looking at the general RSA structures outlined in the PBAC guidelines. The fol- lowing data were extracted from each appraisal: assessment outcome (positive or negative), additional data provided (such as CDE reports and HIRA reports), the total cost-effectiveness ratio, market size, structure of trial, trial outcomes, and the availability of cost-effectiveness analysis. RESULTS: The analysis revealed that 44% of PBAC decisions incorporated some form of an RSA, and 91% of products with RASs received a positive PBAC decision. The majority of RASs were rebate recovery or price volume arrangements, where the PBAC was concerned with the product’s use in a larger than specified population. CONCLUSIONS: The results of this study indicate that the PBAC readily enters into RASs when doubt exists surrounding the potential cost or efficacy of a drug. Accurately identifying areas of product risk and proposing an RSA to address it can lead to a favourable decision from the PBAC.

PHP70
CORRELATION OF RECENT HTA DECISIONS BETWEEN TAIWAN AND KOREA: IMPLICATION FOR LAUNCH STRATEGIES
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OBJECTIVES: The objective of this study was to compare the Health Technology Assessment (HTA) timing and decisions for recently launched products in South Korea and Taiwan, and to provide insight into launch strategies in these markets. METHODS: We analysed all products that were assessed for reimbursement by the National Health Insurance Administration (NHIA) in Korea and the Centre for Drug Evaluation (CDE) in Taiwan from January 2012 to March 2014. Where relevant, the details of the assessment and decision as well as the details of the HTA timing and decisions were extracted from the NHIA meeting minutes, CDE reports and HIRA reports. RESULTS: Since January 2012, 17 products were assessed by the reimbursement authorities in both Korea and Taiwan. 12 products received positive reimbursement decisions. Assessment details of two products had divergent results. Of 12 products that received the same decisions, seven products were first assessed and reimbursed by Korea and then also reimbursed in Taiwan, while only three products were first assessed and reimbursed by Taiwan and then also reimbursed by Korea. The other two products were assessed at the same time in both countries. Of 5 products that received different reimburse- ment decisions, two products were first assessed by Korea and then also reimbursed in Taiwan later, while only three products were first assessed and reimbursed by Taiwan and then also reimbursed by Korea. The other two products were assessed at the same time in both countries. Though the sample size is limited, these data suggest a possible positive influence of Korean HTA decisions on those in Taiwan. The average time difference between the Korea and Taiwan HTA assessments was 7.7 months, while Taiwan-HTA assess- ments lagged behind Korea by 2.6 months. CONCLUSIONS: In general, Taiwan HTA assessments lag behind Korea by 2-3 months. This may result from a proactive launching strategy from manufacturers, as HTA decisions made in Korea may have a positive influence on those in Taiwan.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP71
A CRITICAL REVIEW OF CHINESE PHARMACOECONOMICS STUDIES IN THE LAST FIVE YEARS
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OBJECTIVES: More papers about pharmacoeconomics and outcome research were published in China. The aim of this study was to evaluate the quality of Chinese pharmacoeconomics study and outcome research through analyze papers published in the peer-reviewed literature in Chinese over the last five years. METHODS: We conducted full text paper searches in public databases from 2009 to 2013 in China. A search strategy and inclusion criteria were set up to iden- tify the articles to be included. The search identified 820 studies, of which 411 were included. Then papers were evaluated through a framework which was based on Pharmacoeconomics guideline. RESULTS: Our results showed that a large number of published studies were of suboptimal quality. Most of pharmacoeconomics and outcome research were conducted by doctors (33.6%) and pharmacists (54%) in China. Prospective studies (65.9%) were the most common study design, while most data were derived from the clinical trials; Only 8% of them included articles clearly stated the study perspective; More than half studies (56.2%) only computed drug expenditure in cost estimation; 2.2% of articles conducted discounting; 63.5% of studies performed the incremental analysis, however, most studies presented the cost-effectiveness ratios as incremental cost-effectiveness ratio; Sensitive analysis were reported by 71.3% of the included studies, nonetheless, the choice of variables for sensitivity analysis wasn’t justified. A few studies (7.3%) presented the transferability of the results. CONCLUSIONS: The above data signify that the quality of pharmacoeconomic evaluations needs improvement. There were just few studies which had well-designed schemes, high-qualified data and suitable methodology, partly owing to the doctors and pharmacists’ lack of pharmacoe- economics expertise and knowledge. It implied China should improve the training of pharmacoeconomics and outcome research training in doctors and pharmacists. Moreover, a further study of the new technology on pharmacoeconomics should not be neglected.

PHP72
APPLICATION OF THE METHODS OF EVIDENCE BASED MEDICINE FOR THE ANALYSIS OF EUROPEAN HEALTH SYSTEMS AND HEALTH POLICY APPROACHES
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OBJECTIVES: Evidence based medicine has been used for about two decades as a methodology for obtaining, presenting and presenting health related topics. The present study investigated the question of the appearance of the ideas of evidence based medicine in documents describing the functioning of European health care systems. METHODS: The documents available in the European Observatory on Health Systems and Policies database were considered to reliably represent the health system of European countries. Structured text analysis was carried out according to previously described methodology. All evaluation steps were carried out in parallel by two researchers (K.M. and S.L.). Two studies carried our previously on related topics were used to relate the results obtained in the present study with data of the literature. RESULTS: The cumulative length of the documents was 6449 pages; there was no document without mentioning evidence based medicine. Among the various mentions of evidence based medicine, we were able to categorise 208 representations of the idea into one of the following 4 topics: 1. resources of health care, 2. health technology assessment, 3. organisation of health care and 4. environment of health care within the society. Evidence based medicine was mentioned 57 in connection with the resources of health care, whereas 31 mentioning were related to health technology assessment. Organisation of health care was men- tioned least as evidence based medicine at 56 occasions, whereas the idea of evidence based medicine was related to the social environment of health care in 64 instances. CONCLUSIONS: The results of the present data collection indicate that the methodology of evidence based medicine has already been widely used within the documents describing health systems and policies in Europe. However, there were considerably differences in the extent and depth of applying evidence based medicine methodology.

PHP73
PHARMACOECONOMICS AND ITS APPLICATIONS – EMERGING ROLE IN INDIA
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OBJECTIVES: Pharmacoeconomics is the application of economics to assess health care products or health technology and health care interventions. It gives clinical and humanistic outcomes of health care products and interventions. It gives health care decision makers, providers and patients with valuable informa- tion for optimal use and allocation of limited health care resources. In India, the idea of Pharmacoeconomics and RtS emerged at the 1990s. Pharmacoeconomics and RtS is relatively low among policy makers, academia and industry. As India’s pharmaceutical market changes and evolves, the study of pharmacoeconomics and associated research is expected to gain momentum. METHODS: Secondary research was conducted using PubMed. Several search terms like “pharmacoeconomics”, “cost minimization”, “cost benefit”, “cost utility”, and “cost effectiveness” analysis were used. These terms were also used in different combinations, e.g., “Cost Minimization Analysis and Pharmacoeconomics” and “Cost Benefit Analysis and Pharmacoeconomics”. The results of this study were then analyzed to examine the trends which drive pharmacoeconomics in India. Results: “Cost Minimization Analysis and India Pharmacoeconomics” gave only two results. Fifteen results were obtained for the search “Benefits Assessment and Pharmacoeconomics”. Out of which four studies were relevant to the objective. “Cost Utility Analysis and Pharmacoeconomics and India” resulted in 4 results out of which two were comparative results of two types of costs (cost minimization analysis) and cost effectiveness analysis and pharmacoeconomics and India” resulted in 15 results; 10 in last 10 years and only 2 were relevant. CONCLUSIONS: As seen from the results, not many pharmacoeconomics researches have been conducted in India suggesting the dearth of literature in this area in India. As the India pharmaceutical market evolves and policies change, greater amount and rigorous pharmacoeconomics research may be needed.

PHP74
FOSTERING PATIENT SAFETY CULTURE IN HOSPITAL TO IMPROVE HEALTH CARE SERVICE. HOSPITAL SURVEY ON PATIENT SAFETY CULTURE
Jia P1, Zhang L1, Mao X1, Zhang M1
1Sichuan University, Chengdu, China
OBJECTIVES: To explore the attitudes and perceptions of patient safety culture for health care workers in China by using a modified Hospital Survey on Patient Safety Culture (HSPSC) questionnaire. METHODS: The survey measuring 10 dimensions of patient safety culture with 36 items was conducted from 32 hospitals in 15 cit- ies all across China. We computed descriptive statistics and Chi-Square test was performed to explore the differences on the perception of patient safety culture in groups of different work units, positions and qualification levels. SPSS 17.0 was used to perform data extraction and analysis. RESULTS: A total of 1500 question- naires were distributed of which 1160 were responded validly (response rate 77%). Seven hundred and twenty two (66%) of the respondents were nurses, 386 (33%) were surgical clinicians and 343 (30%) were internal medicine clinicians. The posi- tive response rate for the 10 patient safety culture dimensions ranged from 45% to 88%, the mean positive response rate was 65%. The lowest positive response rate of dimension was “Staffing” (45%), while the highest positive response rate of dimension was “Organizational Learning-Continuing Improvement” (88%). The positive response rate of two dimensions of nurse was lower than that of physicians (“Overall Perceptions of Patient Safety” and “Communication Openness” P < 0.05). Furthermore, the positive response rate of physicians with high qualification (chief physicians) on two dimensions (“Overall Perceptions of Patient Safety” and “Communication About Errors” P < 0.05) was higher than those having a low qualification level (resi- dents). CONCLUSIONS: The results show that amongst the health care workers surveyed in China there was a positive attitude towards the patient safety culture within their organizations.
HPF76 HEARING THE PATIENT’S VOICE IN HEALTH CARE: A SURVEY ANALYSIS OF PATIENTS’ PERCEPTIONS OF DIFFICULTIES IN SHARED CLINICAL DECISION-MAKING
Jia P, Zhang L, Mao X, Zhang M
Sichuan University, Chengdu, China
OBJECTIVES: To explore the factors which affect shared decision-making and develop strategies to get patients actively involved in clinical decision-making. METHODS: The survey was conducted in one of the third-grade hospitals in southwest part of China for a total of 565 patients involved. SPSS 17.0 was used to perform data extraction and analysis. RESULTS: The survey yielded to 600 questionnaires with a 94% response rate. There were 68% of patients who had some knowledge of the disease. Most of the patients (92.94%) have a positive attitude to participate in clinical decision making and 95% patients hope to know the medical information of treatment. Account for 60.24% patients would like to obtain information from doctors. While, only 46.21% patients can achieve the goals. Meanwhile, There were 79.2 % patients who are satisfied with the current treatment plan. The patients’ biggest concerns were: treatment effect, cost and doctors’ skills. The biggest difficulties that patients faced were: not enough information and patients could hardlyornot how to make a decision. CONCLUSIONS: Combined with research results, we give some suggestions. Firstly, perfect the compensation mechanism of medical system and enhance patients’ self-efficacy. Secondly, make a equal land expropriation reasonably, and avoid farmers suffering from the jobless situation. Thirdly, develop the family doctor system actively. Fourthly, develop the country’s number of medical staffs, reduce the families’ numbers of the RELAH and ensure them have families’ accompanying when ill.

HPF78 ASSESSING THE EFFECTIVENESS AND COST-EFFECTIVENESS OF AUDIT AND FEEDBACK ON PHYSICIAN’S PRESCRIBING INDICATORS
Solamonya Fülöp, Rashidian A., Dinandt R., Kebrabasea A., Hosseini M., Abdollahi M.
Ministry of Health, Tehran, Iran, 2Tehran University of Medical Sciences, Tehran, Iran
OBJECTIVES: To improve the effectiveness and cost-effectiveness of prescribing audit and feedback intervention in improving physician prescribing. METHODS: A four-arm randomized clinical trial with economic evaluation conducted in Tehran. Three interventions (routine feedback, revised feedback, and printed educational material) and a no intervention control arm compared. Physicians working in outpatient practices were randomly allocated to one of the four arms using stratified randomized sampling. Each intervention was developed based on a review of literature, physician interviews, current experiences in Iran and with theoretical insights from the Theory of Planned Behavior. Effects of the interventions on improving antibiotics and corticosteroids prescribing in relation to quality and cost were assessed from a health care provider’s perspective and incremental cost-effectiveness ratios calculated. RESULTS: Comparing the new-design feedback arm and the no intervention arm, we observed significant reductions in the proportion of prescriptions including Dexamethasone, (1.64 difference in percentage change; p value: 0.006) and Cefixime (0.99 difference in percentage change; p value: 0.01). We also observed significant reductions in the printed educational material arm’s proportion of prescriptions including Cefixime (0.93 difference in percentage change; p value: 0.04) as compared with the no intervention arm. ICER values corresponding to Dexamethasone incretable and Cefixime were 0.41 and 1.03 US$ per unit reduction in the number of prescriptions respectively. CONCLUSIONS: According to the results of this study, we recommend a four-arm design, and the way the messages are conveyed in feedback forms is an important indicator of audit and feedback’s potential success in improving prescribing behavior. Considering the increased effectiveness of the cost-effectiveness of new-design feedback intervention arm has been proved.

HPF79 TRAINING HIGH-LEVEL LOCAL RESEARCHERS TO IMPROVE THE QUALITY OF CLINICAL STUDIES IN DEVELOPING COUNTRIES: CHALLENGE AND STRATEGY
Zhou X., Sun X., Li Y.
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OBJECTIVES: Analyzing all randomized controlled trials (RCTs) published in The Lancet in 2013 to discuss the influence factors on the publication of high-quality clinical studies. METHODS: A systematic search included all RCTs published in The Lancet in 2013. The information about the research topic and the number of included participants, first author’s research background, and the type of research institutions were collected, and analyzed their proportions. RESULTS: 110 eligible RCTs with 734,085 participants were included. The top three topics of the RCTs were infectious diseases 22 (20.0%), cardiology and vascular medicine 17 (15.5%), oncology 12 (10.9%), but the top three number of participants were 210,350 (28.7%) in obstetrics and gynecology, 198,471 (27.0%) in oncology, and 154,637 (21.5%) in infectious diseases. The proportion of RCTs which enrolled participants from developed countries was 86.4%, only 13.6% ones enrolled participants in developing countries. The first authors from the developed and developing countries were 87.3% and 12.7% respectively. The proportion of RCTs which was the same as participants, 52.7% RCTs were done by universities, only 25.2% and 13.6% were conducted by hospitals and research institutions respectively. CONCLUSIONS: Developing countries have a much heavy burden of disease and serious shortage of high level clinical researchers. Using results from developed countries to guide the prevention and treatment of even the same diseases in the developing countries may not proper due to various local conditions. We appeal to promote the cooperation between the universities and hospitals in the developed and developing countries. The localization of the training material should be encouraged to train more high-level local clinical researchers and produce more high-quality clinical evidences for the developing countries through joint-program.
MARK-UP, nevertheless, 6 out of the 7 local CEA studies have received 1% to 5% mark-up outcomes. A comprehensive search of electronic databases (EMBASE, PubMed, Cochrane Library, Web of Science, CINAHL, CNKI, VIP, CBR and Wangfang) and HTA websites were completed after October 9, 2013. Two trained reviewers independently screened for eligible studies, extracted data and assessed quality. Qualitative description was used to report the outcomes. RESULTS: After an initial screen of 272 studies, 18 studies (n=45,516) were selected for meeting inclusion criteria: 3 studies with 32,499 patients were health and 15 studies with 13,877 patients were systematic reviews. The clinical and cost-effectiveness of DVS was varied between diseases. Overall, DVS was shown to be associated with a reduction in operative time, length of hospital stay, blood loss, and transfusion rate compared with open and laparoscopic surgery on prostatectomy, nephrectomy, and hysterectomy colorectal surgery. DVS was more expensive than open and laparoscopic surgery for the cost of acquiring, operating, and maintaining the robotic techniques. Most economic studies showed no significant difference was found in cost-effectiveness of DVS comparing with comparators. CONCLUSIONS: DVS may have an impact on several clinical outcomes. However, the evidence was limited to systematic review and health economic evaluations. Furthermore, the cost of DVS is higher than open laparoscopic and laparoscopic surgery. Taking all of this evidence together, decisions about the robot-assisted surgery need to be made carefully.

THE PERFORMANCE OF THE PRAGMATIC STRATEGY TO BRING IN PHARMACOECONOMIC EVIDENCE FOR DRUGS REIMBURSEMENT DECISIONS IN TAIWAN

OBJECTIVES: Local pharmacoeconomic evidence was seldom included in the manufacturers’ new drugs submission in Taiwan before. A series of pragmatic strategies were conducted to encourage the presentation of pharmacoeconomic evidence (CEA) in the dossiers. This study aims at examining the performance of these strategies. METHODS: An incentive of mark-up for conducting local CEA studies has been provided by the National Health Insurance Council to encourage manufacturers to submit CEA evidence for new drugs reimbursement application. The National Health Institute of Health Assessment Technology (NIHTA) has started to use a self-developed checklist (Checklist Epoch): mid-2012 till 2013. The number and the quality of local CEA evidence identified from the dossiers submitted by the manufacturers in the three epochs were compared. RESULTS: In the Mark-up epoch, no local CEA evidence has been presented in the dossiers. However, 5 and 7 local CEA studies have been identified from the dossiers in the Mark-up epoch and the Checklist epoch, respectively. None out of the 5 local CEA studies has received the mark-up, nevertheless, 6 out of the 7 local CEA studies have received 1% to 5% mark-up for the reimbursement price. CONCLUSIONS: The pragmatic strategy seems an effective approach to encourage the manufacturers to present local CEA evidence in the dossiers, which could improve the quality of decision making. In addition, the capacity of conducting local CEA studies has been gradually established.

OBJECTIVES: The special committee of cost-effectiveness at the Japanese health ministry advisory panel was established in 2012 and the need for economic evaluation guidelines was proposed. The research team funded by the Japanese Ministry of Health, Labour and Welfare released the guidelines for the promotion of health care technologies in 2013. We compared the Japanese guidelines to existing guidelines in other Asian countries and to the NICE guidelines (UK). METHODS: We reviewed the evidence submitted in HTA processes in Taiwan, Thailand and South Korea up to February 2014. Similarities and differences between Japanese guidelines and those from other Asian countries as well as NICE guidelines were identified. RESULTS: Pharmacoeconomic evaluations are mandatory in the UK, South Korea and Thailand, recommended in Taiwan, and optional in Japan. In Japan, economic evaluations are currently not formally considered in pricing and reimbursement decisions. Japanese guidelines are relatively open, leaving room for discretion and analysis. Guidelines of different countries were broadly consistent in terms of preferred analytical technique (cost-effectiveness analysis), need of systematic reviews of evidence and consideration of effectiveness data as well as efficacy, but varied in terms of other factors (e.g. health states and costs). CONCLUSIONS: This comparative exercise provides an overview of economic evaluation guidelines adopted by 5 Asian countries and UK. The recommendations differ in some aspects, but Japanese guidelines are relatively open, which should facilitate adaptations of models between countries. One of the hurdles for adapting models is likely to be the variability in approaches recommended to obtain utilities.

BENCHMARKING THE IMPACT OF HTA ON NEW MEDICINES DEVELOPMENT AND COVERAGE DECISION MAKING

OBJECTIVES: To evaluate the impact of HTA on new development and market access of new pharmaceutical products in Australia, Canada, England, France, Germany, Italy, Spain and the USA. METHODS: An annual benchmarking study was developed in collaboration with 9 multinational pharmaceutical companies to establish an appropriate set of developmental performance metrics to identify if scientific advice was received, was it received, from whom and the outcome and specific HTA requirements included into the development process. In addition data were also collected across 8 jurisdictions (Australia, Canada, England, France, Germany, Italy, Spain and the USA) to identify what evidence was submitted, the time it took and what additional evidence was requested. Data on 19 projects that entered phase III and 864 (in 456 days) HTA requests were generated. Additional comparators for HTA submission were requested by all jurisdictions except USA. England and France showed the highest percentage of products being reimbursed as per the regulatory label (50% and 55% respectively). CONCLUSIONS: Companies are actively taking scientific advice and incorporating HTA requirements into their development process, although they are still challenged by divergence in HTA process and decision making across jurisdictions. Benchmarking HTA processes at the product level supports companies in driving excellence in risk management and strategic planning.

COMPARISON OF ECONOMIC EVALUATION GUIDELINES BETWEEN JAPAN AND OTHER ASIAN COUNTRIES

OBJECTIVES: Japan lags behind Europe, Australia, and several Asian countries in implementing HTA regulations. This study aims to evaluate the history and current situation of the Japanese HTA system, and what Japan needs to do in order to successfully implement national HTA regulations. METHODS: Past and current Japanese HTA regulation are assessed by analysing both English and Japanese publications and legal documents, as well as comparing these with the systems in other Asia-Pacific countries: Australia, South Korea, Taiwan, Thailand. RESULTS: There are differences in the applicability of HTA systems in Japan, other measures, such as laboratory values, also accepted, preferred methods to determine utility values (generic instruments with scoring algorithm developed in Japan, and benefit prediction methods (probabilistic sensitivity analysis) are used. CONCLUSIONS: This comparative exercise provides an overview of economic evaluation guidelines adopted by 5 Asian countries and UK. The recommendations differed in some aspects, but Japanese guidelines are relatively open, which should facilitate adaptations of models between countries. One of the hurdles for adapting models is likely to be the variability in approaches recommended to obtain utilities.

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OBJECTIVES: As medical representative's job involves travelling, waiting, stress due to targets and extended work hours in the field, their health related quality of life was given less attention. This study aims to report the health related quality of life, an exploratory study was done to understand factors influencing health related quality of life. METHODS: In this exploratory study a pilot tested questionnaire was used. The questionnaire contained items on demographic characteristics, work and life habits. For health related quality of life measurement both descriptive and visual analogue score of EQ SD 5L questionnaire were used. The data collected was analyzed using SPSS 16.0. The test of significance of results were done using Kruskal-Wallis test. RESULTS: This is a part of large group study which is underway to record health related quality of life among medical representatives, the results presented here are of 150 medical representatives, of the population studied 45.3% were not involved in doing any physical activity. Mean BMI was 23.5±2.45 and VAS score was 84.46±12.59. There was significant difference of VAS score among the groups involved in doing and not doing any physical activity (p<0.001).

CONCLUSIONS: Even though the population studied was young, involvement in physical activity makes a difference in their health related quality of life.

HEALTH CARE USE & POLICY STUDIES – Promoting Behavior & Health Guidelines

PHP98
THE IMPACT OF UNFAMILIARITY IN PALLIATIVE CARE UNDER GUIDELINES RELATED QUALITY OF LIFE
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1Pharmaceutical College, Manipal University, Manipal, India, 2Shanghai Jiaotong University, Shanghai, China, 3University of Hong Kong, Hong Kong, China, 4Sichuan University, Chengdu, China

OBJECTIVES: As medical representative’s job involves travelling, waiting, stress due to targets and extended work hours in the field, their health related quality of life was given less attention. This study aims to report the health related quality of life, an exploratory study was done to understand factors influencing health related quality of life. METHODS: In this exploratory study a pilot tested questionnaire was used. The questionnaire contained items on demographic characteristics, work and life habits. For health related quality of life measurement both descriptive and visual analogue score of EQ SD 5L questionnaire were used. The data collected was analyzed using SPSS 16.0. The test of significance of results were done using Kruskal-Wallis test. RESULTS: This is a part of large group study which is underway to record health related quality of life among medical representatives, the results presented here are of 150 medical representatives, of the population studied 45.3% were not involved in doing any physical activity. Mean BMI was 23.5±2.45 and VAS score was 84.46±12.59. There was significant difference of VAS score among the groups involved in doing and not doing any physical activity (p<0.001).

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HEALTH CARE USE & POLICY STUDIES – Promoting Behavior & Health Guidelines

PHP99
STUDY OF ANTIBIOTIC PRESCRIPTION PATTERN AND ANTIBIOTIC SENSITIVITY IN PATIENTS WITH RESPIRATORY INFECTION IN THREE DIFFERENT SPECIALTIES
1Creativ-Ceutical, Paris, France, 2306 Hospital of PLA, Beijing, China, 3Creativ-Ceutical, London, UK, 4University of Marseille, Marseille, France

OBJECTIVES: Pharmacoeconomics is a newly developed discipline in China. Economic assessment is increasingly used as supportive evidence driving pricing and reimbursement decisions. Nevertheless, guidelines are necessary to homogenise their practice and promote their use. Among the different guidelines that have been published, two in 2006 and in 2011 significantly support the importance of pharmacoeconomics in China. Simultaneously, pharmaceutical companies are increasingly present in the Chinese market, this tends to increase the speed of such publications. This paper aims to quantify the impact of the first ten weeks of 2014, 9 articles are already particularly intense, which can be interpreted as real trend.

METHODS: A literature review was undertaken using the Pubmed database. Keywords used in the search strategy were: ‘China’, ‘Pharmacoeconomics’, ‘Economic Evaluation’, ‘Cost-Effectiveness’, ‘Cost of Illness’, ‘Cost-Benefit’, ‘Cost-Utility’, ‘Cost- Minimization’ and ‘Budget Impact’. We used a timeframe of ten years before the first pharmacoeconomic guideline to present. This corresponds to 01/01/1996 to 14/03/2014. In order to take into consideration only international publications only, some English papers were translated. A final search strategy was selected to detect the articles directly related to pharmacoeconomics and only in China. RESULTS: 272 articles were found with the primary search strategy and 99 were selected using the final criteria. On average, 17 articles were published every year until 2006 while 8 were published between 2006 and 2010, and 16 after 2010. The publications’ pace increases exponentially from 2011 to finally reach 19 publications in 2013. In the first ten weeks of 2014, 9 articles are already particularly intense, which can be interpreted as a real trend.

CONCLUSIONS: This study reveals a correlation between pharmacoeconomic guidelines and volume of publications. Even if the place of this new discipline remains minor because of the initial level of submission, significant efforts are undertaken to submit and use pharmacoeconomic studies as fully-fledged, leading to pricing and reimbursement decisions.

HEALTH CARE USE & POLICY STUDIES – Quality of Care

PHP93
AN ASSESSMENT OF QUALITY OF CARE IN THE RESPIRATORY CARE CENTER BASED ON SERVICES PROVIDED BY PHYSICIANS WITH DIFFERENT RESPONSIBILITIES AND SPECIALTIES
1Creative-Ceutical, Paris, France, 2306 Hospital of PLA, Beijing, China, 3Creative-Ceutical, London, UK, 4University of Marseille, Marseille, France

OBJECTIVES: It has been shown in literatures that full-time intensivists improve the quality of patient care and reduce medical resource utilization. The study compares the care provided by critical care in Respiratory Care Center staffed by fully-fledged, leading to pricing and reimbursement decisions.

CONCLUSIONS: This study reveals a correlation between pharmacoeconomic guidelines and volume of publications. Even if the place of this new discipline remains minor because of the initial level of submission, significant efforts are undertaken to submit and use pharmacoeconomic studies as fully-fledged, leading to pricing and reimbursement decisions.

HEALTH CARE USE & POLICY STUDIES – Quality of Care

PHP91
CURRENT STATUS AND DEFICIENCY OF HEMOSTASIS IN SURGERY: A SYSTEMATIC LITERATURE REVIEW, INCLUDING CHINESE LITERATURE
Tsoa J1, Chen XJ1, Yue N2
1Johnson & Johnson Medical Asia-Pacific, Singapore, 2Johnson & Johnson Medical China, Beijing, China

OBJECTIVES: Perioperative bleeding sometimes results in severe consequence. An understanding of hemostasis approaches is crucial in managing the operations. This review aims to show the development of hemostasis in surgery around the world including China. METHODS: Literature in PUBMED was searched between 2009 and 2014; search terms included hemostasis and surgery, filters included human, English and clinical trials. A similar search was done in Chinese CNKI database. Search results were carefully reviewed and studies compatible with our inclusion criteria were then selected. RESULTS: From an initial search which yielded 99 references in PUBMED and 50 references in CNKI, 54 articles in PUBMED and 16 articles in CNKI were included in the review. Results are shown in the text in these articles. We found that conventional hemostasis (classic technique of tying and knots, resorbable ligature) was gradually replaced by novel techniques such as bipolar tissue sealant device, ultrasound scalpel, hemoclips, blue-violet light from an initial search which yielded 99 references in PUBMED and 50 references in CNKI, 54 articles in PUBMED and 16 articles in CNKI were included in the review. Results are shown in the text in these articles. We found that conventional hemostasis (classic technique of tying and knots, resorbable ligature) was gradually replaced by novel techniques such as bipolar tissue sealant device, ultrasound scalpel, hemoclips, blue-violet light.

CONCLUSIONS: Some of the novel hemostasis approaches in surgery could decrease blood loss perioperatively as well as reduce operative time, hospital stay, the rate of complications and the whole cost. However, some shortcomings still exist and more correlative researches should be performed in the future.

HEALTH CARE USE & POLICY STUDIES – Promoting Behavior & Health Guidelines

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for by full-time intensivists, part-time responsible chest physicians, and full-time responsible chest physicians but no difference in acquiring mortality.

**PHP94**

CRITICAL EVALUATION OF LABELING REQUIREMENTS OF NUTRACEUTICAL BRANDS

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1Association of Community Practitioners of India, Nagpur, ME, India, 2Institute of Management Sciences and Research, Nagpur, Nagpur, India

**OBJECTIVES:** This study focuses on the regulations made by government of India for Nutraceuticals labeling requirements and the need of the change in the monitoring system in the Philippines. The present study was performed on 30 samples randomly from Nutraceutical segments from local Pharmacies and studied the labels carefully. **RESULTS:** The follow-up by Nutraceuticals manufacturer to labeling regulations found very moderate in our study. We found that regulations about list of ingredients, nutritional value, declaration regarding veg non-veg, declaration regarding food additives and other crucial parts of label are poorly followed by Nutraceutical Manufacturer in India. **CONCLUSIONS:** As we have studied the regulations regarding labeling of Nutraceuticals, we found that this regulations are sufficient and appropriate. Again through this research work we come to make this conclusion that local Nutraceutical manufacturers have not name serious regarding labeling which is threatening in some aspects so they used to make mistakes in labeling knowingly or unknowingly.

**PHP95**

DEVELOPING A DRUG PRICE REFERENCE INDEX IN THE PHILIPPINES

Hasma MA, Guerrero AMS, Ladioray MJ
Department of Health Philippines, Manila, Philippines

**OBJECTIVES:** To develop a method of setting a Drug Price Reference Index (DPRFI) in the Philippines to ensure good value for money in the procurement and reimbursement of essential medicines. **METHODS:** A database of prevailing drug procurement prices was created from actual purchase orders submitted in 2012 by government procuring entities in the Philippines. The database includes information on the unit cost, volumes of procurement, source/supplier/manufacturer, brand, mode of procurement and location of the hospital for each formulation and strength of all drugs in the National Formulary. Univariate regression analyses were performed for commonly sourced essential drugs exploring possible determinants of drug costs, which include quantities procured and hospital bed capacity. Further cost-comparisons were made for other potential variables such as mode of procurement, supplier/manufacturer and distance of distribution. **RESULTS:** Price data was analyzed for 20 drug products with the highest share of procurement in terms of volume and quantity purchased. Price dispersion was considerable for all drugs analyzed. The price differentials, i.e. high/low ratio, was found to be up to 60 times when comparing the highest to the lowest priced drugs. The variations in prices were not associated by volumes procured, distance of distribution and hospital bed capacity. Suppliers were also observed to charge different prices for the same brands to different public hospitals, indicating information asymmetry on reasonable prices of drugs. **CONCLUSIONS:** Based on the observed wide variations in drug procurement prices in the Philippines, setting the DPRFI at the mean national value for most drugs was found to be an appropriate method to set ceiling prices for public sector procurement. For monopolized pharmaceutical products, other methods may be more appropriate such as value-based pricing, price negotiations and external reference pricing to relevant countries.

**PHP96**

ANALYSIS ON POLICIES OF BIOSIMILAR MARKET IN CHINA

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1Sanofi China, Beijing, China, 2Sanofi China, Beijing, China

**OBJECTIVES:** This study aims to review relevant regulations with regards to biosimilar products in China, and further understand the external environment that shapes the biosimilar market. **METHODS:** A literature review on laws, regulations and policies released by key government stakeholders and other additional documents, fully describe the current environment of biosimilar market in China. **RESULTS:** Multiple policies have been issued at central government level to encourage the development of biologics industry in China. Nevertheless, rather than in favor of biosimilar market access for biologics, those policies are more R&D and manufacturing quality control focused. There is no clear regulatory pathway for biosimilars in China to date. Due to the lack of clear standard for biosimilars to prove their bioequivalence to the originators, biosimilars are treated as new drugs at each stage of market access, resulting in a delay of getting approval in China. Currently, local biosimilar developers are actively building their capabilities in innovative biologics such as monoclonal antibodies, while MNC players are continuing to bring in new molecules. As original products patent expiry peak period is coming, biosimilars, whose prices are relatively affordable, have potential huge opportunities to grow. On the other side, the fierce competition among biosimilars with the same reference biologics and upcoming MNC’s next generation antibody therapies are also putting a threat to biosimilar market as a whole. **CONCLUSIONS:** If pathways cannot be tailor-made for biosimilars in the future, thus hinders the fast launch of biosimilar products in China, population may not be able to enjoy more cost-effective therapies and government may also lose the chance to benefit from the saving of the total health care expenditure.

**PHP97**

CURRENT SITUATION OF HEALTH CARE ORGANIZATIONS’ WASTE MANAGEMENT

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**OBJECTIVES:** There are challenges to assess the current situation of health care organizations’ waste management by the level and to formulate methods for further improvement. Thus, this study aims to assess the current situation of biosimilar market in China is a highly fragmented process and involves a lot of different government and academic institutions. As a result, civil society, such as NGOs and health care stakeholders, have a relatively weaker compared to western countries, and they are not able to take intrinsically influential roles during market access decision-making process. This further leads to a high administration-oriented and low market-oriented drug market access present circumstance. Currently, the timeline of drug market access in China is much longer than that of the mature market. **CONCLUSIONS:** The definition of market access in China needs to be redefined and global perspectives should be incorporated. A re-structured concept will better serve China’s changing environment.

**HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector**

**PHP100**

EVIDENCES AND CRITERIA RELATED TO THE HOSPITAL SERVICE QUALITY AND SAFETY

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**OBJECTIVES:** Even the Ministry of Health is taking its attention to improve quality and safety of medical services, developing and implementing relevant policy and directions, quantity of complaints and occupational mistakes coming from citizens and hospital staffs are still not going down. Therefore it is very necessary for every health organizations to analyze the situation. **METHODS:** To study processes for evidences and requirements of quality, information is collected by quantitative method and the cross sectional survey form was used. **RESULTS:** On the service standard survey, 31% of patients were satisfied in level 1 hospitals, 50.0% in level 2 hospitals and 73.3% in level 3 hospitals are replied as they follow certain standards for their services. But respondents replied as 47.4% of the standards for medical services, which is the most percent, are not comparable for forwards. When summarizing the results, we can say it is not clear what service standards the medical staffs...
follow or they do not have customized service standards. Moreover, basing on the therapeutic efficacy of health interventions, current health status and treatment of diseases. Evidence review, evidence grading and meta-analysis of trials are standardized and routinely conducted. However, recent technological developments have significant impacts on future directions of EBM. With recent advances in health information technology, electronic medical records (EMRs), proteomics and genomics, clinical evidence has become increasingly abundant and diverse. At the same time, the inputs into medical decision making have also developed pharmacoeconomic evaluations for traditional medicine. Multi-criteria decision approaches may provide a tool to guide explicit allocation decisions.

OBJECTIVES: Priority setting in the allocation of new medical interventions is increasingly based on formulated values. Before drafting the new medical service items and fee schedule, the National Health Insurance Act of Taiwan identifies four prioritizing rules: human health, medical ethics, cost-effectiveness, and the finances of the Insurance respectively to compliance with our study objectives are to compare the policy makers’ actual value preferences with these four official formulated principles and to guide the Ministry of Health and Welfare in Taiwan in the priority setting of new medical interventions. METHODS: We used a multi-criteria decision analytical framework. In total 65 respondents participated in a discrete choice experiment to weigh the relative importance of six policy criteria for priority setting. Regression analysis was used to rank order a set of 22 new medical interventions on the basis of these criteria and ranked 12th out of 22 medical interventions. Policy makers in the field of middle-age, cost effectiveness as the most important criteria for priority setting of interventions, followed by low budget impact. Signs of coefficients of many beneficialities and large individual benefits did not have the expected direction. Certain interventions were ranked in the top 5; however, the top 2 are chemotherapy and orthopedic surgery rank highest. Cochlear implant ranks 12th out of 22 medical interventions. CONCLUSIONS: Policy makers’ values are partially in agreement with principles formulated in National Health Insurance laws. Multi-criteria decision approaches may provide a tool to guide explicit allocation decisions.

PHP102
FEASIBILITY OF PHARMACOECONOMIC EVALUATIONS OF TRADITIONAL CHINESE MEDICINE FROM THE PERSPECTIVES OF THE HEALTH INSURANCE REVIEW & ASSESSMENT SERVICE IN SOUTH KOREA

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OBJECTIVES: Having maintained close association with China through the ages, a great amount of herbal medicine is produced and consumed. Patients pay for this medicine as out-of-pocket expense, although the outcomes are not well measured and understood by either the government or the public. Furthermore, they acknowledged that existing pharmacoeconomic guidelines may not always be appropriate and understood by either the government or the public. Moreover, basing on the therapeutic efficacy of health interventions, current health status and treatment of diseases. Evidence review, evidence grading and meta-analysis of trials are standardized and routinely conducted. However, recent technological developments have significant impacts on future directions of EBM. With recent advances in health information technology, electronic medical records (EMRs), proteomics and genomics, clinical evidence has become increasingly abundant and diverse. At the same time, the inputs into medical decision making have also developed pharmacoeconomic evaluations for traditional medicine. Multi-criteria decision approaches may provide a tool to guide explicit allocation decisions.

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PHP106
THE COVERAGE WITH CLINICAL EVIDENCE-INFORMED DECISIONS (CCEDs): A NEW HEALTH CARE PAYMENT MODEL IN CHINA
Hui L., Liu G.
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OBJECTIVES: This new payment model, based on clinical evidence-informed decisions (CCEDs), was designed to bring down medical costs and improve the quality of care. CCEDs also come with opportunities to limit both underuse and overuse, to eliminate risk selection problems, lower administrative cost, enhance transparency of results and to design, funding and implementation are being piloted across provinces/cities. Our research findings suggested that health insurance schemes of the private insurers and uncertainty around profitability places significant challenges on the future development of ‘serious illness insurance’. However, implementation of these insurance schemes has positively impacted health care coverage and access to drugs.

PHP110
ARCHIMEDES: A LARGE SCALE SIMULATION SYSTEM FOR HEALTH CARE RESEARCH AND ITS APPLICATIONS FOR ASIAN COUNTRIES
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The Archimedes Model is a carefully validated, clinically realistic, simulation model of diseases and health care. By using advanced methods of mathematics, computing, and data systems, the Model enables researchers and decision makers to make better informed decisions. The Archimedes Model includes a wide range of diseases/conditions (diabetes, cardiovascular diseases, COPD, obesity, cancers) and detailed descriptions of health care delivery systems, interventions, tests, and treatments and patient and physician behaviors. The Model has been used by many organizations (e.g., governments, pharmaceutical companies, insurance companies, disease organizations) across the globe to help answer a wide variety of questions related to clinical trials, policy setting, performance measurement, and health economics and outcomes research. The Model is being used to conduct health care research to improve health care delivery systems across the globe including US, France, Italy, Sweden, Norway, Poland, Japan, Brazil, and California. We will highlight a number of projects that were supported by EU and Japan, in which the Model was used to guide decision making around management of diabetes. We will also discuss the potential applications of adapting the Archimedes Model to other Asian countries (e.g. India or China) beyond Japan.

PHP107
CHALLENGES AND OPPORTUNITIES IN THE MALAYSIAN HEALTH CARE SYSTEM – Malaysia Health Care Services Act (MHCA) 2018
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INTRODUCTION: Malaysia is a multicultural society with a population of over 28 million and classified as an upper middle-income country by the World Bank. Malaysia inherited a health care system at independence from British colonial rule and provides universal and low cost access to the health care needs of all citizens. Implementations in health indices such as reduction in mortality rate and increase in life expectancy using a relatively small amount of GDP (~4%) being spent on health services shows that Malaysians have benefited from a well-developed health care system. CHALLENGES: Demographic and disease pattern transitional trends in Malaysia are resulting in more chronic diseases and better health outcomes pose challenges in sustaining the system. Historical-based health financing has also created inequity in access and allocative inefficiency. Equity access issues such as uneven human resource distribution and limitations in secondary access to consult specialists remain a problem despite generally improved access to facilities for rural population. Urbanization however has created vertical inequity and strains to existing public health facilities. The inadequately availability of public health facilities and manpower has led to a proliferation of private health facilities. Unethical prescribers’ behaviour, queue jumping and dependency on profit-oriented private health care providers further complicate the issues.

PHP108
COLLABORATIVE APPROACH IN ACCESSING HOMOGENEOUS MEDICAL DATA IN GRID-BASED ENVIRONMENT (ENHANCING DISEASES CLASSIFICATION)
Khoi D.V.
1University Sains Malaysia, Penang, Malaysia
OBJECTIVES: The proposed initiative presents the collaborative approach in classification of preliminary characteristics of diseases using sample clinical data that allows the integration of parallel processing in homogeneous grid-based environment. The research focuses on three objectives mainly: 1. To provide collaborative classification in homogeneous resources. 2. To conduct parallel processing in extraction of preliminary characteristics using electronic medical records (EMR) data. 3. To perform characterization for disease features in grid-based neural network classification.

PHP109
PAYMENT MODELS ON ACCESS TO HEALTH CARE AND DRUGS
1, 2, 3Wang Y., Saif S., Sherwin G., Akpinar P.
OBJECTIVES: In mainland China, a large gap in the funding of catastrophic illnesses has existed for the past decade. In 2012, ‘serious illness insurance’ was proposed by the Government that involves using a portion of funds from the public insurance to cover catastrophic illness. Further work on the guidelines for the government allowed. Commercial health insurers collaborate with local authorities to provide this coverage through various models in different cities and regions. This research seeks to understand current models in different regions and to evaluate the implications for health insurance reform and to better understand the current landscape of the serious illness insurance. Primary research with a mix of stakeholders including private health insurers and regulatory authorities was also conducted in different provinces/ cities to further evaluate the regulatory framework, disease-specific coverage, funding pathways and implications for access to drugs.

PHP111
‘SERIOUS ILLNESS INSURANCE’ IN CHINA: IMPACT OF NOVEL PUBLIC-PRIVATE PAYMENT MODELS ON ACCESS TO HEALTH CARE AND DRUGS
1, 2, 3Shin A., Khoi D.V., Khan A.H.
Manipal College of Pharmaceutical Sciences, Manipal, India
OBJECTIVES: Proposal of an ideal model for obtaining the best possible health outcomes at different socioeconomic levels of community. The ‘Better Care Plan’ involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community. In next step “better care plan” involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community. In next step “better care plan” involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community.

PHP112
BEST POSSIBLE HEALTH OUTCOMES AT DIFFERENT SOCIOECONOMIC LEVELS OF COMMUNITY: THE BETTER CARE PLAN
Sinj A., Khoi D.
Manipal College of Pharmaceutical Sciences, Manipal, India
OBJECTIVES: Proposal of an ideal model for obtaining the best possible health outcomes at different socioeconomic levels of community/population in India. CONCLUSION: Various social inequities viz. race, ethnicity, religions and economic factors affect operationalization of health decisions as well as health outcomes invariably. These all inequities define socioeconomic levels of any community. Assessing health equity needs comparing health and its social inequities/determinants within different levels. It is attainable call to standardize the process of health care decision making, to obtain best possible health outcomes. Hereby, we propose an ideal model, a “Better Care Plan” which will help in opting best possible health outcomes at different socioeconomic levels. Foremost, we require to understand the mindset of people on health care needs. We found that one requires clear communication, mutual collaboration between clinician, patient and other health care professionals; professionally competent and compassionate staff and their services; continuity of care and professional excellence required mostly for chronic ailments. In next step “better care plan” undertakes evaluation of the impediment issues that might rise at various points related to patient, staff and system. Diverse quality dimensions proposed by different studies and models would be aimed to standardize the process of health care decision making. The six areas of “Better Care Plan” involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community. In next step “better care plan” involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community. In next step “better care plan” involves focus on patient, rationale; efficacy, opportunity, safety and accessibility. This will help in obtaining optimal health care outcomes at different socioeconomic levels of community.
OBJECTIVES: The aim of the current study is to explore and to observe the impact of cigarette smoking and alcohol use on adverse drug reactions occurrence of antiretroviral drugs among HIV/AIDS patients. METHODS: Retrospective analysis of all patients diagnosed with HIV/AIDS in Universiti Sains Malaysia and HPP, from Jan 2007 to Dec 2012 was conducted at infectious disease department of Hospital Pulau Pinang, Malaysia. Patient socio-demographic details along with recorded smoking and alcohol consumptions. Out of total included patients 571 (76.8%) were male and 172 (23.1%) were female. Among the patients, 512 (68.9%) were smokers and 340 (45.8%) patients were alcohol users. A total number of 425 (57.2%) adverse drug reactions were recorded while the remaining 262 (35.1%) were reported among alcohol users. Univariate analysis indicates a significant relationship between the smoker (p-value = 0.009, 95% CI = 1.111 - 2.079, Odds ratio = 1.520) and alcohol users (p-value = 0.008, 95% CI = 1.1 - 1.994). CONCLUSIONS: The study indicates the incidence of adverse drug reactions is higher in male than in female patients. However, a multicenter study was Chinese 427 (60.3%) followed by Indians 96 (13.6%), Malay 83 (12.5%) and minorities 34 (4.8%). There were three main modes of transmission including heterosexual contact 464 (69.9%) followed by homosexual contact 47 (7.1%) and IVDU (12.5%). The route of transmission was mainly male heterosexual contact 455 (68.5%) followed by homosexual contact 50 (7.6%) and IVDU (16.3%). The co-infection is significantly associated with gender (p = 0.001), and IVDU (p = 0.001) with co-infection of HIV-HCV. The co-morbidity observed in the current study was Pulmonary Tuberculosis (23.6%), Pneumocystis pneumonia (14.4%), Hyperlipidemia (4.4%), Dyslipidemia (3.2%), Anaemia (4.5%), Infection - Heart Disease (2.5%), Diabetes Mellitus (8.2%), Hypertension (6.5%), Asthma (1.4%), Oral Candidiasis (5.2%), Syphilis (3.1%), Liver Cirrhosis (1.1%), Cerebral Toxoplasmosis (2.3%), Virological Failure (1.1%). CONCLUSIONS: The incidence rate of HIV-HCV co-infected patients and HCV in 18.4% individuals with HIV infection was 33.6% observational retrospective study of all patients diagnosed of HIV infection and on HAART therapy from Jan 2007 to Dec 2012 was conducted at infectious disease department of Hospital Pulau Pinang, Malaysia. Patient socio-demographic details along with the clinical outcomes were recorded. The reported ADRs were assessed for causality by using Noranjo's algorithm scale. Data was descriptively analyzed by using statistical package for social sciences (SPSS 20). RESULTS: Out of 743 patients that underwent HAART therapy, 571 (76.8%) were male and 172 (23.1%) were female patients. The mean CD4 count, ALT and AST levels in female patients were 511 (73.1%) occurred in males and 114 (26.8%) in female patients. Lipodystrophy 151 (20.3%) was significantly associated common ALT (29.6%) and 25 (5.8%) female patients were recorded. Lipodystrophy was followed by skin rash 80 (18.8%) that included 56 (13.1%) male and 24 (5.7%) female patients. Anemia was reported 74 (17.4%), of which 49 (11.1%) observed in male and 25 (5.8%) female patients. A statistical significant relationship on Chi-square test was observed between the gender and the occurrence of adverse drug reactions (p-value = 0.002). However an univariate analyze the relationship between ADRs with gender resulted in insignificant value (p-value = 0.367, 95% CI = 0.862 - 1.712, Odds ratio = 1.215). CONCLUSIONS: The study indicates the incidence of adverse drug reactions is higher in male than in female patients. However, a multicenter study with a large sample size may provide us with better understanding of this relationship.
individuals or have no recommendations. The annual incidence of varicella in the general population ranged from 13.7 to 76 per 100,000 in Asia-Pacific countries with universal vaccination, and from 100 to 512 per 100,000 in Asia-Pacific countries without universal vaccination. Studies in China, Japan, and South Korea showed varicella incidence peaking in spring and winter. Limited publication has reported varicella incidence in the Asia-Pacific region. Major sources of varicella are cited in this study. Infection control and financing health care resource utilization focused on inpatient care. The most frequent complications among hospitalized patients were skin and respiratory complications. Hospitalization rates were associated with varicella. Management of varicella was conducted and data were collected from 150 patients who were registered not on treatment from December 2011 to December 2013. Multiple logistic regression analysis was applied to identify the risk factors for mortality among HIV patients. RESULTS: A total of 40 patients were died during the follow-up period. Patients with age between 39-59 years (OR 0.49, 95% CI 0.28-0.84), baseline World Health Organization (WHO) staging III and IV (OR 0.09, 95% CI 0.04-0.20 and OR 0.11, 95% CI 0.04-0.27), patients with opportunistic infections (OR 4.93, 95% CI 2.83-8.84), were found to have less risk for mortality compared to their counterparts. Patients with low BMI (OR 2.05, 95% CI 1.21-3.49), CD4 count >200 cells/µl (OR 3.88, 95% CI 2.27-6.65) were found to have more risk. CONCLUSIONS: Age group 18-38, patients within the WHO staging I and II, CD4 count ≤200 cells/µl were all significant predictors of mortality. Therefore, patients with the aforementioned predictors should be followed closely and frequently.

INFECTION – Cost Studies

PIN12
A RETROSPECTIVE COHORT STUDY OF RISK FACTORS FOR DEATH AMONG HUMAN IMMUNODEFICIENCY VIRUS INFECTED ADULT PATIENTS
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OBJECTIVES: Globally, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) reduces life expectancy by several years. Mortality is high among non-treated patients. However, the predictors of mortality have not been adequately studied. Hence, the main objective of the study was to determine predictors of mortality among HIV positive adults who are not on antiretroviral treatment, in a South Indian hospital. METHODS: A facility-based retrospective cohort study was conducted and data were collected from 150 patients who were registered not on treatment from December 2011 to December 2013. Multiple logistic regression analysis was applied to identify the risk factors for mortality among HIV patients. RESULTS: A total of 40 patients were died during the follow-up period. Patients with age between 39-59 years (OR 0.49, 95% CI 0.28-0.84), baseline World Health Organization (WHO) staging III and IV (OR 0.09, 95% CI 0.04-0.20 and OR 0.11, 95% CI 0.04-0.27), patients with opportunistic infections (OR 4.93, 95% CI 2.83-8.84), were found to have less risk for mortality compared to their counterparts. Patients with low BMI (OR 2.05, 95% CI 1.21-3.49), CD4 count >200 cells/µl (OR 3.88, 95% CI 2.27-6.65) were found to have more risk. CONCLUSIONS: Age group 18-38, patients within the WHO staging I and II, CD4 count ≤200 cells/µl were all significant predictors of mortality. Therefore, patients with the aforementioned predictors should be followed closely and frequently.

INFECTION – Cost Studies

PIN10
INFECTIOUS DISEASES IN CHINA AMONG THE URBAN POPULATION AND HIGH-RISK GROUPS
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OBJECTIVES: To assess the prevalence of health care-associated infection (HAI) in 2012 among grade A hospitals in China. METHODS: This study included data from the 2011-2012 Japan (Ns= 30,000) National Health and Wellness Surveys(NHWS) which is a cross-sectional survey. The NHWS includes a national sample of adults (18+ years) which included items on vaccination history as well as high-risk group status as defined by the World Health Organization(WHO). Vaccination rates were calculated and characteristics of vaccinees were reported descriptively. Logistic regressions were conducted to predict vaccination behavior from sociodemographics and risk-related variables. RESULTS: 17.1% of adults in Japan reported being vaccinated for influenza in 2012 compared with 19.17% in 2011. Even among patients ≥65 years) to 57.69% (chronic neurological conditions). The latest common reason for non-vaccination was belief that it was not needed (17.8%); other common reasons for non-vaccination included believing that the vaccine is not effective (12.9%) and not getting a vaccine before (9%). Respondents who were vaccinated and were less likely to have CHD, chronic lung conditions etc.), vaccination rates were low, ranging from 24.83%(caregivers) to 42.86%(patients with immunodeficiencies). The most common reason for non-vaccination was the belief that it was not important (45.3%); other common reasons included believing that the vaccine is not necessary (13.0%) and that prior infection leads to future resistance (12.3%). Respondents who were vaccinated were more likely to be female (OR=1.006), older(OR=1.212), university educated(OR=1.225), and employed(OR=1.433) with higher incomes(VSMA more) or (OR=1.128) when compared to those who did not receive the vaccine. The vaccinated subjects also exerciced more on average(OR=1.006), and feared needles less(OR=0.986). The strongest predictors of vaccination were having an immunodeficiency disease (OR=3.613), heart disease (OR=2.573), chronic liver(OR=2.653), chronic renal condition(OR=1.618) or chronic metabolic conditions (OR=1.532) (all p<0.05). CONCLUSIONS: Overall vaccination rates were low in Japan with no increase in vaccination rates from the prior year. All WHO-recommended vaccination groups had rates less than 20% and a large gap remains between these recommendations and vaccination behavior. In 2011, the influenza vaccination rates among adults in the United States were 36.2%, almost three times the vaccination rate in urban China.

HOSPITAL QUALITY OF INFECTION CONTROL
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1Health Science University of Mongolia, Ulaanbaatar, Mongolia, 2School of Nursing, HSUM, Ulaanbaatar, Mongolia, 3School of Nursing, Health Science University of Mongolia, Ulaanbaatar, Mongolia

OBJECTIVES: Infection control and its Prevention system were established and its role, responsibility and right were clarified in Mongolia in May 4, 2010 by the decree of Minister of Health “Strengthening infection control system of Health care organizations and intensifying preventive actions of Hospital infections”. The Goal of this study is to implement a guideline for evaluation and development of infection control within Mongolian hospitals and its prevention and some recommenda- tions. METHODS: 1. Method of cross sectional study was used in research of cur- rent condition of infection control Department activities. 2. Disinfection quality and safety was studied by Retrospective and Description method. 3. Knowledge of disinfection of hand and infection control for medical staff are studied by descriptive and cross- sectional study. RESULTS: Assessment of current condition for activity of Infection control Department in national level was conducted among 6 tertiary level hospi- tals, 8 sub-tertiary level hospitals and 28 primary level hospitals. CONCLUSIONS: 1. Infection control for department and teams at health care organizations work with proper structure of management and members, and their activities vary according to its level. 2. The health care organization’s hygiene standards and condi- tions are different, especially extramural. Disinfection of hand and infection control for medical staff’s ability to hand disinfection is reduced according to its level. 3. Sterilizing quality is good enough, but its initial test and monitoring by technical methods are insufficient in primary health facilities. 4. 80-84% of medical staff attended infection control training and have adequate knowledge of hospital infections.

HOSPITAL QUALITY OF INFECTION CONTROL
Daza D1, Davaalkham D2, Tuya S3, Odongua N3
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OBJECTIVES: Infection control and its Prevention system were established and its role, responsibility and right were clarified in Mongolia in May 4, 2010 by the decree of Minister of Health “Strengthening infection control system of Health care organizations and intensifying preventive actions of Hospital infections”. The Goal of this study is to implement a guideline for evaluation and development of infection control within Mongolian hospitals and its prevention and some recommenda- tions. METHODS: 1. Method of cross sectional study was used in research of cur- rent condition of infection control Department activities. 2. Disinfection quality and safety was studied by Retrospective and Description method. 3. Knowledge of disinfection of hand and infection control for medical staff are studied by descriptive and cross- sectional study. RESULTS: Assessment of current condition for activity of Infection control Department in national level was conducted among 6 tertiary level hospi- tals, 8 sub-tertiary level hospitals and 28 primary level hospitals. CONCLUSIONS: 1. Infection control for department and teams at health care organizations work with proper structure of management and members, and their activities vary according to its level. 2. The health care organization’s hygiene standards and condi- tions are different, especially extramural. Disinfection of hand and infection control for medical staff’s ability to hand disinfection is reduced according to its level. 3. Sterilizing quality is good enough, but its initial test and monitoring by technical methods are insufficient in primary health facilities. 4. 80-84% of medical staff attended infection control training and have adequate knowledge of hospital infections.

INFECTION – Cost Studies

PIN14
CLINICAL OUTCOMES AND HOSPITAL COSTS ASSOCIATED WITH EMPIRICAL TREATMENT OF HOSPITAL-ACQUIRED PNEUMONIA WITH VANCOMYCIN OR LINEZOLID IN A CHINESE TERTIARY CARE HOSPITAL: A RETROSPECTIVE COHORT STUDY

A804
VALUE IN HEALTH 17 (2015) A719–A813
CONCLUSIONS: Our analysis demonstrates that outcomes of diabetes, adverse skin reactions induced by antibiotics generate considerable costs, both for the payer and the service provider. The costs, which are incurred by either party, are comparable, providing evidence that the pricing of procedures, proposed by the public administration of medicines, is valid since 2012, has been adequate to the expenses, borne by the service provider.

ECONOMIC EVALUATION ON HEPATITIS B VACCINATION STRATEGIES FOR PREVENTING MOTHER-TO-CHILD TRANSMISSION IN CHINA

OBJECTIVES: Through analyzing the main immunization strategies for preventing mother-to-child transmission of HBV in China, figure out the optimized strategy which is based on cost-effective and short-term benefit, and cost-benefit analyses. METHODS: The multilevel decision tree-markov model was constructed by TreeAge Pro Software 2011, which could simulate the progression of HBV disease after various immunization strategies for preventing mother-to-child transmission.

OBJECTIVES: To evaluate published cost-effectiveness analyses (CEA) assessing nucleos(t)ide analogues (NAs), interferon, and pegylated interferon for chronic hepatitis B (CHB). METHODS: Main medical databases in both English and Chinese were searched up to October 2012. Simple linear regression analyses observed significantly reduced ICER per QALY associated with entecavir when compared to no treatment in high or middle-income countries. When compared to treatment, all NAs were associated with an ICER per QALY of less than 1 GDP per capita. Telbivudine, entecavir, and pegylated interferon did not have significant impact on ICER per QALY when lamivudine was the reference. One study published in Chinese was considered high quality and reported the lowest ICER per QALY associated with entecavir when compared to no treatment in patients with positive or negative hepatitis B e antigen (HBeAg).

OBJECTIVES: To evaluate the long-term economic and clinical impact of PCV13 versus PCV10. Using this model, we considered that the additional cost of PCV13 was worth the additional benefit of increased coverage and protection against pneumococcal disease.

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RESULTS: The average hospitalisation costs per patient was 2380 yuan. CONCLUSIONS: Our analysis demonstrated that outcomes of diabetes, adverse skin reactions induced by antibiotics generate considerable costs, both for the payer and the service provider. The costs, which are incurred by either party, are comparable, providing evidence that the pricing of procedures, proposed by the public administration of medicines, is valid since 2012, has been adequate to the expenses, borne by the service provider.

ECONOMIC EVALUATION ON HEPATITIS B VACCINATION STRATEGIES FOR PREVENTING MOTHER-TO-CHILD TRANSMISSION IN CHINA

OBJECTIVES: Through analyzing the main immunization strategies for preventing mother-to-child transmission of HBV in China, figure out the optimized strategy which is based on cost-effective and short-term benefit, and cost-benefit analyses. METHODS: The multilevel decision tree-markov model was constructed by TreeAge Pro Software 2011, which could simulate the progression of HBV disease after various immunization strategies for preventing mother-to-child transmission.

OBJECTIVES: To evaluate published cost-effectiveness analyses (CEA) assessing nucleos(t)ide analogues (NAs), interferon, and pegylated interferon for chronic hepatitis B (CHB). METHODS: Main medical databases in both English and Chinese were searched up to October 2012. Simple linear regression analyses observed significantly reduced ICER per QALY associated with entecavir when compared to no treatment in high or middle-income countries. When compared to treatment, all NAs were associated with an ICER per QALY of less than 1 GDP per capita. Telbivudine, entecavir, and pegylated interferon did not have significant impact on ICER per QALY when lamivudine was the reference. One study published in Chinese was considered high quality and reported the lowest ICER per QALY associated with entecavir when compared to no treatment in patients with positive or negative hepatitis B e antigen (HBeAg).
disease incidence and serotype coverage and health care utilization to compare costs and clinical impact of PCV-13 versus PCV-10 on IFI prevention and antibiotic and antifungal, and AOM, among vaccinated children (direct effect) and the entire population with indirect (herd effects).

Patients were entered in the model by age groups: 0-2 years, 2-4 years, 5-17 years, 18-34 years, 35-49 years, 50-64 years, and 65 years or older. Each cohort was vaccinated with IPV every 6 months starting at 0 months of age. The incidence of invasive meningococcal disease and meningitis and costs and data were used to achieve national specificity. Direct/Indirect effectiveness of PCV-13 and PCV-10 were calculated based on PCV-7 efficacy data, using assumptions regarding the PCV-13 effectiveness relative to PCV-10 and age-specific and antifungal, and AOM, among vaccinated children (direct effect) and the entire population with indirect (herd effects).

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Results: The SVR rate of PEG-IFN-2a cohort and PEG-IFN-2b cohort were 85.44% and 79.52%.

Sensitivity analysis conducted with bootstrapping method indicated a great possibility that PEG-IFN-2b (40kD, Y shape) cohort and PEG-IFN-2a (40kD, Y shape) combined with RBV and the control group (PEG-IFN-2a combined with RBV). The effectiveness measure was sustained viral response (SVR). Costs, were measured by direct medical costs, were obtained from medical records. Costs, were measured by direct medical costs, were obtained from medical records.

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HOW CAN A MULTILEVEL PROMOTION OF BREASTFEEDING REDUCE THE REQUIRED BUDGET FOR ROTAVIRUS VACCINATION IN THE PHILIPPINES?

CONCLUSIONS:

Intervention strategies should be considered to provide protection against rotavirus infection since it contains anti-rotavirus maternal antibodies and other nonspecific inhibitors. Multilevel promotion of breastfeeding is a complex intervention that modifies behaviors through multiple determinants of health. This intervention can prolong the duration and increase the prevalence of exclusive breastfeeding. This study aims to investigate the effect of multilevel promotion of breastfeeding on the required budget for rotavirus vaccination in the Philippines.

METHODS: We conducted a top-down, age-structured cohort model over a 5-year-time horizon for the 2013 Indonesia birth cohort. We compared two situations: (i) baseline, reflecting the current situation for the population of under-5 years-old, and (ii) the situation with multilevel promotion of breastfeeding. We performed Monte Carlo simulations to examine the economic acceptability and affordability of the rotavirus vaccination.

RESULTS: Vaccination coupled with multilevel promotion of breastfeeding could reduce rotavirus-diarrhea by 495,235 cases. At a price of US$ 5.0 per dose, multilevel promotion of breastfeeding could reduce the required budget for the implementation of three-dose rotavirus vaccination by US$ 50,000, compared to the current absence of specific promotion.

CONCLUSIONS: Multilevel promotion of breastfeeding could potentially reduce the required budget for rotavirus vaccination. Mortality rate and vaccine price were the most influential parameters on the sensitivity analyses.

COST-UTILITY ANALYSIS OF 10- AND 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINES IN THE PHILIPPINES

OBJECTIVES: The objective of this study is to evaluate the cost-effectiveness of introducing pneumococcal conjugate vaccine in a public vaccination program in the Philippines. METHODS: A cost-utility analysis was conducted using a lifetime horizon. A Markov simulation model was used to examine the comparative cost-effectiveness of PCV10 and PCV13 against the current scenario of no vaccination. A health system perspective was employed to explore different funding schemes, which include full or partial vaccination coverage subsidized by the government and self-paid vaccination in the private sector. An annual discount rate of 3.5% for future costs and outcomes was applied. Results were presented as an incremental cost-effectiveness ratios (ICERs) per QALY gained. Sensitivity analysis was performed to determine the impact of parameter uncertainty. RESULTS: With universal vaccination by the government at a cost per dose of Php 624 and PCV10 and Php769 for PCV13, there would be 68,631 and 67,631 QALY gained per Php 1, respectively, compared to no vaccination. Partial vaccination of 25% and 50% of the birth cohort yielded considerably higher ICER values that are still below the ceiling threshold of Php 170,000 per QALY gained, because of the loss of herd protection. The analysis also found that with a partial vaccination strategy of the government, having at least 10% of the target cohort self-pay a higher market price of Php 2,056 for PCV10 and Php3,545 for PCV13 would make vaccination cost ineffective, because of the high out-of-pocket costs.

CONCLUSIONS: The inclusion of PCV in the national immunization program with either universal or partial coverage would be a cost-effective intervention in the Philippines compared to no vaccination. However, the affordability and sustainability of PCV implementation over the long term should be considered by decision makers.

COST-UTILITY ANALYSIS OF OPTIMAL DOSING OF OSELTAMIVIR UNDER PANDEMIC INFLUENZA USING A NOVEL APPROACH: LINKING HEALTH ECONOMICS AND TRANSMISSION DYNAMIC MODELS

OBJECTIVES: Some recent pharmacological evaluations support that higher exposure over the long term should be considered by decision makers. However, the affordability and sustainability of PCV implementation over the long term should be considered by decision makers.

METHODS: This study was conducted to evaluate the effect of a pharmacist initiated influenza vaccination program on knowledge, attitude and practice of healthcare providers in a private hospital in Malaysia.

RESULTS: The knowledge, attitude and practice scores were 2.37±0.72 out of 8. The HB patients also had poor Health Related Quality of Life (mean score of 37.22±30.0 out of 100). The pre-interventional data were available from 126 patients of interventional group and 151 patients of control group, respectively. The HB patients had poor Health Related Quality of Life (mean score of 37.22±30.0 out of 100). The pre-interventional data were available from 126 patients of interventional group and 151 patients of control group, respectively. The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice (mean scores 2.37±1.0 out of 8). The HB patients had poor Health Related Quality of Life (mean score of 37.22±30.0 out of 100). The pre-interventional data were available from 126 patients of interventional group and 151 patients of control group, respectively. The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice (mean scores 2.37±1.0 out of 8).

CONCLUSIONS: The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice, and HRQoL were compared. The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice, and HRQoL were compared.

ASSESSMENT OF QUALITY OF LIFE IN HUMAN IMMUNODEFICIENCY VIRUS POSITIVE PATIENTS WITH ADVERSE REACTIONS TO ANTIRETROVIRAL THERAPY IN TERTIARY CARE HOSPITAL

OBJECTIVES: The main aims of the study was to estimate the health related quality of life(HRQoL) between Adverse drug reaction (ADR) and Non ADR retroviral patients who are on anti retroviral therapy. METHODS: A prospective spontaneous reporting system was conducted. The level of ADR treatment, three categories (mild, moderate, severe) was considered a strain with comparable virulence to typical seasonal influenza. Model parameters such as probabilities, costs (2013 USD), length of stay, and utilities were derived from the literature. RESULTS: When the price of the vaccine was Php1,500, the ICER per QALY gained was Php 68,086 and Php 67,631 for PCV10 and PCV13, respectively.

CONCLUSIONS: The study concludes that vaccination should be considered as a valuable component of pandemic influenza planning and control.

INFECTIO – Patient-Reported Outcomes and Patient Preferences Studies

META-ANALYSIS OF XUEBIJING JOINT ULINASTIN TREATING SEPSIS

OBJECTIVES: To compare the efficacy of Xuebijing injection and ulinastatin injection in the treatment of inflammation and sepsis by evaluating plasma tumor necrosis factor (TNF-α), interleukin-6, procalcitonin (PCT), the average length of stay and the average duration of mechanical ventilation. METHODS: Literature searches were performed through electronic databases. RESULTS: Current results indicated that the application of Xuebijing injection for the treatment of sepsis provided a lower level of interleukin-6 and procalcitonin, a shorter length of stay and duration of mechanical ventilation.

EFFECT OF HEALTH EDUCATION PROGRAM ON KNOWLEDGE, ATTITUDE, PRACTICE AND HEALTH RELATED QUALITY OF LIFE IN HEPATITIS-B PATIENTS

OBJECTIVES: The current study was conducted to evaluate the effect of a pharmacist initiated influenza vaccination program on knowledge, attitude and practice of healthcare providers in a private hospital in Malaysia.

METHODS: The study was conducted as non-clinical randomization control trial. It was divided into three phases: pre-interventional assessment, training of hospital pharmacists, development and implementation of the intervention program and post-interventional analysis. The pre-interventional phase analysed the Hepatitis-B (HB) patients’ knowledge, attitude and practice and current status of Health Related Quality of Life (HRQoL). RESULTS: Three hundred and ninety HB patients were targeted for the study. The pre-interventional analysis revealed poor knowledge (mean score 8.48±2.7 out of 20), negative attitude (mean scores 3.87±1.2 out of 7) and bad practice (mean scores 2.37±0.72 out of 8). The HB patients also had poor Health Related Quality of Life (mean score of 37.22±30.0 out of 100). The post-interventional data were available from 126 patients of interventional group and 151 patients of control group, respectively. The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice.

CONCLUSIONS: The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice, and HRQoL were compared. The educational intervention significantly increase in the HB patients’ knowledge, attitude and practice, and HRQoL were compared.
patients were found to be 100 ± 27.9 and 109 ± 15.0. Among males, difference was observed in mean of HRQOL between ADR patients (99±17.92) and non ADR patients(107.16±14.80). Same difference was observed in mean of HRQOL among females which was102.18±28.68 in ADR Patients and113.6±15.95 in ADR absent patients.

CONCLUSIONS: There is a need for a greater awareness among the health care professionals regarding prevention of occurrence of any infection by more frequent interventions by physicians, thus improving medication adherence which leads to maximisation of HRQOL in HIV patients.

PIN31 SOCIAL ASPECTS OF HCV TREATMENT IN KAZAKHSTAN

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OBJECTIVES: Multiple treatments are available for chronic hepatitis C virus (HCV) infection. Ethical, clinical, economic, and social barriers often prevent these patients from initiating treatment. In this study, we aimed to assess the current treatment options now available. These barriers to care have received little attention in the literature, and yet, knowledge of the ethical and social justice aspects of HCV treatment can enhance the quality of care. This study systematically reviewed evidence on the social and lifestyle determinants of antiviral use and discrimination.

RESULTS: Clinical and individual level barriers to HCV treatment are well evidenced. These include patient and provider concerns regarding co-morbidities, adherence, and side effect management. Social factors affecting treatment access are less well evidenced. In attempting to map these, key barriers fall into the following domains: social stigma, housing, criminalisation, health care costs, and adherence. Key facilitating factors to treatment access include: combination intervention approaches encompassing social as well as biomedical interventions and integrated delivery of multidisciplinary care. No trial evaluated a combination of different treatment modalities. Adolescents were less addressed as a high-risk population. Successful treatment of HCV infection has undeniable long-term benefits with respect to quality of life. When treating these patients, efforts will need to be made to provide the quality of care to them.

INFECTION – Health Care Use & Policy Studies

PIN32 AN ANALYSIS OF THE UTILIZATION OF CEPHALOSPORINS FROM 2007 TO 2011 IN GUANGDONG PROVINCE OF CHINA

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OBJECTIVES: To analyze the relationship between the change of drug mix for Cephalosporins and their cost increases in order to provide a reference for future research on improving policy making on antecedents, and anti-viral medications. METHOds: Build a foundation based on drug DDD unit, analyze the index analysis system of the influence of drug mix of Cephalosporins on drug cost on different levels. RESULTS: The total procurement costs of Cephalosporins for Guangdong Province from 2007 to 2010 increased by 27% and 42% respectively, compared with 2011 and 2012. The total procurement cost of Cephalosporins for Guangdong Province from 2007 to 2011 increased by 27% and 42% respectively, compared with 2012. The total procurement cost of Cephalosporins for Guangdong Province from 2007 to 2011 increased by 27% and 42% respectively, compared with 2012. The total procurement cost of Cephalosporins for Guangdong Province from 2007 to 2011 increased by 27% and 42% respectively, compared with 2012. The total procurement cost of Cephalosporins for Guangdong Province from 2007 to 2011 increased by 27% and 42% respectively, compared with 2012. The total procurement cost of Cephalosporins for Guangdong Province from 2007 to 2011 increased by 27% and 42% respectively, compared with 2012. The decline of price inhibits the Cephalosporins drug price growth to a certain extent. Technological innovation is the motivating factor to cause the Cephalosporins drug price to increase. There is a link between the level of administration route and the rationality of drug use. The competition among different manufacturers is an important factor that affects the total expenditure of Cephalosporins.

PIN33 THE DIFFERENCES BETWEEN INFECTIOUS & PARASITIC DRUG APPROVALS IN JAPAN AND THE USA

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OBJECTIVES: Infectious and parasitic diseases encompass some of the most deadly diseases including HIV, the sixth leading cause of death worldwide. The aim of this study was to investigate the similarities and differences between the approval of new drugs for the treatment of infectious and parasitic diseases in Japan and the USA. METHODS: Drugs approved from 2004 to 2013 were identified through publicly available literature and included in the analysis. RESULTS: Sufficient data were available for 2013 and 2012. In both countries, the most approved parasitic drugs were antimalarials. The most approved drugs for infectious diseases in Japan were antiviral drugs for hepatitis (20%) and HIV (17%), while in the USA, the most approved drugs were antibiotics (33%) and antiviral drugs for hepatitis (20%), mycoses (17%) and bacterial (13%) whereas the PMDA had high incidences of drugs indicated for influenza (24%) and viral infections (excluding HIV and hepa-titis) (18%). CONCLUSIONS: From the analysis presented here, it is clear that there are striking differences between infectious and parasitic disease drug approvals in Japan and the USA. Given the concern in Japan over the emergence of new influenza strains with pandemic potential, this is a great focus, constituting approximately a quarter of all infectious and parasitic disease drugs for the PMDA compared to no submissions to the FDA.

PND1 IVACFATOR FOR PATIENTS WITH CYSTIC FIBROSIS: CLINICAL EFFICACY AND COST-EFFECTIVENESS

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OBJECTIVES: This review appraises the clinical and cost effectiveness of ivacaftor for oral administration for the treatment of cystic fibrosis (CF) in patients aged 12 years and older with one G551D mutation in the CTFR (cystic fibrosis transmembrane conductance regulator) gene. METHODS: A limited literature search was conducted of key populations, and titles and abstracts of the retrieved publications were reviewed. Full-text publications were evaluated for final article selection according to predetermined criteria (population, intervention, comparator,
BEST PRACTICES AND KEY CHALLENGES IN COST-EFFECTIVENESS MODELING

The rational drug use should be confirmed to make sure to guarantee appropriate use in Alzheimer’s disease seems to be a heavy burden of the hospital every year. Every year ranging from 1,507 to 1,631 patients. For donepezil and memantine, Quantities and costs of the prescribed drugs were examined using defined daily dose (DDD) for comparisons. RESULTS: Number of patients was rather the same number, every year ranging from 1,507 to 1,631 patients. For donepezil and memantine, number of DDD per year was increased every year ranging from 7.3–10.0% to 1.6–14.7% compared to the previous year, respectively. The increasing trends were not found in prescribing of rivastigmine, except for the dramatically increase (34.0%) in 2013. Galantamine was prescribed less in 2010 and 2013 accounted for −9.2 and −18.2, respectively. Cost of drug use in Alzheimer’s disease was $3,211,269 in 2009 and $3,228,454 in 2013 with an increasingly trend. CONCLUSIONS: The overall drug use in Alzheimer’s disease seems to be a heavy burden of the hospital every year. The rational drug use should be confirmed to make sure to guarantee appropriate use of drug without overuse.

NEUROLOGICAL DISORDERS – Cost Studies

PND2 ECONOMIC BURDEN OF DRUG USE IN PATIENTS WITH ALZHEIMER’S DISEASE AT PHRAMONGKUTKLAO HOSPITAL AND MEDICAL COLLEGE, THAILAND: A 5-YEAR TREND ANALYSIS

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OBJECTIVE: To determine the trend of drug utilization for Alzheimer’s disease during 2009 and 2013. METHODS: Prescription data of outpatients with Alzheimer’s disease in 2009 – 2013 was extracted from the medical care database of the hospital. Quantiﬁcation and cost of prescribed drugs were examined using defined daily dose (DDD) for comparisons. RESULTS: Number of patients was rather the same number, every year ranging from 1,507 to 1,631 patients. For donepezil and memantine, number of DDD per year was increased every year ranging from 7.3–10.0% to 1.6–14.7% compared to the previous year, respectively. The increasing trends were not found in prescribing of rivastigmine, except for the dramatically increase (34.0%) in 2013. Galantamine was prescribed less in 2010 and 2013 accounted for −9.2 and −18.2, respectively. Cost of drug use in Alzheimer’s disease was $3,211,269 in 2009 and $3,228,454 in 2013 with an increasingly trend. CONCLUSIONS: The overall drug use in Alzheimer’s disease seems to be a heavy burden of the hospital every year. The rational drug use should be confirmed to make sure to guarantee appropriate use of drug without overuse.
NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

PND7 IMPACT OF COPayment REDUCTION OR EXEMPTION PROGRAMME ON GENERIC DRUG UTILISATION: THE SPECIFIED DISEASE TREATMENT RESEARCH PROGRAMME IN JAPAN

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OBJECTIVES: In Japan, the Specified Disease Treatment Research Programme provides copayment reduction or exemption for patients with 56 designated rare and intractable diseases/syndromes according to disease severity and patients’ income levels. The objective of this study is to examine the impact of the Specified Disease Treatment Research Programme on generic drug utilization under the fee-for-service payment system. METHODS: We extracted and analysed claims data with indication for Parkinson’s disease, which is subject to the Specified Disease Treatment Research Programme, from the Social Health Insurance claims data processed from February to April 2011. Extracted data were analysed in terms of patients’ age and income levels, types of public subsidy, prescribed places (clinical hospital or pharmacy) and pharmacologic classes. RESULTS: During the three months, cumulative total number of 72,145 patients in Social Health Insurance programme were prescribed drugs for Parkinson’s disease, of which 10,013 were entitled to the Specified Disease Treatment Research Programme. Overall average generic utilisation rate is 15.46% on a volume basis. Average generic utilisation rate for those entitled to the Specified Disease Treatment Research Programme is 4.04%, whilst for patients eligible for medical assistance programme is 21.75%. Generic utilization is fewer in the elderly than in the younger generation. CONCLUSIONS: On 2009, the average utilisation rate in Japan was 21.75%, comparable to placebo or other active medications in diabetic and non-diabetic PN patients. Two reviewers independently screened for eligible studies, assessed risk of bias, and extracted data. Mean difference (MD) and 95% confidence interval (CI) were used for pooling continuous data. RESULTS: Four RCTs compared ALC with placebo and reported in 3 articles (n = 523) were included. Compared with placebo, ALC significantly reduced Visual Analogue Scale (VAS) of PN symptoms (MD, 1.28; 95% CI, 0.93–1.64; P < 0.0001). In the subgroup analysis, ALC on VAS was similar in different administration route (intramuscular–oral serial subgroup: MD, 1.19; 95% CI, 0.34–2.04; P < 0.006; oral only subgroup: pooled MD, 1.15; 95% CI, 0.33–1.96; P = 0.006), and ALC appeared more effective in non-diabetic PN patients than diabetic PN patients (diabetic subgroup: MD, 1.47; 95% CI, 1.06–1.87; P < 0.0001; non-diabetic subgroup: MD, 0.71; 95% CI, 0.01–1.43; P = 0.05). No severe adverse events related to ALC were reported. The most frequent AEs were headache, pain, headache, paraesthesia, hyperesthesia, retching, biliary colic and gastrointestinal disorders. The rate of serious AEs was higher in ALC and control group. CONCLUSIONS: ALC could reduce VAS in PN patients with acceptable safety. However, further trials with larger population and longer follow-up are required to confirm these findings.

PND9 AGE AND GENDER DISTRIBUTION OF OUTPATIENT CARE PHYSIOTHERAPY SERVICES FOR CEREBRAL PALSY AND OTHER PARALYTIC SYNDROMES IN HUNGARY

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OBJECTIVES: The aim of our study is to assess the utilization of out-patient care physiotherapy services related to cerebral palsy and other paralytic syndromes according to age and gender. METHODS: The data come from the financial data base of the National Health Insurance Fund Administration involving the year of 2009. The activity list was provided by the rulebook on the application of the physiological services related to cerebral palsy and other paralytic syndromes according to age and gender. We searched PubMed up to March 2014 for randomized controlled trials (RCTs) comparing ALC with placebo or other active medications in diabetic and non-diabetic PN patients. Two reviewers independently screened for eligible studies, assessed risk of bias, and extracted data. Mean difference (MD) and 95% confidence interval (CI) were used for pooling continuous data. RESULTS: Four RCTs compared ALC with placebo and reported in 3 articles (n = 523) were included. Compared with placebo, ALC significantly reduced Visual Analogue Scale (VAS) of PN symptoms (MD, 1.28; 95% CI, 0.93–1.64; P < 0.0001). In the subgroup analysis, ALC on VAS was similar in different administration route (intramuscular–oral serial subgroup: MD, 1.19; 95% CI, 0.34–2.04; P < 0.006; oral only subgroup: pooled MD, 1.15; 95% CI, 0.33–1.96; P = 0.006), and ALC appeared more effective in non-diabetic PN patients than diabetic PN patients (diabetic subgroup: MD, 1.47; 95% CI, 1.06–1.87; P < 0.0001; non-diabetic subgroup: MD, 0.71; 95% CI, 0.01–1.43; P = 0.05). No severe adverse events related to ALC were reported. The most frequent AEs were headache, pain, headache, paraesthesia, hyperesthesia, retching, biliary colic and gastrointestinal disorders. The rate of serious AEs was higher in ALC and control group. CONCLUSIONS: ALC could reduce VAS in PN patients with acceptable safety. However, further trials with larger population and longer follow-up are required to confirm these findings.

PND10 ADMINISTRATION OF OUTPATIENT PHYSIOTHERAPY SERVICES IN DISEASES OF THE NERVOUS SYSTEM IN HUNGARY

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OBJECTIVES: The purpose of our study is to assess the frequency related to Diseases of the nervous system within out-patient care and determine the total health care expenses of them in Hungary in 2009. METHODS: CONCLUSIONS: METHODS: Data were derived from the nationwidewide database of Hungarian National Health Insurance Fund Administration (NHIFA), based on official reports of outpatient care institutes. The data come from the financial data base of the National Health Insurance Fund Administration (NHIFA), based on official reports of outpatient care institutes. The cerebral palsy and other paralytic syndromes account for 71.72 % (955073) of total services. The passive procedures are more common than the active in the 20 most commonly used activities list. Our results could serve as a basis of the financial planning of the treatments of the studied diseases of the nervous system.

PND11 REVERSAL OF CHRONIC FATIGUE INDUCED ALTERATIONS BY SESAMOL IN MICE: EVIDENCE FOR INVOLVEMENT OF OXIDATIVE STRESS AND INFLAMMATORY PATHWAY

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OBJECTIVES: A wide body of literature suggest in vivo neuroprotective, antioxidant, anti-inflammatory and anti-agging properties of Sesamol. This study was aimed to elucidate the protective effect of sesamol in experimental model of chronic fatigue syndrome (CFS). METHODS: Firstly, Sesamol was tested for its antiprees- sure potential in mouse models using forced swim test (FST) and tail suspension test (TST). Later, Sesamol was examined in mouse models of chronic stress fatigue induced by chronic forced swimming for 15 days. Brain biochemical [superoxide dismutase (SOD), glutathione-S-transferase (GST), glutathione (GSH), lipid peroxi- dation and nitrite levels] and plasma cytokines [tumour necrosis factor α (TNF-α) and interleukin 6 (IL-6)] levels were assessed to correlate the possible mechanism of action associated with fatigue symptoms. Further, adrenal ascorbic acid measure- ment was done to correlate corticosterone levels. RESULTS: Mice administered with sesamol showed a significant decrease in immobility time in acute FST and TST. Sesamol significantly attenuated progression of CFS in experimental model as compared to control. Sesamol also corrected the other cognitive deficits (locomo- tor activity and memory retention, hyperalgesia) associated with CFS. Furthermore, it rectified the diminished levels of antioxidant enzymes such as SOD, GST and GSH in brain and altered levels of proinflammatory cytokines (TNF-α, IL-6). CONCLUSIONS: This finding suggests fatigue-activity effect of sesamol against chronic induced fatigue in mice. The present outcome offers a therapeutic application of sesamol against CFS and also offers the scope for its development against psychoneurotic disorders.

URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies

PUK1 TADALAFIL IN BENIGN PROSTATIC HYPERPLASIA: PROTOCOL FOR THE SYSTEMATIC REVIEW OF ADVERSE EVENTS

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Optum Global Solutions, Noida, India

OBJECTIVES: Benign prostatic hyperplasia (BPH) is an age related disorder, however its symptoms begin to appear in some men as early as age 40 years. As per estimates every second person has BPH by the age of 60 and 90% of individuals develop BPH by 85 years. Tadalafil is a selective PDE5 enzyme inhibitor approved to treat men with BPH. The aim is to systematically review the medical literature for randomized control trial and double blind randomized controlled trial (DBRCT) on use of Tadalafil in BPH. METHODS: All published randomized controlled trials (RCTs) comparing tada- lafil with a placebo or active interventions for the treatment of BPH with or without any co-morbidity (such as but not limited to erectile dysfunction) were sought from PubMed, EMBASE, Cochrane Library, and Google Scholar. Abstracts, titles and then the full-text manuscripts of all selected articles will be retrieved and assessed by two independent reviewers against the eligibility criteria. Disagreements regarding the inclusion will be resolved through discussion. A pre-designed data extraction form will be used by two reviewers for the extraction of AE and other study findings. Cochrane risk of bias assessment checklist will be used for the risk of bias assessment of RCTs and DBRCTs. Results: Descriptive and quantitative data synthesis will be done for AE reported in all the studies. Meta-analysis will be performed using RevMan (v5.0). RESULTS: Though there are several studies assessing tadalafil use for erectile dysfunction, a syste- matic review/meta-analysis of the evidence reporting its AE profile when used for
the treatment of BPH is lacking. This systematic review registered with PROSPERO (registration number: CRD42014007248) aims to provide the evidence for the AE associate with tadafinil use in BPV indication. CONCLUSIONS: Tadafinil use in BPV has now been increasing over the years. The data from published RCTs will help to reduce hospital readmission in addition to cardiovascular complications. The reduction of kidney infection in Trp 16/16, BALB/c: 26% vs 87% (n = 16], BALB/c: 26% vs 87% [n = 15], reduced kidney tissue damage and gene expression of K1, II-6 and TNF-α in kidney tissues. The reduction of kidney infection and tissue damage resulting from C5aR blockade was more profound at 48h and 72h post infection. C5aR blockade led a small reduction of neutrophil infiltration at 1h and 24h but not at 72h. C5aR blockade effectively protected mice from UPEC-induced kidney infection suggesting that C5aR signal is a critical pathogenic factor in UTIs, thus representing a promising target for treating or preventing human UTIs.

URINARY/KIDNEY DISORDERS – Cost Studies

PUK7 BUDGET IMPACT ANALYSIS OF PERITONEAL DIALYSIS VERSUS CONVENTIONAL IN-CENTER HEMODIALYSIS IN MALAYSIA

Ravanandran S1, Ahmad G2, Teo AH3, Chen L4, Liu FX4
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OBJECTIVES: The increasing prevalence of patients with end-stage renal disease in Malaysia is driving up the costs of dialysis care dramatically. Several studies have projected significant cost savings by increasing the proportion of patients on peritoneal dialysis (PD). This study investigates the five-year health care budget impact of variable distribution of adult patients treated with PD and in-center hemodialysis (ICH) on government funding in Malaysia. METHODS: An Excel®-based budget impact model was constructed to assess dialysis-associated costs when changing dialysis modalities between PD and ICH. The model incorporates the current modality distribution and accounts for Malaysian government dialysis-associate costs. The model was validated against Taiwan Renal Data System by Taiwan Society of Nephrology. The transplant rate, incidence, mortality, and transplant rate from Malaysian renal registry reports, were used to estimate dialysis patient population for the next five years. The alternative scenarios used are: a stable distribution of PD (8%) and ICH (92%) over five years. Alternative scenarios included the prevalence of PD increased by 2.5%, 5.0%, and 7.5% or decreased 1% yearly over five years. All four scenarios were accompanied with commensurate changes in ICH. RESULTS: Under the current best available cost information, an increase in the prevalent PD population from 8% in 2014 to 28%, or 5% in 2018 is predicted to result in five-year cumulative savings for the Malaysian government of RM13.9 million, RM27.9 million, and RM41.9 million respectively. The impact of 7.5% increase in PD population are: in 2014 to 4.0% by 2018, the total expenditure for dialysis treatments would increase by RM5.6 million over the next five years. CONCLUSIONS: Under the best available cost information associated with PD and HD paid by the Malaysian government, increasing the proportion of patients on PD could result in reduction in dialysis-associated costs in the future.

PUK8 FINANCIAL IMPLICATIONS TO TAIWAN HEALTH SYSTEM FROM CHANGING THE DIALYSIS MODALITY MIX

Yang W.C1, Hsu CC2, Liu FX3
1Taipei Veterans General Hospital, Taipei, Taiwan, 2National Health Research Institutes, Taipei, Taiwan, 3Renox Healthcare Corporation, Deerfield, IL, USA

OBJECTIVES: In 2012, 0.3% of Taiwan end-stage renal disease (ESRD) patients were treated with PD. For 6.64% of National Health Insurance (NHI) dialysis spending. We investigated the five-year financial impact of changing the distribution of patients undergoing peritoneal dialysis (PD) and in-center hemodialysis (ICH) in Taiwan. METHODS: An Excel®-based budget impact model was constructed to assess dialysis-associated costs. The model incorporates Taiwan current modality distribution and accounts for ESRD outpatient and inpatient total health care cost. The financial data was derived from Taiwan National Health Insurance Research Database (NHIRD) for 2006. The baseline scenario assumed a stable distribution of PD (10%) and ICH (90%) over five years. The financial impact as well as its associated costs in the future.

PUC2 PREVALENCE AND ASSOCIATED COMPLICATIONS OF ACUTE KIDNEY INJURY AMONG DENGUE PATIENTS

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OBJECTIVES: Dengue fever is a mosquito borne infectious disease that is mainly prevalent in tropical and subtropical zones of the world. One of the potential complications of this disease is acute kidney injury (AKI). Current studies aim to assess the incidence and risk factors for AKI among dengue patients. METHODS: A retrospective review of medical records of dengue infected patients enrolled from May 2005 to December 2013 was conducted at a tertiary care hospital in Manipal. RESULTS: Total 124 patient records (male: 63, female: 61) with mean age of 29.57± 15.09 were reviewed retrospectively. Out of 124 patients, 104 (83.9%) suffered with classic DF, 19 (15.3%) with dengue hemorrhagic fever (DHF) while only 10.8% with Dengue shock syndrome (DSS). The prevalence of AKI among Dengue patients was found to be 7.2 % (9 patients). On the basis of Acute Kidney Injury Network (AKIN) criteria, 2(22%) had stage 1 AKI while remaining 7(78%) had stage 2 AKI. For the purpose of analysis of risk factors for AKI, patients were categorized into group A (with AKI) and group B (without AKI). Mann Whitney “U” test was used to compare differences between groups. A higher serum creatinine (112.39 ± 56.87; p: 0.001), bilirubin (70.81 ± 48.73; p: 0.038), urea (104.50 ± 58.08; p: 0.001), WBC (12.25 ± 9.90; p: 0.013) and HB (90.91 ± 60.04; p: 0.021) levels were observed among AKI dengue patients. Though the duration of hospital stay of group 1 was more than group II, but this difference was statistically insignificant (t=7.33, df= 61.34; p: 0.192). CONCLUSIONS: AKI is a least studied and poorly understood complication of dengue fever. Such patients are at verge of developing DH/SS resulting in complicated clinical course and increased mortality. A cautious diagnosis and timely management would be the first and foremost step for management of such patients.

PUC5 ACTIVATION OF ENDOGENOUS ANTI-INFLAMMATORY MEDIATOR CYCLIC AMP CONFESSION PROTECTION IN MURINE ACUTE PYELONEPHRITIS INDUCED BY UREAPATHOBIONT ASCOLI

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OBJECTIVES: To investigate the effect of forskolin, on susceptibility/severity of acute pyelonephritis and innate immune responses to pathogen using an established experimental model, mimicking urinary tract infection and presenting real world clinical scenarios (i.e. renal tubular epithelial cells, monocytes/macrophages). METHODS: Forskolin is produced by the Indian Coleus plant (Coleus forskohlii), which is commonly used to raise levels of cyclic AMP (cAMP) in the study and research of cell physiology. Forskolin has been shown to down-regulate the expression of genes involved in inflammation. Kidney infection was assessed in forskolin or control reagent treated mice at 6, 24, 48h after bladder inoculation of UPEC (96h). Bacteria load in kidneys was analysed by real-time PCR. RESULTS: Administration of forskolin significantly reduced bacterial load in kidneys and bladder. Data System based analysis revealed at 6h and 24h time points by 10 folds, this was associated with reduced intrarenal production of pro-inflammatory cytokines and chemokines (e.g. TNFα, IL-1β, KC, MCP-1) and attenuated intrarenal infiltration and accumulation of leukocytes (e.g. CD45+, Gr-1, F4/80+) as well as intrarenal myeloperoxidase (MPO) activity. In vitro, forskolin inhibited LPS or UPEC mediated pro-inflammatory cytokine and chemokine production by primary renal tubular epithelial cells/myocytes/macrophages. CONCLUSIONS: These findings demonstrate that administration of forskolin is beneficial for controlling the development of UPEC mediated acute pyelonephritis in mice. The protective effect of forskolin (via cAMP activation) in this experimental acute pyelonephritis can be explained at least in part by limiting excessive inflammatory responses through acting on both renal parenchymal and inflammatory cells.
the prevalence of PD increasing by 2%, 3%, and 5% or decreasing by 1.0% each year for five years, were analyzed. **RESULTS:** Under the current best available cost information, an increase in the prevalent PD population from 10% in 2014 to 18%, 22%, or 30% in 2018 is predicted to result in five-year cumulative savings for NIH dialysis budget by NT$1,100 million (0.33%) over the next five years. **CONCLUSIONS:** A systematic review was conducted to investigate the prevalence of chronic renal failure in Guangzhou, China and to explore its determinants. **METHODS:** Direct inpatient service costs data were drawn from the reimbursement claim database in Guangzhou City, which covers the entire Urban Employee Basic Medical Insurance and Urban Resident Basic Medical Insurance enrollees of Guangzhou City. The records of patients who were admitted to hospitals between January 2010 and December 2012 with a diagnosis of chronic renal failure were all included. Descriptive and regression analyses (through the extended estimation method) were conducted to evaluate differences on direct hospital costs. **RESULTS:** A total of 3,524 hospitalisation records were identified. The mean (standard deviation, SD) age of patients was 60 (18) years old and the majority were male (54%). Patients were more likely to receive inpatient treatments at tertiary hospitals (83%), followed by secondary (16%) and primary hospitals (1%). The mean (SD) of direct hospital costs per visit was 16,440 (22,677) USD, which account for 38% of inpatient annual costs (USD 42,700) for patients with chronic renal failure. **CONCLUSIONS:** Both demand and supply side factors were significantly associated with the direct inpatient service costs of chronic renal failure. The establishment of urban basic medical insurance schemes has reduced the financial burden for the insured urban population.

**PUC10**

**HEALTH AND ECONOMIC IMPACT OF COMBINATION THERAPY VS. MONOTHERAPY FOR TREATMENT OF BENIGN PROSTATIC HYPERPLASIA IN HONG KONG**

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2 The Chinese University of Hong Kong, Hong Kong
3 Medical University, Kuala Lumpur, Malaysia

**OBJECTIVES:** Alpha-blockers (AB) or 5-alpha reductase inhibitor (SARI) monotherapy is standard benign prostatic hyperplasia (BPH) treatment. Recently, combination therapy with multiple agents e.g. AB (e.g. tamsulosin) plus SARI (e.g. dutasteride), has gained growing interest to improve clinical outcomes. The possible superiority of combination therapy over monotherapy remains unclear. The study aims to examine health and economic impact of combination therapy versus SARI monotherapy in a hypothetical cohort of patients treated at the public hospital in Hong Kong (HK).

**METHODS:** A Markov model was developed to project the overall QALYs, life-years, cost-saving and improvement of quality of life (QoL) associated with combination therapy versus SARI monotherapy. The model was built according to the HK-specific treatment practice. Model parameters including probability of treatment, utility of health states, lengths of stay, and utilities were derived from previous literatures. Efficacy data was adopted from the 4-year Combination of Avodart and Tamsulosin (CombAT) trial. The study was performed from a public payer perspective. Projected economic and clinical outcomes over 4 years include drug cost, cost of BPH treatment, number of acute urinary retention (AUR) and transurethral resection of the prostate (TURP). Both 1-way and multivariate probabilistic sensitivity analyses were undertaken to evaluate robustness of results. **RESULTS:** Compared to tamsulosin, combination therapy could prevent 28 AURs (77.8% reduction) and 69 TURPs (79.3% reduction) over 4 years. Compared to tamsulosin, combination therapy can lead to cost reduction of HKD1,574,079 (USD20,600), HKD3,221,084 (USD41,780), and HKD91,916 (USD12,000) due to reduced numbers of AUR, TURP and pre- and postoperative medical intervention, respectively and additionally a delay in patients’ progression to AUR and TURP. The incremental cost per capita is HKD1,045 (USD134) over 4 years. The results are highly sensitive to drug cost, drug efficacy and probability of BPH patients experiencing TURP. **CONCLUSIONS:** Combination therapy could lead to reduction in the number of AUR and TURP and the associated cost.

**PUC11**

**COST-EFFECTIVENESS OF PERCENT FREE PSA FOR PROSTATE CANCER DETECTION IN CHINESE MEN WITH A TOTAL PSA OF 4.0-10.0 NG/ML**

Lee T.Y., Yee H.L., Yip P.H.

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2 Pfizer Pharmaceuticals Korea Ltd., Seoul, South Korea

**OBJECTIVES:** Among LUTS/BPH patients, OAB symptoms are most troublesome. This study aimed to investigate the cost-saving and improvement of quality of life (HRQoL) and explored the related factors in LUTS/BPH patients with OAB. **METHODS:** This nationwide-observational study was conducted in 30 urology centers in Korea during December 2011 to January 2012 to analyze more than 50,000 visits of LUTS/BPH patients (in International Classification of Disease code symptom score, ICD) in 24-item ICIQ-SF, and 24-item ICFB-QOL in the treatment of hyperphosphatemia in patients with CKD (2.70 QALYs, £25,916 /QALYs, UK; 3.71 QALYs, €27,086/QALYs, EU) and comparison with Sevelamer in the treatment of ESRD patients with hyperphosphatemia who were previously treated with calcium -based binders (for complete population was considered, the ICERs of LC versus sevelamer were £15,285/QALYs and 9,337/LYS). There are five literature that suggests, sevelamer is a cost-effective drug for the treatment of hyperphosphatemia in patients with CKD (2.70 QALYs, £25,916 /QALYs, UK; 18-life years, Canada). **CONCLUSIONS:** We get different results from the existing international studies which could not inform decision makers in China. So, it’s necessary for us to carry out the research in the Chinese setting in the future.

**PUB12**

**THE PREVALENCE OF PROSTATE CANCER IN CHINESE MEN WITH ABNORMAL PROSTATE-SPECIFIC ANTIGEN (PSA) LEVELS OF 4.0-10.0 NG/ML**

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2 Flinders University, Adelaide, Australia
3 Beijing Novartis Pharma Co., Ltd, Beijing, China

**OBJECTIVES:** The prevalence of prostate cancer in the Chinese population with abnormal prostate-specific antigen (PSA) levels of 4.0-10.0 ng/ml is low. The diagnostic accuracy for prostate ultrasonic guided prostate biopsies (TRUS-Bx) which may cause major complications. We assess the cost-effectiveness of two diagnostic strategies for prostate cancer detection in Chinese men with abnormal PSA levels of 4.0-10.0 ng/ml and normal digital rectal examination of prostate (DRE). **METHODS:** Using a decision tree model, we performed a cost-effectiveness analysis to compare the two strategies: 1) direct prostate biopsies (TRUS-Bx) and 2) combination therapy versus 5ARI monotherapy in a hypothetical cohort of patients with PSA levels of 4.0-10.0 ng/ml and normal DRE enrolled in a single medical institute from Jan 2002 to December 2005 was conducted. The outcome measures were the incremental cost-effectiveness ratio, and costs were calculated through activity-based costing and National Insurance Scheme billed amounts. Sensitivity analysis was undertaken. The effectiveness was measured by means of the number of detected cases and actual cases (detected cases minus lost cases). **RESULTS:** The strategy of percent free PSA with TRUS-Bx was dominant and found to be the most-cost-effective. The incremental cost-effectiveness ratio for free PSA + TRUS-Bx compared with TRUS-Bx was USD 58. Strategy 2 (TRUS-Bx) would be more cost-effective if the cost of percent free PSA increased to USD 36.78 or prostate cancer prevalence increased to 42%. **CONCLUSIONS:** The use of percent free PSA prior to TRUS-Bx is the most-cost-effective diagnostic strategy and will become more cost-effective as prostate cancer prevalence increases in the ageing population and the free PSA test costs down.

**PUC13**

**ECONOMIC EVALUATION OF THE TREATMENTS FOR HYPERPHOSPHATEMIA AMONG PATIENTS WITH CHRONIC KIDNEY DISEASE: A REVIEW**

Li X., Yan X.

1 Peking University, Beijing, China

**OBJECTIVES:** The aim of this study was to synthesize the evidence on cost-effectiveness of treatment for hyperphosphatemia in chronic kidney disease patients. **METHODS:** Using “hyperphosphatemia” , “chronic kidney disease,” “cost” and “economic evaluation,” Mendeley (http://www.mendeley.com) was used to search for articles. Among 70 articles, we selected eight related articles for review. **RESULTS:** First, researches in this area are more concentrated in developed countries, such as UK and US. Second, cost-effectiveness of treatment for hyperphosphatemia is not clear. Third, the cost-effectiveness of treatment for hyperphosphatemia was not lower than the drug cost. Fourth, there is a need to develop economic evidence on the treatment of hyperphosphatemia for the insured urban population. **CONCLUSIONS:** Further researches on this area are needed.
an outcome measure in interventional studies. Psychological distress is a subset of HRQoL that specifically evaluates the impact on mental health. In addition, social support and patients’ perception of illness have been shown to predict all-cause mortality in ESRD patients. However, local data comparing PRO and social support in hemodialysis (HD) vs. peritoneal dialysis (PD) patients are lacking. Hence, the objective of this cross-sectional, observational study was to evaluate and compare patient-reported and laboratory outcomes in our multi-ethnic HD and PD patients.

**METHODS:** Eligible chronic dialysis patients from National University Hospital were recruited. PRO measures include Kidney Disease Quality of Life-Short Form, EuroQol-5 Dimensions and Kessler Psychological Distress Scale. Social support was assessed using Family Functioning Measure. Relevant sociodemographic information and medication list/laboratory parameters were captured using a pre-tested health services utilization questionnaire, and clinic notes/electronic medical records respectively. All data were analysed and compared between HD and PD patients using Stata version 10.

**RESULTS:** A total of 113 patients were recruited (HD: n=81, PD: n=32). There were no significant differences in HRQoL, social support, level of distress and most laboratory parameters between HD and PD patients. However, HD patients had significantly higher serum albumin levels (38.2±3.6 g/L vs. 32.5±4.5 g/L, p<0.001) while PD patients had significantly higher serum corrected calcium levels (2.41±0.2 mmol/L vs. 2.27±0.2 mmol/L, p=0.004) and number of medications (10.1±3.1 vs. 8.8±2.9, p=0.039).

**CONCLUSIONS:** Barring cost and patient-specific factors, HD and PD are likely equivalent therapeutic options for ESRD patients in Singapore. However, the findings need to be confirmed in a larger study.
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