Tuesday Research Poster Presentations

POSTER SESSION III: Poster Display Hours – 8:45 - 13:30
Poster Author Discussion Hour – 12:30 - 13:30

POSTER SESSION IV: Poster Display Hours – 15:30 - 19:15
Poster Author Discussion Hour – 18:15 - 19:15

POSTER SESSION III:
PMD: MEDICAL DEVICES/DIAGNOSTICS ROWS A-F
PCV: CARDIOVASCULAR DISORDERS ROWS F-K
PGI: GASTROINTESTINAL DISORDERS ROWS K-L
PRS: RESPIRATORY-RELATED DISORDERS ROWS L-N

POSTER SESSION IV:
PHP: HEALTH CARE USE & POLICY STUDIES ROWS A-K
PMH: MENTAL HEALTH ROWS K-L
PND: NEUROLOGICAL DISORDERS ROWS L-N
## Research Poster Presentations – Session III

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PMD1: ISO-OSMOLAR CONTRAST MEDIA AND ADVERSE RENAL AND CARDIAC EVENTS AFTER PERCUTANEOUS CARDIOVASCULAR INTERVENTION

McCullough PA¹, David G², Todoran TM³, Brilakis ES⁴, Ryan MP⁵, Gunnarsson C⁶,¹Baylor Heart and Vascular Institute, Dallas, TX, USA, ²The Wharton School, University of Pennsylvania, Philadelphia, PA, USA, ³Medical University of South Carolina, Charleston, SC, USA, ⁴Minneapolis Heart Institute, Minneapolis, MN, USA, ⁵CTI Clinical Trial and Consulting Services, Covington, KY, USA

OBJECTIVES: There is limited evidence examining MARCE (major adverse renal and cardiovascular events) in clinical practice with respect to the use of iso-osmolar contrast media (CM, IOCM) and low-osmolar CM (LOCM). The objective of this research was to assess the relationship between the type of CM (IOCM or LOCM) and MARCE events in patients undergoing inpatient angioplasty in a real-world setting. METHODS: Inpatient visits with a record of a primary procedure code for coronary or peripheral angioplasty from the Premier Hospital Database from January 1, 2008 through September 30, 2013 were analyzed. Angioplasty visits were stratified into two cohorts based on contrast media agents used: [1] IOCM (iodixanol) and [2] LOCM (iohexol, ioversol, iopamidol, ioxaglate, ioxilan, or iopromide). The outcome of interest was the MARCE composite end point, defined as renal failure with dialysis, acute kidney injury with and without dialysis, acute myocardial infarction, angina, stent occlusion/thrombosis, stroke, transient ischemic attack, or death. Multivariable regression analysis was conducted using the hospital fixed-effects specification to assess the relationship between MARCE events and type of CM used. RESULTS: Among 333,533 visits across 357 hospitals the incidence of MARCE was 7.41%. In the fully adjusted model, after controlling for observable and unobservable time invariant within-hospital characteristics administration of IOCM versus LOCM was associated with a 0.69% absolute and 9.32% relative risk reduction in MARCE rate. CONCLUSIONS: In this large retrospective multicenter study of patients undergoing inpatient angioplasty, IOCM administration was associated with a 9.32% relative risk reduction of MARCE events as compared with LOCM administration.

PMD2: ECONOMIC EVALUATION OF NT-PROBNP GUIDED THERAPY IN PATIENTS WITH CHRONIC HEART FAILURE

Lu X, Mao Y, Roche Diagnostics Limited, Shanghai, China

OBJECTIVES: The objective of the analysis was to determine the economic impact (change in healthcare expenditures) over a 12-month horizon of introducing serial measurements of NT-proBNP to guide therapy on top of current standard of care vs. usual care of chronic heart failure (CHF) in China. METHODS: Decision tree was developed to simulate the process of CHF patients receiving standard of care and usual care. Inpatient care cost, medication cost and laboratory cost were incorporated as cost inputs in the analysis, and indicators such as basic therapy success rate were included as clinical inputs. RESULTS: The total cost of NT-proBNP guided therapy and usual care was US$1240.7 and US$1592.4 respectively. In the aspects of effectiveness, NT-proBNP guided therapy decreased the number of hospital admissions by 70.3%, hospitalization length by 69.6% and number of death by 66.4% respectively compared with usual care. One-way sensitivity analysis via changing every input by 20% showed that the basic therapy success rate of NT-proBNP guided therapy had the greatest impact on the results while the parameter determined the number of patients at the high risk of re-hospitalization or death. CONCLUSIONS: NT-proBNP guided therapy can reduce treatment cost and improve clinical efficacy by lowering hospitalization rate and length, and reducing the mortality rate of CHF patients. In general, from the economic point of view, it is recommended that NT-proBNP guided therapy could be promoted in the clinical diagnosis and treatment of CHF.

PMD3: THE CLINICAL AND COST-EFFECTIVENESS OF DIFFERENT MATERNAL SYphilis SCREENING STRATEGIES IN BRAZIL

Romero CP¹, Stevenson MD², Dixon S²,¹Oswaldo Cruz Foundation, Fiocruz, Rio de Janeiro, Brazil, ²University of Sheffield, Sheffield, UK
OBJECTIVES: The study goal was to estimate the costs and clinical outcomes avoided through antenatal syphilis screening at different stages of maternal syphilis in Brazil, comparing rapid point-of-care tests (RTs), performed at least twice, with conventional (non-treponemal and treponemal) diagnostic tests. METHODS: A decision tree model was constructed considering a hypothetical pregnant population with primary (9-90 days), secondary (six weeks to six months) or tertiary and latent syphilis (two years or more) which was tested either with RTs or standard tests. These stages have distinct clinical, immunological and histopathologic characteristics and different infection transmission rates mother-to-child. A literature search was undertaken for parameters values relating to prevalence, tests accuracy, treatment compliance, vertical transmission rate, and costs of treatment in all maternal syphilis stages. The literature review was supplemented with data from Brazilian national data. The numbers of adverse birth outcomes (congenital syphilis, neonatal deaths, miscarriage or stillbirths and non-infected babies) caused by maternal syphilis were estimated. Identification of infected partners and any subsequent treatment were excluded from the model. Sensitivity analysis was undertaken to assess the potential generalisability of the results. RESULTS: For a population of 10,000 pregnant woman performing RTs resulted in fewer adverse events (63 cases of congenital syphilis; 23 cases of neonatal deaths and 48 miscarriage or stillbirths, and 134 infected children) compared with standard care. The RTs were also associated with lower costs of testing and treatment compared with standard tests (US$65,421; US$72,873, respectively), representing a saving of US$7,452. If the costs of RTs increase by 12.5% or treatment compliance of 2° RTs decreases to 65% the strategy of RTs is no longer the dominant alternative. CONCLUSIONS: Our study shows that screening with rapid syphilis tests is estimated to dominate standard tests in Brazil. We believe this result to be generalizable to low and middle-income countries.

PMD4: ECONOMIC ANALYSIS OF ALK RELATED COMPANION DIAGNOSIS METHODS BEFORE THE TARGETED THERAPY FOR NON-SMALL CELL LUNG CANCER

He J1, Lu X2, Mao Y2, Hu S3, 1Shanghai Medical Information Center (Shanghai Health Development Research Center), Shanghai, China, 2Roche Diagnostics Limited, Shanghai, China, 3Shanghai Health Development Research Center, Shanghai, China

OBJECTIVES: To analyze the health outcomes, cost and cost effectiveness of different testing methods to categorize patients with non-small cell lung cancer and guide targeted therapy. METHODS: Decision tree model was developed to simulate 3 groups of 100,000 NSCLC patients who adopted 3 ALK testing methods (FISH, Ventana IHC, and RT-PCR) respectively recommended by China guideline and were treated with Crizotinib as first line treatment if ALK was positive. Medical cost occurred and health outcomes acquired in 5 years were calculated to carry out cost effectiveness analysis. Clinical and economic data were mainly retrieved from literature summary. RESULTS: Ventana IHC guided therapy group was less costly and more effective compared with PCR guided therapy group. In addition, the ICER of FISH guided therapy group versus Ventana IHC guided group was US$177,725/QALY, far more than the threshold, which was US$47,553 using 3 times of Shanghai GDP per capita in 2014. Therefore, Ventana IHC group was more cost effective than FISH group. CONCLUSIONS: Among the three ALK testing methods, we suggested that Ventana IHC should be optimally selected as the companion diagnosis method and be introduced into NSCLC targeted therapy management scheme.

PMD5: WHAT IS THE ECONOMIC IMPACT OF CCP TEST MISCLASSIFICATION IN RHEUMATOID ARTHRITIS DIAGNOSIS? A BENCHMARKING SIMULATION STUDY IN SPAIN.

Andalucía C., Gallo G., Mascalino B., Thermo Fisher Scientific, Uppsala, Sweden

OBJECTIVES: Rheumatoid arthritis (RA) diagnosis requires a combination of clinical, laboratory and imaging investigations. It is known that the detection of antibodies to cyclic citrullinated peptides (CCP) may occur long before the onset of RA symptoms. The diagnostic accuracy of CCP testing is important. However, the clinical and economic consequences of CCP-misclassifications have not been investigated. In RA, the consequences of misclassification are particularly costly: subjects with a CCP False Positive (FP) results are managed as RA patients, bringing about consequences of CCP misclassification. RESULTS: Depending on the CCP test used, FPs ranged between 1.7% (Thermo Fisher Scientific) and 4.3% (Roche), and FNs between 11.7% (Roche) and 24.2% (Inova Diagnostics). FPs total costs were lowest when using Thermo Fisher Scientific (10724€2-25406€3.5), and highest when using Roche (26798€2-25406€3.5), and highest when using Roche (26798€2-25406€3.5).
CONCLUSIONS: Results show that the Thermo Fisher Scientific CCP test correctly classifies more RA patients / healthy subjects compared to comparator CCP tests. As a consequence, the Thermo Fisher Scientific CCP test demonstrates superior value from patient, health care provider, and payer perspective.

**PMD6: ECONOMIC EVALUATION OF STRATEGIES FOR OPPORTUNISTIC CERVICAL CANCER SCREENING**

**OBJECTIVES:** The aim of this study was to access the strategies for opportunistic cervical cancer screening in hospitals and provide scientific evidence for selecting the optimal strategy via comparing the screening effectiveness and disease management cost of different strategies. **METHODS:** A Markov cohort model was established to simulate 2 cycles of cervical cancer screening in 100,000 volunteer women aged from 30 to 65. The cost and effectiveness of different strategies were calculated from the perspective of China’s healthcare system. Three strategies were compared, including co-testing of HPV & cytology, co-testing of HPV & cytology with reflex to CINtec PLUS, and co-testing of HPV 16/18 genotyping & cytology with reflex to CINtec PLUS. **RESULTS:** Compared with co-testing of HPV & cytology strategy, more CIN2+ cases could be detected over two screening cycles with less annual incidence and mortalities of cervical cancers at slightly higher cost per cases of CIN2+ detected when adopting co-testing of HPV & cytology with reflex to CINtec PLUS strategy. Co-testing of HPV 16/18 genotyping & cytology with reflex to CINtec PLUS could find the most CIN2+ cases and cause the least annual incidence and mortalities of cervical cancers with the least cost per CIN2+ case. **CONCLUSIONS:** In general, co-testing of HPV 16/18 genotyping & cytology with reflex to CINtec PLUS strategy is the optimal strategy which can bring the best screening effectiveness if the total budget could be affordable.

**PMD7: QUICK AND COMPREHENSIVE ASSESSMENT OF NARROW BAND IMAGING (NBI) USING IN DIGESTIVE TRACT EXAMINATION**

**OBJECTIVES:** Narrow Band Imaging (NBI) could filter red light during endoscopy compared to white light imaging (WLI), which could reduce interference effect on imaging. The objective of this research is evaluating clinical effect and cost-effectiveness of NBI in digestive tract examination. **METHODS:** National report about NBI used for gastric cancer and colorectal cancer were collected from health technology assessment institutions such as NICE, ASGE, and CBER. We also searched literature database included PubMed, Cochrane Library and Embase, collecting researches about NBI used for gastric cancer and colorectal cancer. Clinical effect and cost-effectiveness of NBI were evaluated from the results of national report and literatures. **RESULTS:** For colorectal cancer, 8 reports from NICE, 6 reports from ASGE and 16 papers were included. Among national reports, 4 of 7 clinical trials illustrated NBI has better imaging effect (accuracy, sensitivity, specificity) than WLI in colorectal lesions diagnosis. 2 of 3 meta-analysis showed NBI has good imaging effect and 3 clinical guidelines suggest NBI using in observing mucosal surface of colorectal polyps. 8 of clinical trials among literatures demonstrated outstanding imaging effect for colorectal lesions. 3 reports and 2 literatures mentioned economy of NBI, which showed a result of cost reduction with a Resect and Discard Strategy in colorectal cancer screening using NBI. For gastric cancer, 5 reports (NICE: 4 ASGE: 1) and 22 literatures were included. The 5 reports (1 guidelines, 1 clinical trials, 2 meta-analysis and 1 technologic report) showed NBI has better effect in early gastric cancer (EGC) than WLI. All literature affirmed imaging effect of NBI, especially in EGC test. **CONCLUSIONS:** From results of reports and literatures, we concluded NBI using in colorectal lesions screening could had better effect with lower cost. Besides, NBI could be used in EGC screening for the brilliant imaging effect.

**PMD8: ECONOMIC EVALUATION OF STRATEGIES FOR PUBLIC CERVICAL CANCER SCREENING**

**OBJECTIVES:** The aim of this study was to evaluate the strategies for China public cervical cancer screening and make recommendations on selecting the optimal strategy by comparing the screening effectiveness and disease management costs of different strategies. **METHODS:** A Markov cohort model was developed to simulate 2 cycles of cervical cancer screening in women aged from 30 to 65 in population of 1,000,000. The costs and effectiveness of different strategies were calculated from the perspective of China’s healthcare system. Five strategies were compared, including cytology only primary screening, cytology primary screening with reflex to CINtec PLUS, HPV primary screening with reflex to cytology, HPV 16/18 genotyping primary screening with reflex to cytology, and HPV 16/18 genotyping primary screening with reflex to CINtec PLUS. **RESULTS:** In the cytology primary screening strategy groups, more CIN2+ cases could be detected at less cost per case of CIN2+ detected when using CINtec PLUS as reflex, which will also decrease annual incidence and mortalities of cervical cancers. In the HPV primary
OBJECTIVES: Intertrochanteric hip fractures are common and devastating injuries especially for the elderly. We aimed to assess the effectiveness of two commonly used types of intramedullary devices for the treatment of unstable intertrochanteric hip fractures. We hypothesize that fracture constructs using devices that provide additional rotational control for these unstable fractures, will demonstrate a lower rate of construct failure and better outcomes overall. METHODS: A comprehensive systematic literature review and a pairwise meta-analysis of randomised controlled trials (RCTs) and comparative observational studies comparing an Integrated 2 screw de-rotation cephalo-medulary device * (IDRC) versus a traditional single screw cephalo-medulary nail** (TSS) was performed. We assessed the following outcomes, revisions, non-unions, post-operative device related complications (shaft fracture, varus collapse and cutouts), hip and thigh pain and health related quality of life (HRQoL). We report odds ratio (OR) for dichotomous outcomes and mean difference (MD) for continuous outcomes. RESULTS: Four studies met the inclusion criteria, 2 RCTs and 2 observational studies (N=533, mean age 75 and 66% women) published between 2013 and 2016. There was no significant difference for revisions [OR 0.53 (95% CI, 0.2 to 1.40) p=0.2] and non-union [OR 0.13 (95% CI, 0.01 to 2.63) p=0.19]. There was a significant difference in implant related failures [OR 0.12 (95% CI, 0.05 to 0.30) p=0.0001] and 60% less people complained of pain OR 0.40 (95% CI, 0.22 to 0.73) p=0.0003 respectively in favour of the integrated 2-screw nail compared to the single screw nail. There was no evidence that study design substantially influenced the estimate of effects. CONCLUSIONS: Our meta-analysis suggests that there is no difference between the two nails on revision and non-union outcomes. The integrated 2-screw de-rotation/compression, cephalo-medulary device reduces post-operative implant related complications and pain in patients with intertrochanteric fractures compared to the single screw device. *InterTAN ** Proximal Femoral Nail Antirotation
PMD11: COMPARING COST-EFFECTIVENESS OF STRATEGIES FOR ANTENATAL HIV TESTING: VCT AND ROUTINE TESTING IN URBAN NIGERIA.

Ibekwe E1, Haigh C1, Prof Francis Fatoye F2,1Manchester Metropolitan University, UK, Manchester, UK, 2Manchester Metropolitan University, Manchester, UK

OBJECTIVES: Globally, in 2015, 90% of 2.6 million children living with human-immune-deficiency virus (HIV) became infected through mother-to-child-transmission (MTCT). Nigeria has the largest number of new infections with 41,000 and bears one-third of global burden of MTCT. Almost 60% of pregnant women in Nigeria receive ante natal care (ANC) and deliver in hospital; however, uptake of ANC HIV testing with standard voluntary counselling and testing (VCT) is 29%, leaving more than half of sero-positive mothers undiagnosed. Low testing rate weakens the link between prevention of MTCT program. A switch to innovative routine HIV testing warrant settings specific understanding of the cost-effectiveness. This study compares cost effectiveness of two strategies for offering HIV test. METHODS: A pre-post study was conducted. The pre-test involved administering HIV testing to pregnant women on self-referral voluntary counselling and testing (VCT). In the post-test, the mid-wife offered women group HIV counselling and testing during ANC. HIV testing data involving testing and staff costs were collected, and cost-effectiveness analysis (incremental cost-effectiveness ratio (ICER), cost per new diagnosis and cost of averted cases) were calculated. RESULTS: In comparison, routine testing identified more women living with HIV 44 (15%) against VCT, which identified 15 (10.5%). Routine testing averted 6.60 new HIV infection per year compared to VCT at 3.75. The cost per new diagnosis of HIV in pregnant women was lower for routine testing ($290.86 versus $396.30 per new diagnosis) and similarly, the cost for averted transmission ($1264 versus $1698). The incremental cost-effectiveness ratio (ICER) is $236.31. CONCLUSIONS: Evidently, routine HIV testing is economically dominant over VCT; identified more women living with HIV and averted more infections in children. The ICER is below acceptable threshold. A nation-wide adoption of routine testing is recommended for timely identification of sero-positive mothers and reduction of MTCT and associated resources in management of infected children.

PMD12: EFFECTIVENESS OF TELEMONITORING INTERVENTIONS FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Sul AR, Lyu D, Park D,NECA, Seoul, Korea, Republic of (South)

OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is characterized by irreversible or poorly reversible airflow obstruction in the lung. Self-management strategies are becoming more important in the treatment of COPD. In this study, the clinical effectiveness of telemonitoring for COPD was investigated. METHODS: To conduct systematic review, we searched MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials and CINAHL up to March 2016. We selected randomized controlled trials (RCT) comparing telemonitoring group and control group for COPD. We analyzed dichotomous data as relative risk (RR), and continuous data as mean difference (MD) or standardized mean differences (SMD) while using random-effects models. Critical outcomes were COPD exacerbation, quality of life or health status and all-cause mortality. RESULTS: Twenty four RCTs were included. As a result of meta-analysis, there were no variables showing statistically significant results between two groups. Exacerbation rate (6 studies) was not different between two groups (RR 0.67, 95% CI 0.31 ~ 1.42). Due to the moderate degree of the heterogeneity among studies (I2 = 67%), subgroup analysis was performed. Intervention period could be the one of the factors describing the heterogeneity. No difference between group was found for exacerbation period (6 studies; MD 0.12, 95% CI –1.18 ~ 1.43) and number of exacerbations (6 studies; MD -0.76, 95% CI –0.32 ~ 0.07). Also quality of life (10 studies) did not show any difference between the two groups (SMD -0.17, 95% CI –0.41 ~ 0.07). Finally, mortality (5 studies) was not different between the two groups (RR 0.80, 95% CI 0.48 ~ 1.35). CONCLUSIONS: The use of telemonitoring for COPD was unlikely to result in statistically significant improvements in health outcomes. However, in the subgroup analysis, telemonitoring longer than 6 months reduced the exacerbation rates. To clarify the effects of telemonitoring for COPD, further researches are needed with the well-defined intervention and outcome variables.

PMD13: TORIC INTRAOCULAR LENSES FOR THE CORRECTION OF PRE-EXISTING CORNEAL ASTIGMATISM DURING CATARACT SURGERY: A SYSTEMATIC REVIEW OF THE LITERATURE

Zignani M1, Caridad PV2, Ender F1, Breitkopf S2, Shaikh J3, O’Boyle D4,1Alcon Management SA, Geneva, Switzerland, 2Alcon Pharma GmbH, Frieburg, Germany, 3Novartis Healthcare Pvt Ltd, Hyderabad, India, 4Novartis Ireland Ltd., Dublin, Ireland

OBJECTIVES: Astigmatism is a refractive error typically resulting from anterior corneal asymmetry. Preoperative astigmatism ≥0.5 diop ters (D) is present in 77% of cataract eyes. Toric IOL implantation corrects pre-existing corneal
astigmatism, alleviating risk of residual post-operative astigmatism, an important cause of suboptimal post-operative uncorrected distance visual acuity (UCDVA) and dependency for distance spectacles post-surgery. The objective of this study was to assess and compare the quality and quantity of published evidence for toric IOLs to correct pre-existing corneal astigmatism (≥ 0.5 D) and improve postoperative visual acuity outcomes in patients undergoing cataract surgery compared to non-toric IOLs, with or without astigmatism reducing surgical interventions. METHODS: A systematic literature review was conducted using electronic searches on Embase®, MEDLINE®, MEDLINE®-In Process, and Cochrane (January 1974 -July 2016). Articles were selected if they included adult patients, undergoing phacoemulsification, with age-related cataracts and pre-operative regular corneal astigmatism (≥0.5D). Outcomes included postoperative UCDVA, CDVA, and residual astigmatism. Quality assessment of the included studies was performed using the Centre for Review and Dissemination (CRD), York checklist. RESULTS: 19 RCTs, 11 comparative non-RCTs and 34 single arm studies were identified. 14 of the RCTs (representing 64% of treated eyes) included the AcrySoF® Toric IOL brand. The majority of studies reported significantly better postoperative outcomes (UDVA & residual astigmatism) for toric IOLs vs. non-toric IOLs. In the main, a significantly greater proportion of patients achieved postoperative UCDVA of at least 20/25 (0.1 logMAR) and spectacle independence for distance vision with toric IOLs compared with non-toric IOLs. CONCLUSIONS: The evidence suggests that toric IOLs are superior to non-toric IOLs, with or without surgical interventions, in reducing postoperative astigmatism, increasing postoperative UCDVA and spectacle independence. However with 14 out of 19 RCTs the majority of evidence published to date, is based on studies including the AcrySoF® toric IOL platform.

PMD14: SINGLE VERSUS MULTIPLE INHALERS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Treatment for COPD may involve multiple types of inhalation devices. To understand the impact in COPD of single fixed dose combination (FDC) versus multiple inhalers delivering the same class of medication, a systematic literature review was conducted. METHODS: Embase, PubMed and the Cochrane library were searched for studies comparing single and multiple inhalers of the same therapies with regard to clinical, economic and medication burden endpoints in patients with COPD. Articles published in English between 1996 and November 2016, and congress abstracts published from 2013, were assessed for relevant endpoints. RESULTS: Four randomised controlled trials (RCTs; including one non-inferiority trial) and five retrospective studies were identified. Overall, findings from the four RCTs demonstrated comparable efficacy and safety between single and multiple inhalers. Retrospective studies found that the use of a single inhaler was associated with significantly lower healthcare costs in Canada (one study) and the US (two studies), and lower monthly expenditures in the Netherlands (one study). Use of a single inhaler was also associated with fewer urgent care visits (one study), and emergency department visits or hospitalisations (three studies) compared with the use of multiple inhalers. Adherence, evaluated in one RCT, was high and comparable between single and multiple inhaler users. In the US, two claims database studies found the use of single inhalers to be associated with a significantly increased likelihood of compliance, as measured by discontinuations and interruptions, whereas one study from the Netherlands found no difference in persistence between users. CONCLUSIONS: Despite limitations associated with the identified studies, which included different study designs, these results suggest that use of a single FDC inhaler could improve outcomes for patients and healthcare providers in a real world setting. Further research is needed to better understand the impact of inhaler devices in COPD. Funding: GSK (HO-16-13836)

PMD15: ESTIMATING THE COMPARATIVE ACCURACY OF DIAGNOSTIC TESTS: AN EXAMPLE USING TYPHOID FEVER

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OBJECTIVES: Typhoid fevers are infections caused by the bacteria Salmonella enterica serovar Typhi (Salmonella Typhi) and Paratyphi A, B and C (Salmonella Paratyphi). Approximately 17.8 million incident cases of typhoid fever are estimated to occur annually in low- and middle-income countries and incidence is highest in children. This research aims to assess the comparative diagnostic accuracy of diagnostic tests for typhoid fever. METHODS: We conducted a systematic literature to identify studies that compared diagnostic tests for typhoid fever in children to blood culture result. Diagnostic test network meta-analysis was performed building on models previously proposed by applying a Bayesian latent-class extension to the conventional network meta-analysis (NMA) model. We applied known diagnostic properties of bone marrow culture and the relationship between bone marrow and blood culture as informative priors to facilitate the network meta-analysis. We tested sensitivities for the proportion of negative blood samples that were false as well as bone marrow sensitivity and specificity. RESULTS: NMA was conducted on a
subset of 26 studies (involving 47 comparisons) of child studies with blood culture reference tests from South Asia. The lateral flow IgG test performed comparatively well with 89% sensitivity (67% to 98% across scenario analyses) and 83% specificity. The most sensitive test of those investigated for the South Asian pediatric population was reverse passive agglutination with 96% sensitivity, however, scenario analyses yielded large model variability, with the lowest diagnostic sensitivity estimate being 66%. Adding a lateral flow-based IgG rapid test to either of two Typhidot test approaches yield improvements in sensitivity without substantial declines in specificity. **CONCLUSIONS:** In the South Asian pediatric population, lateral flow IgG and reverse passive agglutination tests had high comparative diagnostic accuracy compared to other diagnostics. Combinations of rapid tests may provide a feasible option to increase diagnostic sensitivity and should be evaluated further.

**PMD16: INTEGRATED 2 SCREW DE-ROTATION/COMPRESSION, CEPHALO-MEDULARY DEVICE REDUCES IMPLANT RELATED COMPLICATIONS AND IMPROVES HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH INTERTROCHANTERIC FRACTURES, A SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** Surgical treatment is the optimal strategy for managing intertrochanteric fractures as it allows early rehabilitation and functional recovery. We aimed to assess the effectiveness of two commonly used types of intramedullary devices for the treatment of unstable intertrochanteric hip fractures. We hypothesize that fracture constructs using devices that provide additional rotational control for these unstable fractures, will demonstrate a lower rate of construct failure and better outcomes overall. **METHODS:** A comprehensive systematic literature review and a pairwise meta-analysis of randomised controlled trials (RCTs) and comparative observational studies comparing Integrated 2 screw de-rotation cephalo-mediator device** *(IDRC)* versus a traditional single screw cephalo-mediator nail** *(TSS)* was performed. We assessed the following outcomes, revisions, non-unions, post-operative device related complications (shaft fracture, varus collapse and cut-outs), hip and thigh pain and health related quality of life (HRQoL). We report odds ratio (OR) for dichotomous outcomes and mean difference (MD) for continuous outcomes. **RESULTS:** Three studies met the inclusion criteria, 2 RCTs and 1 observational study (N=457), mean age was 75 and 68% of patients were female. There was no significant difference for revision OR 0.47 (95% CI, 0.15 to 1.50) p=0.20, non-union OR 0.39 (95% CI, 0.05 to 3.42) p=0.40 and pain OR 0.94 (95% CI, 0.35 to 2.51) p=0.9. However, there was a significant difference in post-operative device related complications OR 0.18 (95% CI, 0.06 to 0.52) p=0.002 and HRQoL measured by the Short Form-36 MD 7.40 (95% CI, 2.73 to 12.07) p=0.002 respectively in favour of the IDRC system compared to the TSS single screw nail. **CONCLUSIONS:** Our meta-analysis suggests that there is no difference between the two nails on revision and non-unions and pain, however the IDRC reduces post-operative implant related complications and improves HRQoL in patients with intertrochanteric fractures compared to the single screw nail. *INTERTAN ** Gamma 3

**PMD17: HEALTH AND ECONOMIC BENEFITS OF USING SINGLE VERSUS MULTIPLE INHALERS IN PATIENTS WITH ASTHMA: A SYSTEMATIC LITERATURE REVIEW**

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**OBJECTIVES:** Asthma can limit activities and reduce quality of life. With an increasing choice of medications and devices, comparative evidence may inform treatment decisions. This systematic literature review assessed evidence for using a single, fixed-dose combination (FDC) inhaler versus multiple inhalers to deliver the same medications for patients with asthma. **METHODS:** In 2016, Embase, PubMed and the Cochrane library were searched for publications reporting studies comparing any single FDC inhaler with multiple inhalers to deliver the same class of medications in adults and children with asthma. Publications were limited to English articles published since 1996 and congress abstracts published since 2013. Clinical, economic, adherence and medication burden endpoints were assessed. **RESULTS:** Of 2031 abstracts screened, 33 asthma studies were identified; 18 randomised controlled trials (RCTs; including non-inferiority and double-dummy designs), 11 retrospective, and 4 prospective studies. Findings from 15 RCTs reporting lung function, and 9 RCTs and 2 prospective studies reporting exacerbation rates, showed no significant differences between a single FDC inhaler and multiple inhalers. Two retrospective studies reported lower exacerbation rates with a single FDC inhaler than with multiple inhalers. Economic analyses from retrospective and prospective studies showed that a single FDC inhaler was associated with reduced health care resource use (n=6) and was cost effective (n=3) compared with multiple inhaler therapies. Three retrospective studies reported greater adherence with a single FDC inhaler than multiple inhalers, whereas 5 RCTs reported no difference in adherence. **CONCLUSIONS:** Different conclusions were found in the various investigated studies due to differences in study design. The efficacy (such as lung function and exacerbation rates) of a single FDC inhaler and multiple inhalers was comparable. Results from retrospective and prospective studies showed that using a single FDC inhaler
was associated with decreased resource use and improved cost effectiveness compared with multiple inhalers.
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PMD18: EFFECT OF ACRYLIC MONOFOCAL INTRAOCULAR LENSES (IOLs) ON Nd:YAG LASER CAPSULOTOMY RATES: A META-ANALYSIS

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OBJECTIVES: Cataract surgery is the most frequently performed surgical operation in the EU and Nd:YAG laser capsulotomy is a procedure to treat posterior capsular opacification (PCO), and is the most commonly reported complication after cataract surgery. The aim of this study was to investigate the incidence of Nd:YAG laser capsulotomy reported in the literature for hydrophobic monofocal AcrySof® IOLs versus non-AcrySof monofocal acrylic IOLs (hydrophilic and hydrophobic). METHODS: Randomized controlled trials (RCTs) were identified through a systematic literature search using Embase®, MEDLINE®, MEDLINE®-In Process, and Cochrane platforms (January 1996 through July 2016). Meta-analyses evaluating the incidence of Nd:YAG capsulotomy at ≤1 year, between 1 and 2 years, and >2 years were conducted comparing AcrySof® IOLs versus non-AcrySof hydrophilic and hydrophobic acrylic IOLs. Subgroup analyses were also conducted between groups. RESULTS: 17 RCTs met the inclusion criteria and were included in the main analysis. AcrySof® IOLs had significantly lower Nd:YAG capsulotomy rates at 1-2 years post-surgery (OR, 0.09; 95%-CI, 0.05 – 0.17; p<0.05) and >2 years (OR, 0.33; 95%-CI, 0.16 – 0.69; p<0.05) compared to non-AcrySof acrylic IOLs. In the subgroup analysis, AcrySof® IOLs had significantly lower Nd:YAG capsulotomy rates compared to hydrophilic acrylic IOLs at 1-2 years (OR, 0.09; 95%-CI, 0.04 – 0.17; p<0.05) and >2 years (OR, 0.09; 95%-CI, 0.02 – 0.49; p<0.05). A similar trend was observed vs. non-AcrySof hydrophobic IOLs at >2 years post-surgery. However, this analysis was limited to a low number of studies (n=3) and the observed difference did not reach statistical significance (OR, 0.60; 95%-CI, 0.25-1.43; p=>0.05). CONCLUSIONS: AcrySof® IOLs are associated with a significantly lower incidence of Nd:YAG capsulotomy compared to non-AcrySof acrylic IOLs (hydrophilic and hydrophobic) and hydrophilic acrylic IOLs at ≥2 years post-cataract surgery. Regarding the incidence of Nd:YAG capsulotomy, further research comparing AcrySof® IOLs vs non-AcrySof hydrophobic acrylic IOLs is warranted.

MEDICAL DEVICES/DIAGNOSTICS - Cost Studies

PMD19: IMPACT OF COMPREHENSIVE GENOMIC PROFILING OF PATIENTS WITH FIRST LINE NON-SMALL CELL LUNG CANCER IN THE UK

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OBJECTIVES: To estimate the impact of increased use of Comprehensive Genomic Profiling (CGP) together with targeted and immuno-therapies consistent with NCCN Guidelines®, versus conventional molecular diagnostic testing, on cost and overall survival (OS) in the UK. METHODS: A 5-year budget impact forecasting model was developed to determine the financial implications of incorporating CGP to guide first-line treatment options in an incident cohort of patients with advanced lung carcinoma. Costs including molecular diagnostics, associated medical and treatment expenses were calculated for the duration of first-line treatment. Future treatment regimens were forecasted based on published biomarker status. Costs were identified from literature and technology assessment reports. Extensive sensitivity analyses were conducted to investigate the impact of key model parameters on results. RESULTS: The incremental budget impact with 10% uptake of CGP was estimated to be £0.02 per member per month. This increased usage of CGP equates to a net total budget impact of £17.5M for eligible patients in the UK (15% related to cost of CGP;62% due to treatment costs;23% costs due to improved survival). Number-Needed-to-Treat for 1 additional life year is approximately 3 patients. Patients receiving CGP had longer survival by 2.62 months. Cost offsets are achieved in repetitive biopsy procedures and non-matched drug treatment costs. That is in contrast to increases in costs of molecular testing and matched drug treatment costs. CONCLUSIONS: CGP may be an affordable option to identify the most appropriate treatment regimen for an individual patient. Further research is warranted better understand how current therapies can be best utilized to improve overall survival. Furthermore, health systems may need to move from a tumour type based treatment approach to a mutation specific based indication as mounting evidence suggest cancer is driven by genomically matched indications rather than anatomical location.
PMD20: STRUCTURED EDUCATION PROGRAM FOR INJECTION TECHNIQUE - BUDGET IMPACT MODEL

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OBJECTIVES: Several European studies - including a new French randomized, prospective one (LHYRE) - show that optimizing insulin injection technique is associated with less lipohypertrophy, lower insulin consumption and better glycaemic control. The objective is to estimate the budget impact of a structured education program compared to the usual educational approach for insulin administration. METHODS: A budget impact model, employing a third-party payer perspective, was developed to estimate insulin costs as well the cost for managing diabetes-related complications in a population of patients with type 1 and 2 diabetes and over a 1 to 10 year time horizon. The annual risk of mortality and diabetes-related complications are estimated using a probabilistic patient simulation. Patient characteristics were estimated based on the ENTRED and UKPDS studies. Complication occurrence is calculated on the HbA1C decrease observed after injection technique education is instituted. Decrease of HbA1C and insulin consumption observed after an education program are based on LHYRE results (-5 UI for total daily dose of insulin and -0.5 for HbA1C). A sensitivity analysis using deterministic calculation was performed. RESULTS: Considering a yearly conservative assumption of 100,000 patients benefiting from the structured education program (with annual growth of 10% new patient included) and assuming that 75% of patients will adopt good practices (aligned with LHYRE results), the increment in comparison with no specific educational effort is -4.5 million euros for insulin costs and -0.4 million euros for complication costs over the first year. Results are -14.4 million euros and -1.6 million euros respectively for a 3-year time horizon. CONCLUSIONS: A structured education program for insulin injection technique represents a potentially significant immediate and midterm savings for the French health care system, and could be a key element to help contain diabetes cost trends in this highly-prevalent disease.

PMD21: BUDGET IMPACT ANALYSIS OF DEEP BRAIN STIMULATION FOR THE TREATMENT OF PARKINSON’S DISEASE PATIENTS IN THE ITALIAN SETTING

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OBJECTIVES: This Budget Impact Analysis aims at evaluating treatment costs of Parkinson’s Disease (PD) patients eligible to Deep Brain Stimulation (DBS) in Italy. METHODS: An hypothetical cohort of DBS eligible patients was estimated. Treatment costs were calculated and compared according to two different scenarios. The current scenario assumes that just the 5%-15% of patients is treated with DBS and most of them with medical treatment. The hypothetical scenario assumes that all eligible patients are treated with DBS. Only non-rechargeable devices were considered. Italian National Health Service (NHS) perspective was analyzed in four year-time horizon. Costs considered included direct medical costs related to the management of patients with pharmacological treatment, costs related to first implant of DBS system, direct medical costs related to the management of PD patients after the first implant of DBS system. Both epidemiological and cost data were retrieved from Italian literature. RESULTS: It was estimated that PD patients eligible to DBS in Italy range from 3.700 to 10.300. According to NHS perspective, the hypothetical scenario is associated to an incremental treatment cost that could be equivalent to 1.400€/patient/year compared to current scenario. The incremental cost is due both to an increase in treatment costs for DBS therapy and to a decrease in annual direct medical costs/patient after DBS which diminish by 40% in the implant year (excluding implant costs) and by 75% from the second year following DBS. CONCLUSIONS: Costs related to DBS are one of the main barriers for a higher adoption of this therapy, despite its clinical success and its effectiveness on quality of life have been largely demonstrated. This analysis gives some insights on the incremental costs needed in case all eligible patients receive DBS in Italy. Further economic analysis is necessary in the Italian setting considering also indirect costs and social perspective.

PMD22: THE BUDGET IMPACT OF INTRODUCING A PD-L1 ASSAY TO SELECT PATIENTS WITH METASTATIC NSCLC WHO ARE POTENTIAL CANDIDATES FOR TREATMENT WITH IMMUNE CHECKPOINT INHIBITORS

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OBJECTIVES: Lung cancer is the second most common cancer and the leading cause of cancer mortality. This disease places a substantial financial burden across EU healthcare systems. Novel immune checkpoint inhibitors have been approved or are in development as immunotherapies for certain patients with metastatic non-small-cell lung cancer (mNSCLC). Testing for PD-L1 expression may help to identify patients that are most likely to respond to anti-PD-1 or anti-PD-L1 treatments, optimising the utility of these agents and minimising their economic impact. A budget impact model (BIM) was developed to compare the economic impact of introducing PD-L1 testing to select
previously treated patients for anti-PD-L1/PD-1 treatment, compared to not testing for PD-L1 ("all-comers" scenario). **METHODS:** A BIM was developed in Microsoft Excel 2013 to compare selecting patients using a PD-L1 Assay for treatment with checkpoint inhibitor immunotherapy to all-comers treatment over a two-year period in Italy. A total of 3172 mNSCLC patients previously treated with chemotherapy or for an EGFR or ALK genomic tumour aberration were included, and response to therapy was determined from data in published clinical trials. All cost and clinical data used in the model pertains to PD-L1 testing and subsequent treatment with a PD-1 blocker. A one-way sensitivity analysis was performed to assess the impact of parameter uncertainty. **RESULTS:** When compared to an "all-comers" scenario, introducing a PD-L1 Assay (±1% cut-off for PD-L1 expression), to select potential patients who were most likely to benefit from anti-PD-L1/PD-1 immunotherapy, was associated with a reduction of €2,881.95 in cost per PFS per patient and a per patient per month (PPPM) reduction of €334.0. **CONCLUSIONS:** Utilisation of a PD-L1 Assay to select previously treated patients for treatment with checkpoint inhibitor immunotherapy increased diagnostic costs by €354,783 while decreasing overall treatment costs by up to €72,000,000 (47%).

**PMD23: ECONOMIC ANALYSIS OF THE LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER FOR THE TREATMENT OF VASCULAR ACCESS STENOSIS IN PATIENTS WITH ARTERIOVENOUS FISTULAS**

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**OBJECTIVES:** End stage renal disease affects <1% of the Medicare population but accounts for ~7% of Medicare paid claims. Despite benefits of arteriovenous fistulas for vascular access for hemodialysis patients, reinterventions to maintain patency are common. A recent randomized controlled trial evaluated the safety and efficacy of the LUTONIX® 035 Drug Coated Balloon PTA catheter (DCB) versus PTA for the treatment of stenotic lesions of native arteriovenous dialysis fistulae. **METHODS:** An economic model was developed from a U.S. payer perspective based on 12-month reintervention rates from the Lutonix AV trial. Reintervention costs were based on real-world CMS data for vascular access percutaneous interventions across settings. Payer procedure costs were based on reimbursement amounts for each site of service. The weighted average cost of a reintervention was estimated to be $4,724 based on the distribution of procedure types by setting. An incremental product acquisition cost (i.e., LUTONIX® 035 DCB cost minus PTA cost) was assumed to be $1,000 (ranging from $750 to $1,250). **RESULTS:** The model predicted that LUTONIX® 035 DCB was cost-effective in the first year, with a reasonable incremental cost per reintervention avoided vs. PTA. Although LUTONIX® 035 DCB is assumed to cost more than PTA, it provides $661 in reintervention cost savings per patient, and therefore a total cost of only $339 (range: $89–$589) per patient. The cost per reintervention avoided for LUTONIX® 035 DCB was estimated at $2,418 ($633–$4,204), and this was considered from an inpatient setting. **CONCLUSIONS:** The economic analysis predicted LUTONIX® 035 DCB may be cost-effective. The cost per reintervention avoided for LUTONIX® 035 DCB is comparable to other published studies of cost-effective DCBs.

**PMD24: BUDGET IMPACT ANALYSIS FOR SWITCHING FROM MANUAL TO PRE-FILLED SYRINGES FOR CATHETER MAINTENANCE**

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**OBJECTIVES:** There is strong clinical evidence in the published literature that the use of pre-filled vs. manually-filled saline syringes can significantly reduce the risk of catheter-related blood stream infections (CRBSIs), needle stick injuries, and occlusions. However, to date, the economic consequences of switching from manually-filled to pre-filled syringes for catheter maintenance have not been evaluated. An economic model was developed to evaluate the economic impact of switching from manually-filled to pre-filled syringes. **METHODS:** A budget impact model (BIM) was developed to calculate both the clinical and economic savings associated with switching from manually-filled to pre-filled syringes (BD PosiFlushTM). Using published clinical and cost data, the BIM investigated savings across four separate outcomes: (1) vascular access complications, such as CRBSIs and occlusions; (2) healthcare worker safety (reduction in needle stick injuries); (3) workflow efficiency; and (4) cost reduction. **RESULTS:** The base-case model assumed 125,000 annual patients with either peripheral catheters (80%), central line catheters (10%) or dialysis (10%), who received flushing. Replacing manually-filled syringes with pre-filled syringes revealed cumulative savings of over $624,000 annually, largely driven by reductions in CRBSIs, reduced rates of occlusions and incidence of needle sticks. Use of pre-filled syringes was shown to potentially reduce the annual incidence of CRBSIs by 50, occlusions by 355 and needle stick injuries by 281 events, and make available over 12,000 nurse hours for other forms of patient care. **CONCLUSIONS:** While the model focused on flushing in a hospital setting, pre-filled syringes have the potential to create a significant clinical and economic impact across all settings where catheters are flushed,
including hospital, outpatient, and home health. Adoption of pre-filled syringes presents an opportunity for hospitals to reduce CRBSIs, occlusions, and needle stick injury related costs. Additional benefits are also likely, including workflow efficiencies and improved health care worker safety.

PMD25: BUDGET IMPACT OF A SUPRA-CILIARY MICRO-STENT IN BOTH STAND-ALONE SURGERY AND IN COMBINATION WITH CATARACT SURGERY FOR PRIMARY OPEN-ANGLE GLAUCOMA FROM A UK SECONDARY CARE PERSPECTIVE

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OBJECTIVES: Minimally invasive glaucoma surgery (MIGS) devices have the potential to address an unmet need in primary open angle glaucoma (POAG) treatment by significantly reducing patients' intraocular pressure and medication burden without the risk profile of conventional filtration surgeries such as trabeculectomy or drainage implants. This study assessed the financial impact of the inclusion of a new supra-ciliary micro-stent for patients with mild to moderate POAG. METHODS: A UK national and local payer perspective budget impact model estimated the impact of including the Alcon supra-ciliary micro-stent for patients with POAG as a standalone procedure or in conjunction with cataract surgery. Published national population estimates and POAG incidence and prevalence data for adults were used to estimate patients eligible for MIGS procedures. Comparators, patient utilisation and resource use were derived from published sources, a survey of 40 practicing glaucoma/cataract specialists and interviews with two UK experts in surgical glaucoma. Published costs for the surgical glaucoma procedure, MIGS devices, post-procedure monitoring, and prescription eye drops were included to reflect the total cost of treatment. The base-case assumes that uptake increases over five years. RESULTS: Over five years, an estimated 762,691 patients will undergo 1,176,225 POAG and POAG/cataract procedures (including bilateral disease). Of these procedures, approximately 68,173 will involve implantation with the Alcon supra-ciliary micro-stent. Its inclusion in the POAG treatment pathway results in a neutral budget impact, given a total budget increase of only 0.63% (£10,475,789). Cost savings (£529,504, -0.12%) are expected in the concurrent POAG/cataract population. Overall, the cost of the device is offset by savings in procedure and monitoring costs compared with other MIGS devices and trabeculectomy. Univariate sensitivity analyses confirm that model results are robust. CONCLUSIONS: The inclusion of the Alcon supra-ciliary micro-stent is cost neutral to UK national and local payers, providing access to an innovative minimally invasive treatment for POAG.

PMD26: CLINICAL AND COST IMPACT OF A NOVEL NON-INVASIVE APPROACH FOR THE TREATMENT OF CERVICAL DYSPLASIA FROM A US PAYER PERSPECTIVE

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OBJECTIVES: Current treatments for cervical dysplasia involve removal of affected cervical tissue. This may lead to side effects such as bleeding, infection and preterm delivery. This analysis sought to determine the clinical and cost impact of a tissue-preserving procedure using a novel photodynamic therapy under investigation for treatment of cervical dysplasia (Cevira®, Photocure, Oslo, Norway) as compared to loop electrosurgical excision procedure (LEEP) and cold knife conization (CKC). METHODS: A budget impact model was developed from the perspective of a US payer with 5 million covered lives. The model captured Medicare allowable costs for cervical cancer screening, subsequent colposcopy with biopsy for abnormal screening results, treatment of cervical dysplasia, and side effects from treatment using 2016 reimbursement rates. Clinical data for screening, follow-up biopsy and treatment outcomes were from published data. A scenario analysis determined the impact of treatment modality, including a non-surgical method like Cevira®, on preterm birth and associated costs. RESULTS: In a US health plan with 5 million covered lives, 810,525 women 18 – 44 years would present for cervical cancer screening. Of those, 7,972 women would have abnormal screening and subsequent biopsy that is CIN2/3. The per patient cost to screen and treat at 24 months follow-up was $222 for photodynamic therapy, compared to $220 for LEEP and $222 for CKC. When incorporating costs related to the increased risk of preterm birth for LEEP and CKC, per patient costs were lowest for photodynamic therapy ($268) as compared to LEEP ($322) and CKC ($378). CONCLUSIONS: The per patient cost to screen and treat using tissue-preserving procedures like Cevira® is similar to current treatment strategies but has the clinical benefit of sparing normal cervical tissue, leading to lower rates of procedure-related side effects. Further benefit may be derived from reduction in preterm births and its associated costs and intangible impact on morbidity.

PMD27: DO BUDGET IMPACT ANALYSES FOR SCREENING OF CANCERS FOLLOW INTERNATIONAL GUIDELINES? A SYSTEMATIC REVIEW
OBJECTIVES: Budget impact analyses (BIA) assess the financial consequences of the implementation of new health care technologies. BIAs are increasingly required by decision makers for budgetary planning. Our study aims to systematically review published BIA, applied methods and if international BIA guidelines are followed in evaluating cancer screening programs. METHODS: A systematic literature search was conducted in MEDLINE and EconLit for BIA evaluating cancer screening programs, published in English language 2010-2016. Standardized evidence tables were used to extract main characteristics of the analysis and model along the ISPOR BIA Task Force guidelines including cancer type, model structure, definition of population size/characteristics, perspective, time horizon, included costs, source of epidemiologic and clinical data, consideration of health impact, validation, and uncertainty analysis. RESULTS: Ten studies were identified. Three studies evaluated screening for breast cancer, two for colorectal and cervical cancer and one for lung, prostate and skin cancers. Model designs varied from several types of decision-analytic models (60%) to simple cost calculators (40%). The ISPOR guidelines recommend using a simple BIA model structure such as a cost calculator approach as long as important conditions are credibly captured. The time horizon ranged from one to 20 years; six studies applied a one-year time horizon. Projections beyond one year are recommended by ISPOR guidelines, because cost and population parameters might change. All studies included direct condition-related costs and two studies additionally included indirect cost. Health impact was reported in 40% of the studies. Uncertainty analysis was not always sufficiently reported. Only 40% of the studies reported validation to some extent. CONCLUSIONS: BIA studies evaluating cancer screening programs show a substantial variability in the scope of guidelines consideration. Applied time horizon, reporting validation and uncertainty analysis are areas for improvement. Best practice recommendations need to be followed for assisting sound health plan decision making.

PMD28: A BUDGET IMPACT ANALYSIS OF TRANSCATHETER AORTIC VALVE IMPLANTATION IN FRANCE

OBJECTIVES: Transcatheter aortic valve implantation (TAVI) is a minimally invasive alternative to surgical replacement of the aortic valve (sAVR) and the only option for those considered at too high risk for conventional surgery. Currently in France only 2 devices are available and these only reimbursed for inoperable and high risk patients. We present here budget impact analyses (BIA) to identify the cost to the healthcare system of expanding coverage to treat intermediate risk patients as well. METHODS: An Excel model with a 5 year time horizon was used to account incremental costs for TAVI from the perspective of the compulsory health insurance (l’Assurance maladie obligatoire). The current total number of procedures (TAVI in inoperable and high risk and all sAVR) were derived from the PMSI (Programme de médicalisation des systèmes d’information) from 2012 to 2015. Based on this data and information on reimbursed TAVI devices from the LPPR the population eligible for TAVI was projected. Using procedural and patient management costs from an associated cost-effectiveness model the total budget impact between 2017 and 2022 was calculated and sensitivity analyses performed. RESULTS: At a price for TAVI set to achieve an ICER per life year gained of approximately €10,000, the 5 year incremental cost was estimated at €295 million. When accounting no change in the price the budget impact over 5 years was €22 million (€0.49 to €7.3 million annually) representing an incremental investment of only €1000 per patient. CONCLUSIONS: TAVI is considered a high cost technology and yet the incremental budget impact required to give access to an additional 22,000 patients is very modest. With improved quality of life with TAVI and recent clinical data indicating improved survival with TAVI versus sAVR it is hoped this analysis will support effective decision making.

PMD29: BUDGET IMPACT ANALYSIS OF SUPRA-CILIARY MICROSTENT DEVICE UTILIZATION IN PRIMARY OPEN ANGLE GLAUCOMA PATIENTS IN A SPANISH HOSPITAL OUTPATIENT SETTING

OBJECTIVES: Minimally Invasive Glaucoma Surgery (MIGS) devices fill an unmet need in therapy between topical pharmacological medicines and more invasive filtration procedures. This study evaluates the budget impact of using...
a new supra-ciliary microstent (Alcon Laboratories) device in Spanish hospitals as a stand-alone procedure or in conjunction with cataract surgery primary open angle glaucoma (POAG) patients where previous treatments have failed. METHODS: A budget impact model (BIM) from a Spanish hospital outpatient perspective was developed using Microsoft® Excel®. Population and cost estimates were derived from published sources. POAG disease characteristics were obtained from the literature and an online survey of 40 practicing glaucoma/ cataract specialists in Spain. Comparators and market share data were obtained from independent market research. Resource use assumptions associated with each intervention were obtained through survey results and from interviews with four key opinion leaders. Costs included published device costs, post-procedure follow-up care, and facility costs. RESULTS: An estimated 227,248 trabeculectomy, laser assisted trabeculoplasty or MIGS POAG interventions will occur over five years, 21,452 of which will use supra-ciliary microstent. The use of supra-ciliary microstent will have a low budget impact of 5.3% in the first year (€1,116,370) and an average budget impact of 8.2% over five years, with cost increases primarily driven by patients shifting from lower cost laser trabeculoplasty procedures. However, total intervention costs for supra-ciliary microstent (£1774) are lower than total intervention costs for the other included MIGS procedures (trabecular micro-bypass generation 1: €1829; subconjunctival gelatin stent: €2744) and similar to the common, but invasive trabeculectomy surgery (£1762). MS cost offsets were driven by decreases in procedure-related resource use and post-procedure follow-up care. Univariate sensitivity analyses confirm that model results are robust. CONCLUSIONS: The introduction of supra-ciliary microstent will have a minimal budget impact in Spain while increasing access to a valuable, minimally invasive treatment alternative for glaucoma.

**PMD30: A BUDGET IMPACT ANALYSIS OF INCREASING PERITONEAL DIALYSIS (PD) IN ADULTS EXPERIENCING UNPLANNED START DIALYSIS (URGENT START) IN BRAZIL**

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OBJECTIVES: This study investigates the budget impact of variable distribution of adult patients experiencing unplanned start (urgent start) Peritoneal Dialysis (PD) and Haemodialysis (HD) in Brazil. METHODS: An Excel-based budget impact model was developed to assess dialysis-associated costs when changing dialysis modalities between PD and HD from the Brazilian public payer perspective. For this exercise, as the total number of performed urgent start procedures specifically listed, we have used to estimate target population the quantity of acute renal treatment hospitalizations registered at DATASUS (Brazilian public health database) in 2016: 23,077 hospitalizations. The analysis incorporates the current modality distribution of PD (0%) and HD (100%) and evaluates a proposal to adopt 100% PD in a one year time horizon. Complications rate from each dialysis modality came from a previously published retrospective study, where the following differences between PD and HD was found respectively: Catheter reinsertion (1% vs. 24.4%); Catheter-related infection (0% vs. 11%); Bleeding (0% vs. 3.7%); thrombosis (0% vs. 7.3%) and peritonitis (2.1% vs. 0%). Costs of dialysis methods and complications were estimated from the official 2017 Brazilian public health care reimbursement list (SIGTAP - Sistema de Gerenciamento da Tabela do SUS). Alternative scenario included the prevalence of changing dialysis urgent start from HD to PD in order to analyse the economic impact of this adoption. As this analysis refers to an urgent procedure and in-hospital expenses, the economic impact of adoption and dialysis method-related complication reductions was measured over 30 days of catheter insertion. RESULTS: The change from HD to PD resulted a cumulative saving of BRL$ 3,260,135.79 for the Brazilian public health care system over a 1 year time frame. CONCLUSIONS: This exercise shows that increasing the uptake of PD regimen could potentially reduce dialysis method-associated complications and costs for urgent start therapy in Brazil.

**PMD31: ALK IMMUNOHISTOCHEMICAL TEST IN THE DETECTION OF PATIENTS AFFECTED BY ALK+ NON-SMALL CELL LUNG CANCER: CLINICAL AND BUDGET IMPACT**

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OBJECTIVES: A phase III trial (Profile 1014) showed that patients with advanced ALK positive non-small-cell lung cancer (NSCLC) treated with crizotinib had longer progression-free-survival than patients treated with standard-chemotherapy. To ensure identification of ALK+ patients, the Italian Drug Agency (AIFA) suggested a testing algorithm based on fluorescence-in-situ-hybridization (FISH) or immunohistochemical techniques (IHC). The aim of this study was to evaluate the clinical/economic impact of adopting an immunohistochemical test (Ventana ALK, D5F3) as an option for detecting ALK protein expression in advanced NSCLC patients. METHODS: A budget impact model was developed by adopting the Italian NHS perspective and a time horizon of 5 years, in order to compare two scenarios: current ALK D5F3 adoption rate (28%; Base Scenario) vs increased use of D5F3 (60%; Alternative
PMD32: BUDGET IMPACT ANALYSIS (BIA) OF MECHANICAL THROMBECTOMY IN ACUTE PHASE OF ISCHEMIC STROKE (AIS)


OBJECTIVES: To estimate financial consequences of reimbursement of mechanical thrombectomy (MT) using a stent retriever in patients with AIS in Poland. METHODS: Analysis was performed from two perspectives: public payer and public payer + patient in 2-year time horizon (2017-2018). Two scenarios were considered: with and without reimbursement of MT. Target population was defined as patients with AIS eligible for MT who are contraindicated to intravenous tissue plasminogen activator (IV-rt PA) or are treated with IV rt-PA (and MT is added). Size of target population and market share for MT were estimated by compilation of following sources: National Health Found stats on Diagnosis Related Groups (DRG), data from stroke clinical center and clinical expert opinion. Cost data, treatment effectiveness and mortality were also included and data were input in accordance with economic analysis. One-way sensitivity analysis was performed for the key input parameters. All estimations were done with constructed Excel model. RESULTS: Total number of target population is 8,748 in 2017 and 9,792 in 2018. This include all patients treated with IV-rt PA and those with contraindications for IV-rt PA but eligible for MT. In scenario without MT total annual expenditures in 1st and 2nd year will be 151.2 mPLN and 192.1 mPLN from public payer perspective (152.2 mPLN and 195.4 mPLN from public payer + patient). In scenario with MT reimbursement estimated number of patients treated with MT will be 514 in 2017 and 1,150 in 2018. This will result with increase in total expenditures by 22.5 mPLN and 50.3 mPLN in 1st and 2nd year of analysis regardless of perspective. CONCLUSIONS: Positive decision of reimbursement of mechanical thrombectomy, using a stent retriever, will bring additional cost incurred by public payer or public payer and patients.

PMD33: ECONOMIC ANALYSIS OF THE USE OF NON-INVASIVE PRENATAL TEST (NIPT) FOR PRENATAL SCREENING OF TRISOMY 21, 18, 13 IN PREGNANT WOMEN

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OBJECTIVES: The cell-free DNA Non-Invasive Prenatal Test (NIPT) is highly accurate in the detection of common fetal autosomal trisomy (i.e. T21, T18, T13) in pregnant women. NIPT is performed on a blood sample of the pregnant woman, which contains cell-free DNA that originates from the lysis of maternal and placental cells. The aim of this study was to evaluate the financial impact on the Italian NHS payer's perspective of the use of the screening NIPT, in comparison to current clinical practice (i.e. first and second trimester combined ultrasound and biochemical screening tests; chorionic villus sampling and amniocentesis as invasive diagnostic tests). METHODS: A budget impact analysis, with 3-year-time horizon, was developed within the Italian NHS perspective. The economic analysis was implemented on short-term period until child birth, and the target population was represented by Italian singleton-pregnant screened women (447,616). In relation with clinical and economic outcomes, this analysis compared two scenarios: current clinical practice vs introduction of NIPT as a second-level screening test after current clinical practice. RESULTS: In the light of clinical results, NIPT reduced the number of invasive tests performed by 79%. The overall trisomy detection rate remained constant for T21 and T18 between the two scenarios, and it decreased by 2% in T13. Economic results highlighted that NIPT reduced total testing costs per year by €4.1 million (from million €43.7 to €39.6), due to the decrease of testing costs (by €3.5 million), and ancillary-care costs (by €665,418). Moreover, the cost savings was €9.22 per screened woman. CONCLUSIONS: The introduction of NIPT as a second-level screening test might be a valuable solution for the NHS. It can produce a cost-savings due to a lower number of performed invasive tests than in current clinical practice. These savings could be re-invested in other area improving patient management in women's health.

PMD34: CHANGES IN ACUTE MEDICATION COST OBSERVED IN CLUSTER HEADACHE PATIENTS TREATED WITH SPHENOPALATINE GANGLION (SPG) STIMULATION: A U.K. NHS-SPECIFIC ANALYSIS BASED ON
DATA FROM THE PATHWAY R1 REGISTRY

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OBJECTIVES: On-demand stimulation of the sphenopalatine ganglion (SPG) by means of an implantable neurostimulation system has been shown to be a safe and clinically promising therapy for the treatment of chronic cluster headache. Our objective was to estimate changes in cluster headache medication cost observed in patients treated with the ATI PULSANTE Neurostimulation System, using baseline and 12-month utilization data from the recent Pathway registry and United Kingdom drug costs for reference. METHODS: Detailed patient-level data of n=71 chronic cluster headache patients followed through 12 months in Pathway R1 (NCT01677026) were analyzed to assess weekly utilization of acute cluster headache medications at baseline and 12 months. Cost estimates for all drug/dosage combinations were developed based on current 2017 pharmaceutical prices published in the British National Formulary (BNF 73, 2017), and used the lowest priced product and largest available package size in each instance to determine cost. RESULTS: In the patients receiving SPG stimulation treatment, overall weekly medication costs per patient were reduced by 54.8% from £197.60 to £89.42 (£108.20) from baseline to 12 months. Under a steady-state assumption, the observed drug cost reductions resulted in annualized acute drug cost savings to the U.K. National Health Service (NHS) of £5,626 (reduction from £10,276 to £4,650 per year). CONCLUSIONS: Our analysis suggests that SPG stimulation for the treatment of chronic cluster headache is associated with pronounced reductions in acute cluster headache medication usage, leading to sizable annual savings in medication costs for the United Kingdom’s NHS. On the basis of prior clinical studies investigating SPG therapy, these reductions stem from both effective treatment of attacks with stimulation, and also a reduction in attack frequency observed in stimulation-treated patients.

PMD35: HEALTHCARE COSTS OF PATIENTS WITH ACUTE AND CHRONIC GRAFT-VERSUS-HOST DISEASE FOLLOWING ALLOGENEIC HAEMATOPOIETIC STEM CELL TRANSPLANTATION IN BELGIUM: A RETROSPECTIVE DATA COLLECTION AND ANALYSIS

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OBJECTIVES: Graft-versus-host disease (GvHD) presents a major challenge to successful allogeneic stem cell transplantation (aSCT). Extracorporeal photopheresis (ECP) is a promising alternative to standard immunosuppressive therapies but it was not available at the participating study centre in Belgium. A retrospective analysis was undertaken of resource use and treatment costs with available therapies in patients who developed steroid-refractory or steroid-dependent acute (aGvHD) or chronic GvHD (cGvHD) following aSCT. METHODS: Data were collected on number, duration and cost of hospitalisations, GvHD-related diagnostic procedures, and treatment for the management of symptoms and complications of GvHD. A hypothetical date was identified (the index date; ID) at which clinicians would have referred patients to ECP had it been available. Costs were analysed prior to the potential referral for ECP and compared with those after referral. RESULTS: The study group comprised 26 patients with aGvHD (n=17) or cGvHD (n=9), all eligible for ECP treatment had it been available. The costs of GvHD management at the centre were primarily driven by high inpatient hospitalisation costs. Average monthly inpatient cost was €2,687 per patient prior to the ID and €2,689 between the ID and the end of the study. Average monthly outpatient cost was €753 per patient prior to the ID and €542 between the ID and end of the analysis. CONCLUSIONS: This analysis, undertaken in a small number of patients, suggests that the management of patients with GvHD following aSCT is associated with high healthcare burden in Belgium, primarily related to hospitalisations. A significant unmet need remains for effective GvHD therapies and options such as ECP should be considered. Accessibility to ECP is limited in Belgium and not reimbursed. A similar retrospective analysis is planned to confirm potential changes in healthcare utilisation and costs with ECP treatment.

PMD37: COST-EFFECTIVENESS ANALYSIS OF PRIMARY HPV SCREENING WITH DUAL-STAIN CYTOLOGY TRIAGE IN THE CERVICAL CANCER SCREENING PROGRAM OF BELGIUM

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OBJECTIVES: Previously we have shown that primary HPV screening with dual-stain cytology triage reduced the incidence of cervical cancer 36 % and the mortality by 40 %. Our objective is to determine the cost-effectiveness of dual-stain cytology triage in the 2017 cervical cancer screening program of Belgium. METHODS: The age group for the cervical cancer screening program is 25-65 years with a 3-years interval. Current practice is liquid based cytology (LBC) with reflex HPV testing for ASCUS. The proposed practice is primary HPV screening with reflex dual-
stain cytology. The calculations are based on the honorarium of 2017. The cost calculation is based on screening, diagnostics and treatment. **RESULTS:** The cost for a HPV test is 35 €, for dual-stain cytology is 60 € and for LBC is 28,41 €. The transition from the current practice to the proposed practice will lead to an increase in costs the first three years (4.1 M €, 4.7 M € and 4.7 M €) and a decrease in the fourth (14.3 M €) and fifth (14.8 M €) year. Likewise screening in the 6th, 7th and 8th years will have an increase of respectively 2.2 M €, 3.5 M € and 3.5 M €. The 9th and the 10th year there is a decrease of 13.5 M € and 14 M €. **CONCLUSIONS:** Primary HPV screening program with dual-stain cytology triage can lead to a 5-years screening interval with a budget cost reduction after 5 years of almost 15 M €.

**PMD38: MULTIPLATFORM TUMOR PROFILING DELIVERS VALUE BASED HEALTH CARE IN REFRACTORY CANCER PATIENTS**

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**OBJECTIVES:** Caris Molecular Intelligence® (CMI) is a multiplatform tumor profiling service helping patients with refractory cancer who are past standard of care to find treatment options. In the UK, the National Institute for Health and Clinical Excellence (NICE) has implemented an end-of-life (EoL) premium since 2009. The aim of this study is to assess the cost-effectiveness value of CMI in a health system. **METHODS:** A model described by McCabe and colleagues is adapted to show the value of CMI. To populate the model, threshold cost and real-world incremental cost-effectiveness ratio (ICER) data from the health technology assessments performed by NICE in the past year (November 2015-December 2016) were used as comparators. Data collected in a prospective observational study conducted by Caris demonstrated a survival benefit in patients treated in line with the CMI report. An ICER for CMI was calculated based on the demonstrated survival benefit and the clinical utility. **RESULTS:** To date, NICE recommendations have consistently used a £50,000 per QALY threshold for these EoL treatments. This equates to a health benefit of 7.3 days of additional benefit per £1,000 expenditure by the health care system. A CMI unit price of £5,000 was used in the ICER calculation. According to Caris registry data, CMI can extend overall survival by 138 days (or 0.337 years) for health economic evaluation. CMI-guided therapy is administered in 78% of profiled patients, meaning that a decision impact factor of 0.78 could be included in ICER calculation. The ICER for CMI was calculated as CMI Cost / (QALYs gained x decision impact factor). Based on these assumptions, the ICER for CMI is £19,022 or equivalent to 19.20 days benefit per £1,000 expenditure. **CONCLUSIONS:** Data from this model shows that CMI exceeds the threshold opportunity cost and represents value for health care systems that surpasses many recently approved drugs.

**PMD39: ECONOMIC EFFECTIVENESS OF THE ATTUNE® KNEE SYSTEM - ANALYSIS OF REAL WORLD HOSPITAL LENGTH OF STAY AND INCIDENCE OF EARLY COMPLICATIONS**

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**OBJECTIVES:** Briggs et al. highlight the importance of reducing hospital length of stay (LOS) and early post-operative readmissions to reduce the financial burden of elective orthopaedics. DePuy Synthes (DS) ATTUNE® Knee was engineered to enhance stability, thus potentially accelerating time to normal activities. This study was designed to evaluate whether patients treated with ATTUNE had a shorter LOS and less delayed discharge (DD) and post-operative events compared to patients treated with other implants. **METHODS:** Retrospective analysis of all primary adult TKAs at a single hospital within the United Kingdom between April 2014 and April 2015 was conducted. Three groups of patients were compared by implant type: ATTUNE, DS SIGMA® or Aesculap Columbus®. Outcomes were LOS, DD > 3 days, all-cause 30-day readmissions, all-cause 60-day complications and all-cause 60-day reoperations. Bivariate comparisons of baseline characteristics and outcome measures were generated. Multivariable models were constructed to examine the differences in outcomes between implants and the covariates that may affect these outcomes. **RESULTS:** In this study a total of 716 patients were included (ATTUNE: N=238, SIGMA: N=332, Columbus: N=149); 59.4% were female and had an average age of 69.2 (SD: 9.8). No significant differences were noted in age and sex; however, the proportion of patients ≥ 65 years was significantly greater for Columbus versus ATTUNE (48.3% vs 32.8% respectively). Multivariable regressions showed significantly shorter LOS and significantly smaller proportions of patients with DD for ATTUNE vs. SIGMA and Columbus (LOS (days): ATTUNE: 5.6 (95%CI: 5.2-6.1), Columbus: 6.6 (95%CI: 5.9-7.4), SIGMA: 6.4 (95%CI: 5.9-6.9); DD: ATTUNE: 63.4%; Columbus: 77.2%; SIGMA: 73.8%). Non-significant trends of lower 30-day readmission and 60-day complication and reoperation rates were observed in the cohort treated with ATTUNE vs. Columbus or SIGMA. **CONCLUSIONS:** In
this study, patients treated with ATTUNE experienced significantly shorter LOS and fewer DDs compared to those treated with Columbus or SIGMA.

**PMD40: THE RESOURCE AND COST CONSEQUENCES OF USING ANTIBIOTIC COATED INTRAMEDULLARY NAILS COMPARED TO NON-COATED NAILS IN OPEN TIBIA FRACTURES ACROSS FOUR EUROPEAN CENTRES**

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**OBJECTIVES:** Bone and deep wound infections are associated with increased length of stay and higher costs in patients with open tibial fractures. Infection risks increase with implant usage and open fracture severity. Innovations to reduce risks include antibacterial coated implants. This study models whether use of antibiotic coated implants in patients at high-risk of infection is cost-effective. **METHODS:** An economic model compared infection rates and costs associated with surgery and hospital stay in patients with a Gustilo-Anderson (GA) classification open fractures, for two patient cohorts. All GAII patients in the first cohort received an antibiotic coated tibial nail (ETN PROtect®) whilst the remaining GAi and GAII patients in the same cohort received a standard nail. GAIII patients received the antibiotic coated nail due to their higher infection risk. The second cohort all received a standard tibial nail. Four European trauma centres provided patient-level data on inpatient days, theatre use and related costs for patients with and without infections. Absolute infection risks and relative risk reductions, for antibiotic coated nails compared to standard nails were obtained from a meta-analysis. **RESULTS:** Using the antibiotic coated implant in patients at high-risk of infection (GAIII) was cost saving; the higher cost of the implant was offset by fewer infections, reduced inpatient days and fewer re-operations. Scenario analysis demonstrated using a coated nail in all open fracture patients was cost effective in 3 out of 4 centres. **CONCLUSIONS:** The analyses demonstrated that hospitals could reduce costs by 4-13% by adopting the antibiotic coated nail in patients at high-risk of infection. Infection reduction releases beds and reduces re-operations. Results are sensitive to underlying infection risks; therefore patient selection is important to ensure a cost-effective outcome. Further research is required to improve the identification of high-risk patients most likely to benefit from antibiotic coated implants.

**PMD41: COSTS ANALYSIS OF NOVEL FLASH GLUCOSE MONITORING TECHNOLOGY IN ADULTS WITH TYPE 2 DIABETES MELLITUS (T2DM) UNDER INSULIN TREATMENT IN SPAIN**

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**OBJECTIVES:** Among patients with diabetes, frequent glucose testing is one of the major barriers to achieve optimal glycemic control. The current standard of care is self-monitoring blood glucose (SMBG) involving finger pricking. Flash Glucose Monitoring (FGM) is a novel, sensor based, technology that continuously measures glucose levels and patients obtain their values by sensor scanning. The aim of this analysis is to estimate the costs associated with FGM as a replacement for routine SMBG in patients with T2DM under insulin treatment in Spain. **METHODS:** REPLACE Study showed an average of 3.8 tests a day. Patients using a FGM system spent less time in hypoglycemia, but no reduction in the number of hypoglycemic events was shown. Unit costs for SMBG were 0.04€ per lancet, 0.24€ per strip, 25.20€ per meter and 19.52€ per lancing device. Unit costs for FGM were 59.90€ per FGM reader and 59.90€ per sensor. **RESULTS:** Annual cost of 3.8 SMBG test/day is 433€ per patient compared with 1592€ per patient using FGM. Meaning that with the cost of each FGM reimbursed patient, more than 3 SMBG patients could be afforded. If all patients with T2DM under insulin treatment in Spain (12% of the patients with T2DM) were switched from SMBG to FGM, 12% of the patients (FGM) would concentrate 31% of the glucose measuring resources, while 88% of the patients (SMBG) would take the remaining 69%. In Spain, the cost of SMBG Test Strips equals 2% of the annual Diabetes Budget, if patients with T2DM under insulin treatment were switched to FGM, the amount would raise to 3% of the budget. **CONCLUSIONS:** While FGM is a great innovation that simplifies daily diabetes management and patient adherence to testing frequency, the costs associated with this technology are still a major barrier for patient access.

**PMD42: TREATMENT CHOICES BASED ON MULTIPLATFORM PROFILING PLATFORM, UNLIKE THOSE WITH SEQUENCING ALONE, DO NOT CAUSE A COST EXPLOSION IN REFRACTORY CANCER PATIENTS**

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**OBJECTIVES:** Molecular testing of cancers is quickly becoming standard of care using diverse approaches, either academic or commercial in origin. Some oncologists remain apprehensive about the clinical utility of molecular profiling, based on the degree to which information can be used in a treatment decision, and whether it would lead to
selection of more expensive treatments that may not be accessible. The aim of this study is to examine the decision impact of a multiplatform tumor profiling service, Caris Molecular Intelligence (CMI), and evaluate CMI-guided treatment costs compared to prior and planned treatments in prospective and retrospective clinical studies. METHODS: In 5 physician-led clinical studies, the treatment decision prior to receipt of the CMI report was captured (n=137 patients). A systematic review of treatment data from 10 clinical studies of CMI (n=385 patients) allowed a comparison of planned versus actual (n=137) and prior versus actual (n=229) treatment costs. Costing information was taken from the British National Formulary (BNF) giving a treatment cost per cycle per patient. Decision impact (n=232) and treatment cost per cycle (n=131) were also compared with corresponding data from studies of next generation sequencing (NGS)-only approaches. RESULTS: Decision impact was changed in 88% of CMI-profiled cases compared to 29% of NGS-only approaches. The CMI-guided treatment cost per cycle was £995 in 385 treated patients. Planned treatment costs were comparable to actual treatment costs (£979 versus £945; p=0.7123) and prior treatment costs were also not significantly different to profiling-guided treatments (£892 versus £850; p=0.6319). NGS-only guided treatments cost £2,501 per cycle per patient. CONCLUSIONS: Treatment costs guided by a multiplatform-profiling platform were comparable to planned and prior treatment and do not cause a cost explosion, as the majority of treatments used were conventional chemotherapies. NGS-only approaches rely on more expensive targeted therapies and higher treatment cost per cycle per patient.

PMD43: COMPARISON OF U.S. HOSPITAL COSTS BETWEEN TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) AND SURGICAL AORTIC VALVE REPLACEMENT (SAVR)

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OBJECTIVES: Given TAVR’s broadening application, the budget constraints faced by hospitals, and the higher cost of the TAVR valve compared to SAVR, there is great interest in understanding how hospital costs compare between TAVR and SAVR. METHODS: To evaluate in-hospital costs across U.S. hospitals, we conducted a retrospective analysis of patients undergoing TAVR or SAVR between January 1, 2014 – September 30, 2016 using the Premier Hospital Database. Patients were included in the study if they underwent a TAVR or SAVR procedure based on ICD-9 and -10 procedure codes and were 65 years or older at the time of the procedure. Patients were matched 1:1 using propensity score method based on patient age, Charlson comorbidity index grouping (4 indices), gender, race, and payer type. In-hospital costs were defined as the total hospitalization cost including operating room, supply and board, ICu, lab, etc. plus pharmacy cost, adjusted to 2016 dollars. We supplemented this aggregate-level cost analysis by examining the average in-hospital costs and reimbursement for TAVR and SAVR at two U.S. hospitals. RESULTS: We matched 10,315 TAVR and SAVR patients in the Premier Database. The average, unadjusted, total in-patient hospital cost for TAVR was $64,114 (SD=$35,860) compared to $66,996 (SD=$48,886) for SAVR. The total average supply cost was higher for TAVR by $21,709 (TAVR=$37,486, SD: $21,770 versus SAVR=$15,777, SD: $12,345). TAVR had lower average differences of $10,166 for room and board costs (TAVR=$11,008 versus SAVR=$21,174); $5,813 for operating room costs (TAVR=$7,087 versus SAVR=$12,900); and $2,865 for lab costs (TAVR=$1,670 versus SAVR=$4,535). CONCLUSIONS: Average, total in-hospital cost for TAVR was slightly lower compared to SAVR, mainly resulting from the lower costs for room and board and the operating room helping to offset the higher supply cost for TAVR.

PMD44: HOSPITAL COSTS ASSOCIATED WITH DEDICATED VASCULAR ENDOPROSTHESIS VERSUS PROSTHETIC BYPASS IN POPLITEAL ARTERY ANEURYSM TREATMENT IN FRANCE

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OBJECTIVES: To assess hospital costs of patients with popliteal artery aneurysm (PAA) treated by dedicated vascular endoprosthesis versus prosthetic bypass. METHODS: All hospital stays with PAA treated by endoprosthesis and prosthetic bypass were extracted from the French medical information system (Programme de Médicalisation des Systèmes d’Information, PMSI) 2013 database: implant code was used for endoprosthesis and the combination of both procedure and implant codes for prosthetic bypass. Patients were followed during one year from their first stay (March 2013/March 2014). An algorithm and a medical review excluded rehospitalisations not related to follow up for either treatment. To control confounding factors, patients from both arms were matched according to their age, gender, hospital status (public/private) and principal diagnosis ICD-10 (International Classification of Diseases) code. Associated costs during this period were added up both for the initial surgery and the related rehospitalisations: the mean 1-year cost per patient was estimated and compared between both arms. Valuation was performed considering French official tariffs. RESULTS: In 2013, 573 patients with endoprosthesis and 3,976 patients with prosthetic bypass were identified: 456 patients in each arm could be matched. Patients were 72±10 years old on average, 89% were men. 54% of stays occurred in public hospitals. Median length of initial stay was 3 days [2-6] for endoprosthesis.
implantation and 8 days [6-13] for prosthetic bypass surgery. 42% of endoprosthetic patients and 41% of bypass patients had at least one rehospitalization: respectively, 72% versus 74% of them occurred within 6 months after treatment. The mean 1-year cost was €12,714 ± €9,486 per endoprosthetic patient versus €14,038 ± €11,021 per bypass patient (difference statistically significant; p=0.0014). CONCLUSIONS: Using endoprostheses instead of prosthetic bypass for the treatment of PAA led to a lower mean 1-year cost per patient.

PMD45: USE OF THE IMS CORE DIABETES MODEL (CDM) IN A LONG-TERM PROJECTED HEALTH ECONOMIC COMPARISON OF CSII AND MDI TREATMENTS OF TYPE 1 DIABETES (T1D) IN A NEWLY-DIAGNOSED POPULATION OF PAEDIATRIC PATIENTS.

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OBJECTIVES: Continuous subcutaneous insulin infusions (CSII) are an alternative to multiple daily injections (MDI) of insulin for glycaemic control and reducing the risks of developing long term microvascular and macrovascular complications in type 1 diabetes (T1D). As part of a randomised clinical trial (SCIPI, ISRCTN29255275) we aimed to estimate and compare the long term (60 year) cost-effectiveness of CSII treatment with MDI in paediatrics newly diagnosed with T1D. METHODS: Patients were randomised equally to CSII or MDI and followed-up for 1 year. Glycated haemoglobin (HbA1c), measured at randomisation, 3, 6, 9 and 12 month were used to project future differences between CSII and MDI. Mean total costs for MDI and CSII were estimated at £2,666 and £4,533 for year 1, and £1,665 and £3,303 in subsequent years. Quality adjusted life years (QALYs) were estimated using CORE default settings. Simulations were run for 1000 patients over a thousand iterations and a 60-year timeframe. All costs and outcomes were discounted at 3.5%. RESULTS: Data on HbA1c were available for 97% of participants (CSII=143 MDI=142). Simulations were run with: (i) projected 0.3% HbA1c improvement in CSII patients over 60 years, giving a cost/QALY gain of £207,153 (95% CI: £14,944; £399,362); and (ii) projected 0.2% HbA1c improvement in MDI patients over 60 years, resulting in CSII being dominated. CONCLUSIONS: Based on these exploratory analyses, CSII does not appear to be cost-effective in patients representative of the study population for a projected 60-year lifetime and is dominated by MDI. However, the CDM has not been validated in paediatric populations, and no reliable data on comparative costs and outcomes are available beyond 12 months.

PMD46: A CRITICAL QUALITY APPRAISAL OF STUDIES ESTIMATING THE COST OF RADIOTHERAPY

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OBJECTIVES: To critically appraise the quality of radiotherapy cost studies published between 2004 and 2015. METHODS: Building upon a recent systematic literature review looking at the provider cost in PubMed Medline, Embase (Defourny, 2016), selected studies were examined in-depth focusing on the study quality. The review was performed by three independent reviewers and restricted to studies using cost data published after the QHES grid became available. Selected studies were critically assessed based on 3 existing instruments: CHEERS, CHEC, and QHES. To compare the instruments (inter-instrument agreement) and the agreement between rater, the Kendall coefficient of concordance was calculated. A further refined examination of the references was conducted, focusing on the guidelines’ items relevant for costing. RESULTS: The selection restricted our analysis to 15 articles to be studied in-depth, out of the 52 studies previously selected. The mean score across all articles were respectively 70%, 81%, 72%, mirroring variation in scope of the articles. Over time, instruments’ scores rise with a higher tendency for QHES. Comparison of the instruments per assessor yielded a significant coefficient of 94%, 84% and 87% while the coefficient per rater was significant at 69%, 81% and 77% for each instruments. The inter-rater analysis yielded 10 percent point variation, meaning that they agreed most in rating articles against CHEC, QHES and lastly CHEERS. While the overall mean score was fairly good (74% [31%-93%]), in-depth examination highlights the omission (in the instruments) of criteria covering the type of cost analysis (mean, incremental or full costing) as well as whether the analysis features were modelled or reality-based; these define methodology transparency. CONCLUSIONS: Cost studies’ quality was fairly good while influenced by the instrument more than by the assessor. Existing cost guidance establishes an outline framework while leaving a high degree of freedom in the reporting by the researchers which jeopardize comparability across studies.

PMD47: CLINICAL AND ECONOMIC OUTCOMES OF MICROINVASIVE GLAUCOMA SURGERY (MIGS) WITH STENTS IN PATIENTS WITH MILD-TO-MODERATE OR REFRACTORY GLAUCOMA IN SPAIN

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OBJECTIVES: To review the clinical evidence and estimate annual costs of MIGS with stents in mild-to-moderate or refractory glaucoma from a Spanish hospital perspective. METHODS: Stent types and population examined: (a) trabecular bypass stent with or without cataract surgery (TB+C, TB) and suprachoroidal stent with cataract surgery (S+C) for mild-to-moderate glaucoma; and (b) subconjunctival stent with or without cataract surgery (SC+C, SC) for refractory glaucoma. A review of published trials identified patient characteristics, efficacy (proportion of stent-treated patients with intraocular pressure [IOP] ≤21 mm Hg) and adverse events (AEs). Resource utilization for surgery, AEs, and ophthalmology visits were obtained via expert opinion. Unit costs of ophthalmologist visits, AE-related procedures, mitomycin, and surgeries were sourced from Oblique and BOTplus databases. The price of stents was from the Valencia regional purchasing agency. RESULTS: The efficacy rate was 67.0-100.0% in mild-to-moderate glaucoma (for TB+C, TB, or S+C) and 51.5-71.3% in refractory glaucoma (for SC+C or SC). Hypotony was most frequent in SC+C (24.6%) vs. TB+C (1.0%) and S+C (6.1%). Needling due to bleb failure occurred in 32.3% of SC+C patients. Other AEs include peripheral anterior synechiae (PAS) (≤6.7%), posterior capsular opacification (≤6.0%), stent obstruction (≤54%), and anterior chamber shallowing (≤3%). No AEs impacting hospital budget were observed for TB. Annual costs for TB+C, TB, S+C, SC+C and SC were €2,983, €2,023, €3,189, €4,081 and €2,877, respectively. Costs due to AEs were €61, €0, €77, €238, and €232, respectively. Ophthalmologist visit costs were €540, €406, €731, €1,009, and €929, respectively. CONCLUSIONS: Annual treatment costs were highest for SC+C in refractory glaucoma, in part due to the cost of cataract surgery, ophthalmologist visits, and AEs. When considering costs of MIGS with stents, one must consider the population of interest, whether cataract surgery is performed, subsequent ophthalmologist visits, and the risk of AEs, in addition to the price of stents.

PMD48: MICRO ECONOMIC ANALYSIS OF THE COPD EXACERBATIONS AND HOSPITALIZATIONS BURDEN ON THE HEALTH CARE SYSTEM IN BULGARIA

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OBJECTIVES: COPD is a leading cause for morbidity and mortality worldwide. Exacerbations have a major impact on severity of the disease, the hospitalizations’ rate and their costs. The objective of this study is to analyse the cost of COPD exacerbations and related hospitalization rate in Bulgaria before and after the introduction of new inhaler devices. METHODS: It is an ambispective observational study of real life therapy on a representative cohort of 426 COPD patients. Data for exacerbations, hospitalization rate and their cost was collected according to the severity of the disease. Patients were divided in three subgroups depending on the prescribed therapy. As “new” therapy was considered all INNs introduced on the national market after 2013, INNs before 2013 were coded as “old” therapy and the combination of both was considered as combined therapy. Micro-costing approach was applied to evaluate the total and mean medical costs on exacerbations therapy and exacerbation-related hospitalizations. Descriptive statistics and Kruskal-Wallis test were applied. RESULTS: Patients assigned to new therapy (12%) with new inhaler devices experienced fewer exacerbations with hospitalizations than the patients treated with the medicines available in the Bulgarian market before 2013 (p=0.000029 for exacerbations without and p=0.00420 for exacerbations with hospitalization). The total cost of exacerbations varied from 59 to 309 euro (without hospitalization) and from 3968 to 58840 euro (with hospitalization) depending on the type of therapy. The average cost of exacerbation with hospitalization increased with the progression of the disease and was the lowest for the patients receiving new therapy. CONCLUSIONS: The results suggest that the new therapy with improved inhaled devices might be more effective as a management therapy than the old or combination therapies and could reduce the exacerbation-related cost.

PMD49: REDUCED NEEDLESTICK INJURIES AND HBV INFECTIONS IN CHINESE HEALTHCARE WORKERS FROM BLUNT-TIP SUTURE NEEDLES IN CESAREAN SECTIONS: A MARKOV SIMULATION

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OBJECTIVES: To compare the disease burden and health-related costs of contracting Hepatitis B Virus (HBV) following a needlestick injury in Chinese Healthcare Workers (HCWs) when using normal versus blunt-tip needle sutures in cesarean sections over a 10-year time horizon. BACKGROUND & METHODS: Needlestick injuries can lead to a number of blood-borne infectious diseases i.e. HIV, HBV, or HCV for HCWs exposed to contaminated needles, and contribute to great mental anxiety, reduced productivity, and potentially high treatment costs. For several years, professional organizations such as the WHC have endorsed the use of blunt-tip needle sutures as a preventive and occupational safety measure. Here, a Markov model was built to estimate and compare the HBV infection rate and the total treatment costs per HCW between normal and blunt-tip needle groups. The needlestick...
injury rate in c-sections, HBV infection rate, healthcare costs, Markov states and transition probabilities were collected from three epidemiology papers targeting Chinese populations. **RESULTS:** Although blunt-tip needle sutures command a marginal price premium, they appreciably reduce the incidence of needlestick injuries to surgical personnel (Blunt: 1%, Normal: 6%; p<0.05) and lower treatment costs compared to normal needles. Specifically: (1) The adoption of blunt-tip suture needles reduces HBV infection rates (93 HBV infections/1,000,000 c-sections vs. 557 HBV infections/1,000,000 c-sections), which may be especially pertinent for obstetrics departments performing >1,795 c-sections per year; (2) The net cost benefit per HBV prevented is 112,069 RMB; (3) The 10-year average costs of HBV treatment per HCW is 338,757 RMB; and (4) In case of HBV infection, there is a 1.3% risk of progression to hepatocellular carcinoma (HCC) within 10 years. **CONCLUSIONS:** Based on our study outcomes, the application of blunt-tip needle sutures is associated with a significant reduction in HBV infections and health-related costs in the Chinese context. It may be recommended for clinical use.

**PMD50: POSTERIOR CAPSULE OPACIFICATION AFTER CATARACT EXTRACTION AND RELATED HEALTHCARE COSTS IN GERMANY – A CLAIMS DATA ANALYSIS ON THE IMPACT OF THE IMPLANTED TYPE OF INTRAOCULAR LENSES**

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**OBJECTIVES:** Cataract extraction is the most frequent operative procedure worldwide. The clouded natural lens is replaced by an artificial intraocular lens (IOL) implant, in most cases a hydrophobic or hydrophilic acrylic IOL. The most common long-term complication after cataract surgery is the development of a posterior capsule opacifications (PCO), which is usually treated with neodymium-doped yttrium-aluminium-garnet (Nd:YAG) laser. The aim of this study was to assess real world data on the impact of different IOL material types on the incidence of post-operative PCO treatment as well as associated follow-up costs from a Statutory Health Insurance (SHI) perspective in Germany. **METHODS:** From a sample of six million SHI members, we included patients who underwent cataract extraction and implantation of either an acrylic hydrophobic or hydrophilic IOL in 2010. We assessed clinical outcomes and compared direct costs in a 4-year follow-up period after cataract surgery. **RESULTS:** 3,025 patients were included, a total of 1,192 patients underwent PCO treatment. In more than 99 % of all PCO treatments Nd:YAG laser capsulotomy was applied. PCO that required capsulotomies occurred significantly (p<0.001) less frequent in patients who had received a hydrophobic IOL (31.57 % of 2,078 patients) compared to the group with hydrophilic IOL implants (56.6 % of 947 patients) and costs per patient for postoperative treatment in a 4-year follow-up were 50.03 € vs. 87.81 € (i.e. 75 % higher in the latter group, p<0.001). **CONCLUSIONS:** Considering the high prevalence of cataract, the economic burden associated with treatment of long-term complications after cataract extraction is of great relevance for the German SHI. Implantation of hydrophobic lenses seems to be superior regarding both medical and economic results.

**PMD51: CLINICAL AND ECONOMIC BENEFIT OF UPPER AIRWAY STIMULATION FOR OBSTRUCTIVE SLEEP APNEA IN THE GERMAN SETTING**

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**OBJECTIVES:** Upper airway stimulation (UAS) is a treatment approach intended for patients with medium-to-severe obstructive sleep apnea who have failed or cannot tolerate continuous positive airway pressure therapy. Our objective was to evaluate the clinical and economic benefit of UAS in the German healthcare system. **METHODS:** A five-state Markov model projected the probabilities of hypertension, major adverse cardiovascular or cerebrovascular events (myocardial infarction [MI], stroke), and motor vehicle collisions (MVC) to estimate cardiovascular and all-cause mortality, quality-adjusted life years (QALYs), and total direct costs for UAS versus no treatment from the German statutory health insurance perspective. Baseline characteristics and treatment efficacy were obtained from a recent prospective observational study and derived from literature via multivariate regression. Ten-year relative event risks (RR) and undiscounted lifetime survival benefit were computed as well as incremental cost-effectiveness ratios in Euros per QALY, discounted at 3% for costs and effects. **RESULTS:** Based on a real-world study from Germany, the patients’ mean age at baseline was 57 years, their BMI was 29 kg/m2, and their apnea-hypopnea index was reduced from 31.2 to 13.8 events per hour by UAS compared to no treatment. UAS reduced all types of events projected (ten-year relative risks for stroke, MI, cardiovascular death, and MVC: 0.76, 0.64, 0.65, and 0.34, respectively) and increased survival by 1.27 life years. While the UAS strategy incurred an additional 1.02 QALYs, there were also additional mean costs of 54,578 Euros over the patient’s lifetime, resulting in an incremental cost-effectiveness ratio of €53,698 per QALY gained. **CONCLUSIONS:** Upper airway stimulation adds meaningful benefit
to endpoints relevant to obstructive sleep apnea patients and is a cost-effective therapy for patients ineligible to continuous positive pressure ventilation in the German healthcare setting.

### PMD52: THE COST-EFFECTIVENESS OF DETECTING ARRHYTHMIAS WITH INSERTABLE CARDIAC MONITORS (ICM) IN TURKEY

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**OBJECTIVES:** The effectiveness of Insertable Cardiac Monitors (ICMs – also referred to as implantable loop recorders in the past) in detecting arrhythmia in syncope patients is well established in the literature. This analysis evaluates the cost-effectiveness of post-syncpe, ICM-driven diagnosis following Standard Testing (ST) from a Turkish payer perspective. **METHODS:** This analysis considers all costs of diagnosis via ST and ICM, the costs and consequences of recurrent syncope, and the cost of arrhythmia treatment following diagnosis. Cost inputs are derived from the Turkish Health Implementation Communique and published literature. A Markov model was developed to reflect the recurrence of syncopal events in undiagnosed patients. Arrhythmia diagnosis and recurrent syncpe events in patients with unexplained syncope were modelled over a 10-year time horizon. All costs and consequences were discounted at a 3% annual rate, and extensive one-way sensitivity analyses (SA) were performed (100K MC Simulations). There is no official willingness to pay threshold in Turkey; therefore, it was assumed to be equal to three times GDP per capita at 79,038 Turkish Lira (TRY)/Quality Adjusted Life Year (QALY). **RESULTS:** ICM is cost-effective with an ICER of 34,913.52 TRY/QALY. The mean incremental QALYs are estimated to be 0.417. In 1,000 patients, ICMs are estimated to identify 376 (IQ Range 287-481) more arrhythmic cases compared to ST. Extensive SA on key drivers confirmed the robustness of results. ICM is cost-effective, and below the assumed threshold approximately 78% of the time. Another 10% of the time, ICM delivers more value but at a cost higher than the assumed threshold. **CONCLUSIONS:** The use of ICM substantially increases the arrhythmic diagnostic yield and guides treatment in more patients than ST. When considering all diagnostic costs in combination with the syncopal events avoided and quality of life (QoL), ICM arrhythmia diagnosis is a cost-effective alternative to ST.

### PMD53: REMOTE THERAPY MANAGEMENT OF PATIENTS ON AUTOMATED PERITONEAL DIALYSIS DEMONSTRATES COST SAVINGS IN GERMANY AND ITALY

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**OBJECTIVES:** To estimate the cost-consequences of avoiding healthcare resource utilization by using a two-way data exchange platform with remote therapy management (RTM) capabilities in automated peritoneal dialysis (APD) patients in a simulated environment in Germany and Italy. **METHODS:** 12 APD patient profiles (e.g. therapy adherence, fluid overload, missing/factitious data entry) were used to simulate healthcare resource use with RTM information (like treatment data, blood pressure, weight) and without. Resources considered included emergency room visits, hospitalizations, unplanned clinic visits, clinic calls, home visits, change of device, change to HD, retraining/counseling, or other resources specified by the healthcare provider. 3 nephrologists (Germany n=2; Italy n=1), experts in managing APD patients validated the “without remote monitoring” resources. The “with remote monitoring” resources were estimated by 4 APD teams (1 nephrologist, 1 nurse) (Germany n=3; Italy n=1). A Monte-Carlo simulation (1,000 iterations) was run on resources avoided (resources “without remote monitoring” minus those with). Published literature and public tariffs validated by experts in Germany and Italy were used for costing from a healthcare payer and provider perspective. **RESULTS:** Summary results based on the Monte-Carlo simulation demonstrated that the use of RTM could avoid a total of 49.7±5.6, and 16.0±2.5 resources in Germany and Italy, respectively. Total healthcare resources avoided represented 10,480±5835€ and 5,886±5459€ in savings across the 12 patient profiles in Germany and Italy, respectively from a healthcare payer perspective. Savings were highest for avoided hospitalizations (9,724€ in Germany and 4,443€ in Italy). Opportunity costs for providers resulting mainly from avoidance of unplanned clinic visits clinic calls would total 352€±40€ and 546€±55€ in Germany and Italy, respectively. The 12 profiles were estimated to be representative of 15.4% to 32.6% of the APD patients in Germany and Italy. **CONCLUSIONS:** In a simulation, RTM saved healthcare resources in APD patients by enabling earlier medical intervention, avoiding complications and treatment drop-out.

### PMD54: COST CONSEQUENCE ANALYSIS OF DIFFERENT GENE MUTATION TESTING MODALITIES FOR BRAF V600E MUTATION IN ADVANCED NON-SMALL CELL LUNG CANCER USING A DECISION ANALYTIC MODEL

### PMD55: SMALL CELL LUNG CANCER USING A DECISION ANALYTIC MODEL
OBJECTIVES: To compare clinical and economic consequences of various gene mutation testing modalities vs next generation sequencing (NGS) among patients with BRAF V600E-mutant advanced non-small cell lung cancer (NSCLC) in the United States. METHODS: Using a decision analytic model, patients with BRAF V600E-mutated NSCLC received (1) sequential testing, (2) exclusionary mutation (i.e., KRAS) testing followed by sequential testing, (3) BRAF testing after limited mutation/rearrangement panel, or (4) upfront NGS, which includes BRAF testing. Treatment options for BRAF+ patients included dabrafenib+trametinib combination therapy, chemotherapy, or immunotherapy. Test turnaround time and unit costs were based on literature and clinical experts’ opinions. Patients are assumed to initiate dabrafenib+trametinib upon receipt of positive BRAF mutation test results. Differences in time to receive BRAF mutation test results and targeted therapy initiation, and cost of testing were compared between each modality vs NGS. RESULTS: Time to receive BRAF mutation test results and targeted therapy initiation among candidate patients was estimated at 2.0 weeks for NGS, which was 2.4 weeks faster than mutation panel; 4.9 weeks faster than sequential; and 6.4 weeks faster than exclusionary testing strategy. The time to targeted therapy initiation estimate may be conservative as in a real-world setting some patients may delay dabrafenib+trametinib until disease progression on a prior treatment. Based on CMS reimbursement, NGS cost $623, representing savings of $980 compared to sequential and mutations panel, and a $1238 vs exclusionary strategy. In a sensitivity analysis based on amounts reimbursed by third-party payers (commercial claims data), NGS ($2860) remained the least expensive option by $894 to $1044. CONCLUSIONS: Compared with other testing strategies, our model estimates that upfront NGS as a single test leads to the shortest wait time for mutation testing, resulting in earlier initiation of effective targeted therapy, and lower costs in patients with BRAF V600E-mutant advanced NSCLC.

PMD55: COST-CONSEQUENCES OF USING FLUCICLOVINE (F 18) FOR THE DIAGNOSIS AND STAGING OF RECURRING PROSTATE CANCER

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OBJECTIVES: Prostate cancer (PCa) is the second leading cause of cancer death in men. Recurrence occurs in 1/3 of patients with 1/3 developing into metastatic PCa. Current detection methodologies often do not identify location and disease extent which can aid in therapy selection. Fluciclovine F18 was recently approved by the US FDA for use in positron emission tomography imaging in men with suspected PCa recurrence based on elevated PSA levels following prior treatment. The aim of our analysis was to quantify the impact of using fluciclovine for the diagnosis and staging of recurring PCa from a US payer perspective. METHODS: A decision analytic model based on current clinical practice was developed to estimate the annual impact of fluciclovine use vs. standard of care (SoC). Demographics, test specifications, and clinical treatment decisions were derived from the literature and expert opinion. Procedure and administration costs were based on Medicare National Limitation amounts. Drug costs were 2016 wholesale acquisition costs. RESULTS: For a hypothetical payer with 500000 covered lives 1,326 men in one year would be suspected to have recurrent PCa. Fluciclovine use reduced the number of imaging procedures by 27% and increase correct diagnoses by 13%. As a result, futile post diagnostic treatment (overuse of radiation therapy (RT) and local RT to prostate when the radiation field should have been expanded to include the pelvis) may be avoided. The costs increased from $18.9 to $21.9 million (16%) from increased imagining agent cost. The cost per correct diagnosis was relatively cost neutral with an increase from $24,870 to $25,589 (3%). CONCLUSIONS: Model results suggests that increased fluciclovine use for imaging suspected recurring PCa patients may result in better clinical outcomes (fewer imaging tests, more correct diagnoses and fewer futile treatments), while being relatively cost neutral.

PMD56: WOUND MANAGEMENT IN DIABETIC FOOT ULCER (DFU) - INCREMENTAL COST-ANALYSIS OF TREATING DIABETIC NEUROPATHIC FOOT LESIONS WITH ADJUNCT HEMOGLOBIN CONTACT SPRAY IN GERMANY

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OBJECTIVES: Diabetic foot ulcers (DFU) do not respond well to treatment and cause substantial costs. The topical hemoglobin contact spray Granulox® when applied in addition to the standard wound care regimen results in an acceleration of wound healing and an improvement in wound closure even in stalling wounds. Objective of this study is to analyse the impact of a topical hemoglobin contact spray on cost from the perspective of the German statutory health insurance. METHODS: Based on clinical trial data a 28-week Markov model was programmed covering the
following model states: “Stalled Wound Healing”, “Normal Wound Healing”, “Infected Wound”, “Amputation”, “Ceased”, “Healed”. Analysis of incremental differences were performed and tested for robustness with a sensitivity analysis. RESULTS: Patients with standard wound care regimen caused average total costs during 28 weeks of 1737 €, patients with adjunct topical hemoglobin contact spray resulted in a total of 1027 €. Costs for nursing and dressing changes represented the major cost factor with an average of 806 € in standard wound care regimen and 474 € when topical hemoglobin contact spray was added. The cost decrease of 709 € was confirmed when varying assumptions in the sensitivity analysis. CONCLUSIONS: When applying the topical hemoglobin contact spray Granulox® in addition to standard wound care regimen of diabetic foot ulcer in Germany a substantial cost reduction could be achieved from the perspective of the German statutory health insurance.

PMD57: A COST CONSEQUENCES ANALYSIS OF THE HUMAN BODY POSTURIZER IN ITALY

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OBJECTIVES: The burden of low back pain is very high among the general population with significant economic and social impact on both direct and indirect costs. In Italy, each year, 30 million working hours are lost due to back sickness. Over the past two decades, several treatments have been developed to manage the various stages of the disease: acute, sub-acute and chronic. The aim of this study is to evaluate the cost-consequences of the Human Body Posturizer (HBP), according to the stage of the disease, both in terms of direct and indirect costs. METHODS: A decision tree model was developed, to compare the traditional pathway without HBP (P1) vs the new one with HBP (P2). To estimate drugs costs, the generic prices, reimbursed by the Italian National Health System (INHS), were used. Outpatient and inpatient costs were quantified with the National tariffs while productivity loss was costing using the Italian daily Gross Domestic Product per-capita. The price of HBP was €4,550.74. The time horizon was one-year, therefore no discounts were applied. RESULTS: For acute low back pain, the use of HBP increased direct costs from €64.04 (P1) to €332.02 (P2) without affecting indirect ones. In the sub-acute setting HBP was cost saving with direct costs from €552.48 (P1) to €347.18 (P2) and indirect ones from €900.20 (P1) to €128.60 (P2). Finally, considering the chronic stage, direct costs decreased from €1526.98 (P1) to €340.18 (P2), while indirect ones from €1,929.00 (P1) to €192.90 (P2). CONCLUSIONS: The introduction of HBP could be a cost saving strategy in patients with sub-acute and chronic low back pain, considering both the INHS and Society perspective.

PMD58: CONTINUOUS SUBCUTANEOUS INFUSION VERSUS MULTIPLE DOSE INJECTION OF INSULIN FOR NEWLY-DIAGNOSED T1D PAEDIATRIC PATIENTS: A COST-UTILITY ANALYSIS

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OBJECTIVES: Continuous subcutaneous insulin infusions (CSII) and multiple daily injections (MDI) with insulin are alternative methods of glycaemic control in type 1 diabetes (T1D) aimed to reduce the risk of developing long term microvascular and macrovascular complications. The SCIPI trial (ISRCTN29255275) compared the clinical and cost-effectiveness of CSII treatment with MDI in paediatric patients from the perspective of the NHS. METHODS: Children (aged 7-months-15years) with newly-diagnosed T1D were randomised equally to CSII or MDI for treatment and stratified by age and treatment centre. Resource use (prescribed insulin, concomitant medications, devices, consumables, inpatient, outpatient, emergency, adverse events, general practitioner and school visits) was collected at randomisation, 3, 6, 9 and 12 month intervals. Quality adjusted life years (QALYs) were assessed by the Health Utilities Index (Mark II) completed at all study visits. RESULTS: 293 children were randomised to the trial (median age 9.8 years; median HbA1c 11.8%). Over 12 months, mean total costs were higher by £1,863 (95% CI, £1,620, £2,137) for CSII than for MDI (£4,404 vs £2,541); with the majority of this difference (£1,177) due to the additional cost of consumables and devices (annualised cost of £600 CSII versus £80 MDI). There were no significant differences in QALYs between CSII (0.910) and MDI (0.916) [difference in means of -0.006 QALYs (95% CI, -0.031, 0.018)] and none of the sensitivity analyses affected the base case result of CSII being dominated by MDI. CONCLUSIONS: CSII is not cost effective in patients representative of the study population and is dominated by MDI. However, the generalisability of our data beyond 12 months is uncertain.

PMD59: COST-EFFECTIVENESS OF PREOPERATIVE MRI IN DUCTAL CARCINOMA IN SITU OF THE BREAST

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OBJECTIVES: A complete surgical excision is the key to successful breast-conserving surgery in patients with ductal carcinoma in situ (DCIS) of the breast. Preoperative magnetic resonance imaging (MRI) may allow decreasing re-
interventions for positive margins. Our objective was to perform an economic evaluation alongside the IRCIS randomized controlled trial [NCT01112254] to determine whether preoperative MRI in DCIS is a cost-effective strategy. **METHODS:** The patient population for the economic study consisted of 345 patients (173 in the MRI arm and 172 patients in the control arm). Costs were assessed from the French national health insurance perspective. Resource use were prospectively collected during a 6-month period after randomization and included all breast cancer-related hospitalizations, specialists visits, imaging procedures and biopsies, radiotherapy, transportsations and sick leaves. We estimated the mean cost per patient in each arm and the cost difference between arms. Ninety-five percent confidence intervals and cost-effectiveness acceptability curve (cost per averted re-intervention for positive margin) were estimated using bootstrap replicates (n=10,000). **RESULTS:** The re-intervention rate for positive margins was 20% in the MRI arm (35/173) and 27% in the control arm (47/172). The difference (MRI-control) in re-intervention rates was -7% [95% CI: -17%; 3%]. The number of re-hospitalizations was 48 in the MRI arm and 59 in the control arm. The mean cost per patient was € 9,682 in the control arm and € 9,980 in the MRI arm. The cost difference (MRI-control) amounted to € 298 [95% CI: -470; 1063]. For a willingness to pay of € 500 to avert a re-intervention, the probability of MRI strategy being cost-effective was 93%. **CONCLUSIONS:** Preoperative MRI in DCIS tends to reduce re-interventions for positive margins and is likely to be a cost-effective strategy in France.

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**PMD60:** COST-EFFECTIVENESS OF THE SUFENTANIL SUBLINGUAL TABLET SYSTEM VS IV PCA MORPHINE FOR THE TREATMENT OF ACUTE MODERATE TO SEVERE POST-OPERATIVE PAIN IN IRELAND

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**OBJECTIVES:** To assess the cost-effectiveness of Sufentanil Sublingual Tablet System (SSTS), a non-invasive patient controlled analgesia system (PCA) vs. intravenous (IV) PCA morphine for the treatment of acute moderate to severe post-operative pain from an Irish healthcare perspective. Additional focus was on avoidance of IV line complications. **METHODS:** A decision-tree based cost-effectiveness model was developed to evaluate the costs and consequences of treating patients with SSTS-PCA vs. IV-PCA. Patients entered the model requiring post-operative pain management following surgery and could transition through three health states (successful pain management, fair to poor pain management and discontinuation) within the 48 hour time horizon. Clinical data were derived from the pivotal clinical study comparing SSTS-PCA with IV-PCA morphine (Melson 2014) and indirect treatment comparisons where direct comparisons were lacking. Health related quality of life data were derived from a mapping algorithm converting the NPRS 11-points pain rating scale to EQ-5D (Dixon 2011). Cost inputs include drug/device consumable acquisition, devices and staff time expressed in 2017 Euros. In addition to in-trial adverse events, IV line infections were taken into account; the base case assumes a 16.4% incidence rate and an increased hospital length of stay by two days (Kagel 2004). **RESULTS:** SSTS-PCA is associated with savings of €39.57 vs. IV-PCA morphine per treatment. Small benefits in QALYs (0.000408) due to the short time horizon lead to SSTS-PCA being dominant in all cases. SSTS-PCA demonstrates advantages compared to IV-PCA morphine in the proportion of successfully treated patients (77% vs. 62%), proportion of treatment discontinuations (7% vs. 10%) and costs per successful patient treated (€333 vs. €372). **CONCLUSIONS:** SSTS-PCA is a cost-effective treatment option for the management of acute moderate to severe post-operative pain, associated with fewer complications, lower costs and demonstrates early mobilisation benefits compared to IV morphine PCA in an Irish healthcare perspective.

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**PMD61:** PORT CATHETER VERSUS PERIPHERALLY INSERTED CENTRAL CATHETER FOR ADJUVANT CHEMOTHERAPY IN BREAST CANCER: A COST-EFFECTIVENESS ANALYSIS

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**OBJECTIVES:** In our regional cancer center, the peripherally inserted central catheter (PICC) has become an alternative to the port catheter (PC) in adjuvant chemotherapy for breast cancer. Between 2010 and 2012, a retrospective study comparing the two devices was performed, and published. A total of 68 device-related complications were observed: 25 in PC arm (290 patients) and 43 in PICC arm (158 patients). This study showed that the PICC was a risk factor for complication. The purpose of the present study was a medico-economic evaluation between these two devices. **METHODS:** This study was a cost-effectiveness evaluation. Data were collected retrospectively from the cohort of the initial clinical study. The primary efficacy endpoint was the rate of patients who benefited from the entire chemotherapy protocol at the end of the time horizon (150 days post-exposure). The perspective was the Health Insurance. Costs for each patient were valued from the patient’s medical file. Costs of hospital care and community care were taken into account in the total cost calculation. **RESULTS:** 18 patients, 4 in PICC arm and 14 in PC arm, were excluded from our analysis because they did not achieve their chemotherapy for any other cause than a device-related complication. The total cost of using a PC was €897 per patient. The total cost of using a PICC is €1319 per patient. PICC arm patients were more likely to benefit from all chemotherapy compared
to PC arm (1.05 95% CI [1.01 - 1.10]). The incremental cost-effectiveness ratio for this relative risk was €400.24. A patient with a PICC represents an additional cost of €400 compared to a patient with a PC, for an almost identical effectiveness. CONCLUSIONS: Since value for money is a major issue, the medico-economic argument plays an important role in decisions. From our evaluation the port catheter is the most cost-effective device.

**PMD62: MOBILE CARDIAC MONITORIZATION IS A COST-EFFECTIVE TOOL FOR THE DIAGNOSIS AND MANAGEMENT OF ATRIAL FIBRILLATION COMPARED TO HOLTER: A COST EFFECTIVENESS STUDY IN TURKEY**

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**OBJECTIVES:** Mobile Cardiac Monitoring (MCT) frequently detects paroxysmal atrial fibrillation (PAF) in patients with cryptogenic stroke and transient ischemic accident (TIA). Length of monitoring is strongly associated with detection of PAF, with an optimal monitoring period of at least 21 days. The diagnostic yield of patients monitored with MCT is 61%. This is significantly higher than that of patients who use the Event monitor (23%) or the Holter monitor (24%). The aim of the analysis is to conduct a cost-effectiveness analysis of MCT versus Holter, with direct cost and payer perspective in atrial fibrillation. **METHODS:** Literature search was conducted to understand Atrial Fibrillation (AF) diagnosis process with MCT or Holter, treatment process and health outcomes with or without treatment. A decision tree and Markov model were conducted for calculating the cost effectiveness of MCT vs. Holter monitoring. A healthcare utilization and outcomes questionnaire was prepared based on literature and conducted with 3 Turkish Key Opinion Leaders (KOLs) for understanding the pathway of AF diagnosis and treatment in Turkey. Cost of healthcare utilization with direct cost to Social Security Institution was included in the study with a payer perspective. Monte Carlo simulation and probabilistic sensitivity analysis were conducted. TreeAge Pro 2017 program was used for running the cost effectiveness analysis. **RESULTS:** MCT is cost effective compared to Holter for the diagnosis and management of Atrial Fibrillation with an ICER of 12.839 TL/year depending on WHO’s cost-effectiveness threshold criteria. In 95% of results of cost-effectiveness analysis of 1,000 samples using Monte Carlo Distribution were found that MCT is cost-effective compared to Holter. **CONCLUSIONS:** Early diagnosis is feasible with MCT, which would yield lower healthcare costs for payers. The study findings suggest that MCT is a cost-effective diagnosis tool compared to Holter for Atrial Arrhythmia from payer perspective in Turkey.

**PMD63: COST-EFFECTIVENESS OF A FLASH GLUCOSE MONITORING SYSTEM BASED ON REAL-WORLD USAGE FOR TYPE 1 DIABETES (T1DM) PATIENTS USING INTENSIVE INSULIN: A SWEDISH PERSPECTIVE**

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**OBJECTIVES:** Routine glucose monitoring is valuable for T1DM patients using intensive insulin, and more frequent testing is associated with lower HbA1c (Miller 2013). A novel, factory-calibrated flash glucose monitoring (“FM”) system (the FreeStyle Libre™ system) continuously measures glucose levels from interstitial fluid without requiring routine self-monitoring of blood glucose (SMBG). Data transfers to a handheld reader from the wearable arm sensor. Real-world data collected from over 50,000 FM readers indicates patients scan 16 times/day on average compared to 5-6 tests/day for SMBG users (Miller 2013). The data also showed an association between lower HbA1c and more frequent scans. Therefore, this study evaluates the cost-effectiveness of increased glucose test frequency based on this real-world data, comparing FM vs SMBG in T1DM patients using intensive insulin. **METHODS:** The QuintilesIMS Core Diabetes Model was run over a 50-year lifetime horizon, modelling a population reflecting the IMPACT study (Bolinder 2016). Intervention effects include: HbA1c intervention benefit (0.58%) based on association with number of tests/day; IMPACT study-based reductions in hypoglycaemic events (glucose <70mg/dL; 25.5% fewer daytime events, 33.2% fewer nocturnal events); a 0.03 utility benefit of FM (Matza 2017). Costs were reported in 2016 SEK. Incremental cost-effectiveness ratios (ICER) were estimated, with sensitivity analyses conducted around the scan frequency interquartile range, and exploration of scan frequency impact on severe hypoglycaemic event rates. **RESULTS:** In base case analysis, FM led to 1.071 more QALYs than SMBG (13.597 vs 12.526), and SEK104,397 more in incremental direct and indirect costs (SEK1,786,017 vs 1,681,620) for an ICER of SEK97,468/QALY. Scenario analyses results ranged from SEK27,422/QALY to SEK152,522/QALY. **CONCLUSIONS:** Real-world FM use shows higher glucose test frequency than for SMBG testing. More frequent testing is associated with lower HbA1c and less hypoglycaemia. Given these benefits, FM may be considered cost-effective for T1DM patients receiving intensive insulin in Sweden.

**PMD64: THE VALUE OF BEDS WITH CONTINUOUS LATERAL ROTATION THERAPY TO PREVENT VENTILATOR-ASSOCIATED PNEUMONIA AND PRESSURE INJURIES: A COST-EFFECTIVENESS ANALYSIS**

OBJECTIVES: Immobility of mechanically ventilated patients in the intensive care unit (ICU) increases the risk of pulmonary complications and hospital-acquired conditions (HACs) such as ventilator-associated pneumonia (VAP) and pressure injuries (PrI). Continuous lateral rotation therapy (CLRT) has been shown to reduce the incidence of VAP and PrI, but the economic value of switching to CLRT over standard care is presently unknown. The objective of this study is to evaluate the cost-effectiveness of CLRT specialty beds compared to standard care in ICUs and to determine the return on investment (ROI) associated with its implementation. METHODS: A Markov model was constructed to predict health state transition from the time of ventilation through 28 days using the healthcare sector perspective. Daily transition probabilities were extrapolated from prospective clinical studies comparing CLRT with standard care. Costs were estimated in 2014 USD. Utility scores were extracted from the published literature. Cost per quality-adjusted life-years (QALYs) was calculated, and probabilistic sensitivity analyses (PSA) using 10,000 Monte Carlo simulations were conducted. ROI analysis was also performed to estimate the net benefit and breakeven point of the investment. RESULTS: CLRT was dominant over standard care. The expected cost for a CLRT per patient was $47,140 compared to standard care at $49,229 per patient, showing that CLRT saves cost per patient. The expected effectiveness of CLRT per patient was 0.0454 QALYs compared to 0.0451 QALYs for standard care. CLRT was dominant in 99.94% of the Monte Carlo simulations in the PSAs and 100% of the simulations in the univariate sensitivity analysis. CLRT also showed outstanding ROI reaching the breaking even point after 0.42 of a year. CONCLUSIONS: CLRT appears to be highly cost-effective compared to standard care by preventing ventilator-associated infections and PrIs in an ICU setting.

PMD65: COST EFFECTIVENESS OF URBAN BREAST CANCER SCREENING PROGRAMME IN CHINA

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OBJECTIVES: This study aimed to analyse the cost-effectiveness of the breast cancer screening pilot program among urban Chinese women, as well as to conduct sensitivity analysis, scenario analysis, and the budget impact analysis. METHODS: A Markov model was developed from a societal perspective among asymptomatic Chinese women over 40 years at risk for breast cancer over a lifetime horizon in urban China. We obtained the incremental cost-effectiveness ratio (ICER) and explored the uncertainty using one-way and probabilistic sensitivity analysis. We also explored the ICERs in different geographic areas and cities as well as with different screening intervals and population coverage. In the budget impact analysis, we analyzed the screening funding to detect one case in the program, and the impact of the issued questionnaires’ number on the screening funding. RESULTS: The ICER of screening was ¥3,195/QALY in the urban programme. Compared to no screening, breast screening was cost-saving in all levels of cities and all geographic areas in China. Also, the results did not change with screening intervals. When the population coverage increased, the breast screening was more cost-saving. The treatment costs, the screening costs, and the effectiveness of the screening methods can influence the ICERs but they did not change the results. At the threshold of ¥140,000/QALY, the probability of breast screening being cost-effective compared to no screening in urban areas was almost 100%. The budget impact analysis showed that the screening cost was ¥1,7806 to detect one case in the urban program. If the number of issued questionnaires reached the target, the screening cost for one detected case was only ¥7,122. CONCLUSIONS: The urban breast cancer screening program in China was effective and cost-saving. We recommend to expand the population coverage and to ensure that the issued questionnaires reach the target quantity.

PMD66: COST-EFFECTIVENESS ANALYSIS OF COBLATION TECHNOLOGY VS. MECHANICAL DEBRIDEMENT WITH A SHAVER IN THE TREATMENT OF KNEE CARTILAGE LESIONS- A SPANISH PAYER PERSPECTIVE.

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OBJECTIVES: To conduct a cost-effectiveness analysis between Coblation technology and mechanical debridement with a shaver (MD) in a patient population presenting with chronic pain due to a medial meniscus tear and an International Cartilage Research Society (ICRS) grade III focal chondral lesion. METHODS: A decision-analytic model was developed comparing costs and clinical outcomes between Coblation and MD following a knee chondroplasty procedure in a patient population with medial meniscus tear and an International Cartilage Research Society (ICRS) grade III focal chondral lesion. Costs were obtained from the 2016 Spanish Health Costs database, an annual 3% discount rate was applied to future costs. Clinical outcomes data were extracted from published results of a randomized clinical trial (RCT). The time horizon for the analysis was 4 years for both costs and outcomes.
Model robustness was tested using threshold analysis and multiple one-way sensitivity analyses. **RESULTS:** The RCT reported a lower revision rate with Coblation, 14% compared to 48% with MD (p=0.006). Furthermore, patients treated with Coblation reported a significantly higher Knee Injury and Osteoarthritis Outcome Score (KOOS) at the end of the study (p=0.001). Over a 4-year post-operative period, the estimated total cost per patient was 2,858€ and 4,931€ for Coblation and MD respectively resulting in cost-savings of 2,073€ in favor of Coblation, making Coblation a dominant strategy as a result of lower costs and better improved clinical outcomes. The cost-saving realized with Coblation was robust to sensitivity analyses and threshold analysis determined that Coblation remained the dominant alternative when it was assumed that Coblation revision rate increased from the initially reported rate of 14% up to 69%. **CONCLUSIONS:** The use of Coblation technology vs. MD is a cost-effective option in the treatment of patients with a medial meniscus tear and idiopathic ICRS grade III defect.

**PMD67: COST EFFECTIVENESS OF BARIATRIC SURGERY IN TURKEY: FROM A LONG-TERM PERSPECTIVE**

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**Objectives:** According to the most recent data, obesity rate has increased to 19.9% in 2014 from 15.2% in 2008 in Turkey. Bariatric surgery is among the most recent treatment alternatives increasingly used for morbid obese patients. Reimbursement agencies face the challenge to fight with the cost of obesity and its co-morbidities and also with the cost of bariatric surgery. The main objective of this study is to assess the cost effectiveness of bariatric surgery from a 20 years perspective in Turkey. **Methods:** A Markov model was developed to show the long-term clinical and economic benefits of bariatric surgery. Cost effectiveness of gastric bypass (GBP) and sleeve gastrectomy (SG) were compared with standard of care (SoC) (diet exercise etc) for BMI≥40 patients. The model not only covers the impact of surgery on BMI but also on Type 2 diabetes, cardiovascular diseases, cancer (only in women) sleep apnea and knee pain and complications due to surgery. Analyses were made from the Turkish Social Security Institution’s (SSI) perspective and for both package and fee for service prices. Markov transition probabilities were obtained from published research, Turkish cost data were obtained from literature and expert views. **Results:** Incremental QALYs were 2.59 and 2.63 for GBP and SG respectively. Both modes of bariatric surgery dominated SoC under fee for service payment. With package prices, incremental costs per patient were 4,287 TRY for GBP vs SoC and 3,573 TRY for SG vs SoC. Incremental cost per patients with T2DM was 3,770 TRY for GBP vs SoC. The ICERs were 1,655 TRY and 1,357 TRY for GBP and SG respectively. For patients with T2DM the ICER was 3,370 TRY. **Conclusions:** The results showed that bariatric surgery is a cost effective option for the Turkish health care system both under package and fee for service prices.

**PMD68: THE POTENTIAL VALUE OF MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING IN ACTIVE SURVEILLANCE OF MEN WITH LOW-RISK PROSTATE CANCER: A COST-EFFECTIVENESS MODELING STUDY**


**OBJECTIVES:** Active surveillance (AS) in men with low-risk prostate cancer comprises repeated transrectal ultrasound guided biopsies (TRUSGB) in order to timely detect those tumours that have progressed to high-risk tumours which require treatment. However, AS via TRUSGB is accompanied by limitations concerning missing of high-risk prostate tumours and unnecessary burdensome biopsies. The implementation of multiparametric magnetic resonance imaging (mpMRI) in the AS could potentially overcome these limitations. This study aims to determine the potential cost-effectiveness of implementing the mpMRI in the AS, by evaluating different AS strategies: AS with TRUSGB (reference), AS with mpMRI and confirmatory MR-TRUSGB biopsy in men with a positive mpMRI, and AS with mpMRI only. **METHODS:** A state transition Markov cohort model for men (mean age 60 year) with low-risk prostate cancer was developed to evaluate the cost (2016 euros) and health effects (quality adjusted life years (QALYs)) of different AS strategies over a lifetime horizon from a healthcare perspective. The main outcome measure was the incremental cost-effectiveness ratio (euros per QALY gained). Probabilistic and deterministic sensitivity analyses were performed to assess the (overall) model uncertainty. **RESULTS:** The mean costs and effects for TRUSGB strategy were €5091 and 18.66 QALYs. For the mpMRI with biopsy strategy the mean costs were €4779 and the effects were 18.68 QALYs. For the mpMRI only strategy the mean costs were €5947 with corresponding effects of 18.28 QALYs. The strategy of mpMRI with biopsy was dominant over the TRUSGB strategy. The probability that the mpMRI with biopsy strategy was cost-effective was 94% at a willingness to pay of €50,000/QALY. **CONCLUSIONS:** An AS strategy with mpMRI and confirmatory MR-TRUSGB biopsy in men with a positive mpMRI is potentially cost-effective in men with a low-risk prostate cancer.
PMD69: CLINICAL AND ECONOMIC VALUE OF DEVICE-BASED DETECTION OF ATRIAL FIBRILLATION IN PATIENTS WITH CRYPTOGENIC STROKE

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OBJECTIVES: Patients with atrial fibrillation (AF) have an increased risk of ischaemic stroke, which can be mitigated by anticoagulation therapy. However, guidelines mandate diagnostic confirmation of AF before treatment initiation. This research aims to explore the cost-effectiveness of an insertable cardiac monitor (ICM, BioMonitor 2) shown to have a higher diagnostic yield than the diagnostic standard of care (SoC) involving short-term, intermittent Holter monitoring.

METHODS: Cost-effectiveness analysis for a hypothetical cohort of patients with a prior cryptogenic stroke and suspected paroxysmal, silent AF, from a US payer (Medicare) perspective, including acute and long-term costs. Lifetime Markov model, in MS Excel, considering six health states (post cryptogenic stroke, myocardial infarction, post mild/moderate/severe stroke, death), relevant clinical events (ischaemic and hemorrhagic stroke, transient ischaemic attack, myocardial infarction, systemic embolism, other intra- or extracranial bleed, gastrointestinal bleed, minor bleed), and multiple drug treatment options (aspirin, new oral anticoagulants, warfarin). Diagnostic yield and accuracy, and clinical actions are based on RCTs and diagnostic accuracy studies, and clinician expert input.

RESULTS: An ICM-based diagnostic strategy can avoid 48 strokes per 1000 patients, compared to the standard diagnostic approach, reducing stroke-related costs for Medicare. Total cost per patient are higher in ICM patients (USD 90'100 vs. USD 85'200, discounted) due to device acquisition costs and cost of treating the side effects of anticoagulation therapy such as bleeding. An ICM-based diagnostic strategy allows for life year gains (9.7 versus 9.5 life years per patient, discounted), at an incremental cost-effectiveness ratio of USD 18'500 per life year gained compared to the SoC.

CONCLUSIONS: From a US Medicare perspective, ICMs are a highly cost-effective strategy for the prevention of recurrent strokes in patients with cryptogenic stroke. The increased and earlier access of patients to anticoagulation therapy reduces the burden and cost of secondary stroke events for patients and payers.

PMD70: COST EFFECTIVENESS OF PENTARAY HIGH DENSITY MAPPING CATHETER IN TREATMENT OF VENTRICULAR TACHYCARDIA IN TURKEY

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Objectives: Ventricular tachycardia (VT) is among the main causes of sudden cardiac deaths. There are three methods of VT treatments: implantable cardioverter defibrillator, antiarrhythmic drugs and catheter ablation. The success rate of catheter ablation is over 90% with lower rates of recurrence rate and side effects. Pentaray is a diagnostic mapping catheter assisting complex mapping catheter in treatment of atrial tachycardia, atrial fibrillation, atrial flutter and idiopathic and ischemic VT. The objective of this study is to assess the cost effectiveness of Pentaray in treatment of VT in Turkey.

Methods: A simple decision making model was used in assessing the cost effectiveness of Pentaray. As there are no studies comparing Pentaray with alternatives, use of Pentaray was compared with non-use. The ICER was calculated as cost per avoided VT. The analysis was made from the perspective of the Social Insurance Institution. Cost data regarding the type and frequency of resources used in treatment of VT were obtained from expert views. Epidemiologic data were obtained from literature and expert views.

Results: Percentage of patients with VT in 15-65+ population was taken as 0.1% from expert opinions. The recurrence rates for catheter ablation with and without Pentaray were taken from the literature as 30% and 45% respectively. Number of patients with recurrence was 1.796 and 2.694 respectively for intervention with and without Pentaray. Total cost of treatment of recurrence per patient was 10,565 TRY. Annual total cost for treatment of recurrence was 125,274,215 TRY with Pentaray and 117,699,920 TRY without Pentaray. Conclusions: The ICER was estimated at 8.434 TRY. As this figure is well below the recommendations of the WHO threshold, Pentaray is accepted as a cost-effective option in treatment of VT in Turkey.

PMD71: ECONOMIC EVALUATION OF CEREBRAL OXIMETRY MONITORING IN CAROTID ENDARTERECTOMY: THE EMOCAR RANDOMIZED CONTROLLED TRIAL (MAY 2011 - APRIL 2016)

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Objectives: The risk of cerebrovascular incidents is one of the major challenges of the carotid endarterectomy (CE). The main purpose of this study was to assess the cost-effectiveness of the cerebral oximetry monitoring compared to the usual monitoring during CE.

Methods: The economic evaluation was performed over the 5-month period following the endarterectomy. The analysis includes 686 patients: 346 and 340 in the intervention and...
experimental groups respectively. It was performed from the community perspective. The outpatients and caregivers' resource utilisation were collected with the Wilmer questionnaire. The hospital expenses were estimated through a retrospective HRG survey. QALY's were calculated using an EQ-5D-3L scale and validated French tariffs. Multiple imputations were implemented. Net monetary benefit (NMB) for different values of the willingness to pay (WTP) was estimated using the linear regression technique as proposed by Hoch (1994). Deterministic and probabilistic sensitivity analyses were performed. RESULTS: The costs of health care and QALYs are €10,485 and 0.301 for the control group and €10,320 and 0.289 for the experimental group. There is no significant difference between the NMB of two strategies. However, the regression with exogenous variables showed a center effect. Under the €10,000 threshold, the experimental strategy has a higher NMB than the control strategy. The experimental strategy is preferred to the control strategy. The break-even point of the two strategies is equal to €34,000; both strategies generate the positive benefit. Each strategy contributes to improving the overall health of patients regardless the resources used. CONCLUSIONS: The net monetary benefit indicates the threshold of WTP where the strategies generate a positive net benefit (health gains greater than financial losses). The endogenous identification of the break-even point is a simple tool to compare the innovation efforts in different therapeutic areas.

PMD72: ECONOMIC EVALUATION OF FLASH GLUCOSE MONITORING COMPARED TO SELF-MONITORING OF BLOOD GLUCOSE FOR THE MANAGEMENT OF PATIENTS RECEIVING INTENSIVE INSULIN WITH DIABETES TYPE 1 AND TYPE 2 IN GREECE

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OBJECTIVES: To conduct an economic evaluation of a novel minimally-invasive flash glucose monitor system (FM) vs Self-Monitoring of Blood-Glucose (SMBG) in patients with Diabetes Type 1 (DT1) and 2 (DT2) receiving intensive insulin (MDIs), from a Greek payer perspective. METHODS: The IMS CDM model was used to assess the cost-effectiveness of FM in a lifetime horizon. Patients’ characteristics as well as hypoglycemic event rates were extracted from the trials IMPACT (DT1) and REPLACE (DT2). Default model equations were used for prediction of clinical parameters. All costs (€,2017) considered in the model were derived from national sources or the published literature. FM cost was provided by Abbott SA. Incremental cost per quality-adjusted-life-years (QALYs) gained was calculated. One-way sensitivity analysis was conducted. An international budget impact model was locally adapted to estimate the budget with and without FM at a 3-year horizon. Based on experts, the eligible MDI population was 24,410 DT1 and 8,137 DT2 patients. Resource utilization comprises the daily use of consumables (FM+strips-lancets), hospitalizations for severe hypoglycemia (DT1) and all-cause emergency visits and hospitalizations (DT2). The 3-year market shares of FM were assumed to be 15%-20%-25% (DT1) and 6%-10%-13% (DT2). RESULTS: Cost-effectiveness analysis revealed that FM may create 0.567 and 0.317 additional QALYs compared to SMBG for DT1 and DT2, at a cost increase of €8,255 and €6,236, respectively, resulting in ICERs of €14,567/QALY and €19,703/QALY gained, both well below the Willingness-To-Pay threshold of €34,000. The treatment costs of FM and SMBG were primarily driving the results. The introduction of FM in the Greek market may result in a 3-year payer’s budget increase by €5,114, 658 (5.5%) and €614,473 (1.8%) for DT1 and DT2, respectively, and €5,729,131 (4.3%) for the total MDI population. CONCLUSIONS: FM seems to be a cost-effective option in MDIs with a moderate increase at the budget of the Greek payer.

PMD73: EVALUATION OF THE LONG-TERM COST-EFFECTIVENESS OF REAL TIME CONTINUOUS GLUCOSE MONITORING (RTC GM) VERSUS SELF-MONITORING OF BLOOD GLUCOSE (SMBG) ALONE IN TYPE 1 DIABETES FROM THE SWEDISH SOCIETAL PERSPECTIVE

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OBJECTIVES: To evaluate the cost-effectiveness of Real-Time CGM (RTC GM (G5)) compared to SMBG alone in Type 1 Diabetes (T1DM) patients using Multiple Daily Injections (MDI) from the Swedish societal perspective. METHODS: The Quintiles IMS CORE Diabetes Model (CDM) (v. 9.0) was used to assess the long-term (50 year) cost-effectiveness of RTCGM compared to SMBG alone for a T1DM cohort. Treatment effects and baseline characteristics of patients were sourced from the recently published DIAMOND trial while all other assumptions and costs were sourced from earlier publications. The accuracy and clinical effectiveness of RTCGM (G5) is equivalent to that seen in CGM (G4SW505) used in the DIAMOND trial. Base case (BC) assumptions included a) starting HbA1c 8.6%: b) change in HbA1c: -1.0% for CGM group, -0.4% for SMBG alone; c) 50% reduction in severe hypoglycemic events (SHEs) and 33% reduction in non-severe hypoglycemic events (NSHEs) for the CGM group; d) dis-utilities of -0.0142 for NSHEs and SHEs not requiring medical intervention, and -0.047 for SHEs requiring medical resources. Treatment costs and outcomes were discounted at 3%. RESULTS: The Incremental Cost-Effectiveness Ratio (ICER) for RTCGM vs. SMBG was SEK 180,530/QALY in the base-case.
Sensitivity analyses showed the results were sensitive to changes in percent reduction in severe hypoglycemic events and its associated dis-utilities. An ICER of SEK 188,697/QALY was the result of the sensitivity analysis using the treatment effects from the recent Swedish GOLD study using an earlier version RTCGM. The base-case results were minimally impacted by changing starting HbA1c levels and discount rates. **CONCLUSIONS:** RTCGM has the potential to improve clinical outcomes, quality of life and healthcare efficiencies for the large cohort of MDI-treated patients. The results of this evaluation show that RTCGM (G5) is cost effective within the MDI-treated T1DM population, assuming a willingness-to-pay threshold of SEK 500,000 per Quality-Adjusted Life Year in Sweden.

**PMD74: THE COST-EFFECTIVENESS ANALYSIS OF THE LATENT TUBERCULOSIS INFECTION SCREENING FOR ADULTS 40 YEARS OLD IN SOUTH KOREA.**

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**OBJECTIVES:** According to World Health Organization (WHO), South Korea is the top ranked country among the Organization for Economic Cooperation and Development (OECD) countries in terms of the incidence and mortality of tuberculosis (TB) in 2015. The prevalence rate of latent TB infection (LTBI) in adults over 40 years old is estimated over 30 percent. This study aimed to evaluate the cost-effectiveness of LTBI screening using simultaneously Interferon-gamma Releasing Assay (IGRA) and chest X-ray (CXR) comparing with the current active TB screening using CXR alone in the national health screening program for the adults 40 years old. **METHODS:** A Markov model was constructed to analyze cost-effectiveness of LTBI screening based on the prevalence, successful treatment and mortality rate of LTBI, drug-susceptible (DS) and multiple drug-resistant (MDR) TB. The Markov cycle was one year and its time horizon was 45 years with a discount rate of 5 percent. The transition probability of LTBI to DS TB and the specificity and sensitivity of IGRA and CXR were also applied to the model. Sensitive analyses including a scenario analysis were performed to examine the uncertainty of the parameters on the outcomes. **RESULTS:** The IGRA-CXR screening would spend more 590,000 KRW (about 525 USD) to extend one life year compared to only CXR screening from the health care system perspective. In the sensitive analysis, the transition probability of LTBI to DS TB is the most influence parameter on the results. We concluded the strategy to screen and treat LTBI in advance is more cost-effective than to do DS TB from the scenario analysis in South Korea. **CONCLUSIONS:** In South Korea, the national screening program to detect LTBI using IGRA-CXR for 40 years old is economically attractive. This study would provide scientific evidence to introduce the LTBI screening program in order to control TB incidence in Korea.

**PMD75: ECONOMIC EVALUATION OF NEONATAL SCREENING FOR CONGENITAL HYPOTHYROIDISM**

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**OBJECTIVES:** It has been more than 30 years since the implementation of nationwide newborn screening for inborn error of metabolism in Taiwan and the coverage rate had reached 99% since 1996. For resource allocation and priority setting for the numerous prevention screening programs, it is important to re-evaluate the value of each program. This economic evaluation of congenital hypothyroidism (CHT) screening program was served as the pioneer for all the neonatal screening. **METHODS:** The epidemiology and laboratory data was sourced from 3 semi-governmental nonprofit institutes, each responsible for the screening test one third of the newborn population which around 70,000 babies. We also used the National Health Insurance claim data to estimate all of the related health care expenditures. Face to face interview was conducted to collect the indirect costs and EQ-5D quality of life weight. We compared the cost-effectiveness of nationwide screening with that of none. **RESULTS:** The results showed there were 213, 714 birth of babies with a screening rate of 99.53% in 2015. The laboratory result showed positive rates of the first screening were 0.194% and 8.6% for the re-check respectively. The costs of the first screening were NT$ 550, NT$100 for re-check and NT$ 1,162 for the final confirmation. The medication expenditures were NT$16,384 for the first year and around NT$3,000 for the rest of the years. Overall the benefit is huge. **CONCLUSIONS:** Nationwide newborn screening for CHT is a cost-effectiveness prevention program. The results provide the evidence that confirms the value of CHT neonatal screening.

**PMD76: COST-EFFECTIVENESS OF A SUPRACILIARY MICRO-STENT GLAUCOMA IMPLANT COMBINED WITH CATARACT SURGERY IN MANAGEMENT OF PRIMARY OPEN-ANGLE GLAUCOMA (POAG) FROM THE CANADIAN PAYER PERSPECTIVE**

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OBJECTIVES: Management of POAG ranges from topical medication to incisional surgeries to decrease intraocular pressure (IOP) and prevent visual field loss (VFL). Microinvasive glaucoma surgery (MIGS) fill a therapeutic need for mild-to-moderate POAG, reducing IOP better than cataract surgery alone with fewer adverse events than traditional surgery. The COMPASS trial recently showed that a supraciliary microstent + cataract surgery led to lower IOP and fewer medications required at 24-months than cataract surgery alone. This analysis therefore evaluates the cost-effectiveness of a supraciliary microstent + cataract surgery vs cataract surgery alone from the Canadian payer perspective. METHODS: A semi-Markov model built in MS Excel reflects risk of increasing VFL based on natural history data, with corresponding need for additional interventions. The model transitioned a population reflecting the COMPASS trial (mean VFL -3.47) through health states by glaucoma stage and number of medications for 15 years, simulating post-COMPASS-trial cost and health outcomes. 24-month COMPASS trial data informed intervention-specific distributions of medications that impacted time to trabeculectomy following four failed lines of medication. Risk of progression was conservatively assumed equivalent between strategies. Costs (e.g. interventions, medications) reflect Canadian $2017. Incremental cost-effectiveness ratios (ICERs) were estimated for four potential real-world care scenarios: 1) COMPASS trial medication benefit only; 2) poorer adherence for 2+ medications; (3) trabeculectomy performed after two failed medications; 4) 25-year horizon. RESULTS: Across scenarios, incremental costs ranged from $1.679 (earlier trabeculectomy) to $2.215 (medication-usage only); incremental QALYs were 0.057 to 0.148. ICERs were $12,517/QALY (earlier trabeculectomy), $32,033/QALY (25-year horizon), $38,505/QALY (lower adherence), and $43,015/QALY (COMPASS medication-benefit only). In univariate sensitivity analysis, model results were most sensitive to assumptions on medication use trends but remained robust. CONCLUSIONS: Given results across likely real-world treatment scenarios, this analysis indicates a supraciliary microstent + cataract surgery may be cost-effective to manage mild-to-moderate POAG in Canada.

PMD77: COST-EFFECTIVENESS OF A DIRECT ASPIRATION FIRST PASS TECHNIQUE (ADAPT) FOR THROMBECTOMY REVASCULARIZATION OF LARGE VESSEL OCCLUSION IN ACUTE ISCHEMIC STROKE (FRENCH HEALTH MINISTRY PRME 16-0020)

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OBJECTIVES: To estimate the cost-effectiveness of Direct Aspiration First Pass Technique (ADAPT) versus mechanical thrombectomy with a Stent Retriever (SR) procedure in acute ischemic stroke from a French healthcare providers perspective. METHODS: The cost-effectiveness study was carried out from a prospective, randomized and multicenter clinical trial including 8 French hospitals. Medical and costs data were collected prospectively relating to the initial procedure from the onset symptom to the best recanalization. The direct medical costs data were collected by micro-costing and analytical accounting. The primary outcome is the modified score Rankin scale (mRS) of independent at three-months (score 0-2). Economic acceptability for community of this new technique is analyzed by measuring the Incremental Cost-Effectiveness Ratio (ICER). Sensitivity analyses were performed. RESULTS: We include 381 eligible patients (192 allocated to ADAPT and 189 allocated to SR) from October 2015 to October 2016. The mean hospital costs were €8372 in ADAPT group, and €8069 in SR group (p value = 0.49). The percentage of independent patients at 3 months was 55.17 % in ADAPT group, and 62.06 % in SR group (p-value = 0.23). The resulting ICER reveals the need to invest €4389 in order to achieve an additional percentage of independence with the innovative strategy compared to the standard strategy. CONCLUSIONS: Based on randomized trial, we demonstrate that ADAPT is not more efficient compared to SR. We will then consider the cost per QALY (mapping mRS into EQ-5D) at 12-months.

PMD78: COST-EFFECTIVENESS OF EASYPOD™ DEVICE VERSUS OTHER SOMATOTROPIN DELIVERY TECHNIQUES IN EGYPT IN TREATMENT OF GROWTH HORMONE DEFICIENCY

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OBJECTIVES: Normalization of height in childhood and adolescence with growth hormone deficiency (GHD) is possible via the use of the recombinant human growth hormone somatotropin. Different injection techniques were developed including easypod™ device, prefilled pens (PP), and the regular subcutaneous syringe (SCS). The aim of this study is to determine whether injecting somatotropin using easypod™ device is a cost-effective treatment option in Egyptian children born with GHD. METHODS: A Markov decision-tree model was used to calculate the relative
costs and health benefits associated with each delivery technique over the treatment period (treatment with somatotropin 0.025 mg/kg/day from ages 5 to 13 years) for a number of simulated children born with GHD using patients charts records data. A wastage model was developed to include the difference in wastage among the various techniques. Estimates of patient height were derived from published literature, as was the proportion of patients achieving normal height through somatotropin treatment. Health care resources and drug costs associated with each of the treatment arms were considered, and cost-effectiveness was estimated as discounted (3.5% per annum) Egyptian pounds (EGP) per centimeter-height (cmH) gained. RESULTS: Somatotropin delivery using easypod™ device was associated with an additional (5.15) cmH gained, at an incremental cost per cmH gained of (-13,021 EGP), compared with somatotropin PP. This means easypod™ device dominates. Versus delivery via SCS, easypod™ device resulted in additional (5.76) cmH gained at an incremental cost of (69,099 EGP). This equates to an incremental cost of (11,990 EGP) per cmH gained - below the widely accepted cost-effectiveness threshold in Egypt of (70,000 EGP). CONCLUSIONS: In this model, somatotropin delivery using easypod™ device was a cost-saving option compared with somatotropin PP, and a cost-effective one if compared with somatotropin SCS. The use of somatotropin easypod™ device represents reasonable value for money for the treatment of GHD in Egyptian children.

**PMD79: THE COMPARATIVE PHARMACOECONOMIC ANALYSIS OF USING ABSORB BIORESORBABLE VASCULAR SCAFFOLD SYSTEM FOR PATIENTS WITH ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI)**

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**OBJECTIVES:** Biodegradable stents are novel devices designed to overcome the long-term limitations of permanent stent implantation. The main aim of this study was to perform cost-effectiveness analysis of using Absorb biodegradable vascular scaffold (BVS) system for patients with STEMI. METHODS: Analysis of the published clinical trials was conducted to evaluate efficacy and safety of using Absorb BVS system for patients with STEMI. Taking into account the hypothesis of superior effectiveness of Absorb BVS system for patients with STEMI for pharmacoeconomic analysis was chosen "cost-effectiveness" analysis. MS Excel based model was performed to assess 2 strategies: strategy 1-patients with primary percutaneous coronary intervention (PPCI) with Absorb BVS system; strategy 2-patients received thrombolytic therapy in the hospital. The 1 LYG and 1 surviving patient were included into the model as the effectiveness criteria. Direct costs included emergency, inpatient and outpatient treatment, rehabilitation and cost of PPCI with Absorb BVS system. All the direct costs were calculated from the Russian healthcare system perspective. RESULTS: According to published trials the using of Absorb BVS system for patients with STEMI did not lead to different rates of composite patient-oriented and device-oriented adverse events. Strategy 1 has a higher efficiency - the proportion of survivors at 1 year will be the maximum – 92.7%, as well as the LYG – 5.4. Application of strategy 1 reduces the total cost of reperfusion therapy for all patients with STEMI, the difference amounted to $273,537. According to the CER for 1 LYG and for 1 surviving patient was optimal strategy 1, the difference amounted to $50 and $297, respectively (rate for June 2017). CONCLUSIONS: Using Absorb BVS system during reperfusion in patients with STEMI was effective and economically justified treatment option.

**PMD80: COST-UTILITY ANALYSIS OF A NOVEL BREATH-TRIGGERED AEROSOL INHALER WHICH HAS BEEN DESIGNED TO REDUCE THE CRITICAL HANDLING ERROR OF INSUFFICIENT INSPIRATORY EFFORT**

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**OBJECTIVES:** Up to 70–80% of patients use their inhalers incorrectly (GINA 2017). Approximately 40% of the GINA-defined Step-3+ UK population inhale ICS/LABA through dry-powder inhalers (DPIs). DPIs require forceful inhalation for optimal drug delivery. The CRITIKAL study (Price et al. 2017) found a statistically significant association between ‘insufficient inspiratory effort’ and increased risk of uncontrolled asthma and exacerbations requiring hospitalisation. A cost-utility analysis was developed to explore the societal and economic impact of an ICS/LABA breath-triggered aerosol inhaler which does not require forceful inhalation for actuation, compared with DPIs budesonide/formoterol and fluticasone/salmeterol. METHODS: A Markov model simulated patients switching between controlled and uncontrolled health states over one-year; each associated with different utility values (GOAL study, Briggs et al. 2006). The analysis assumed all inhalers had the same drug efficacy. The CRITIKAL study provided the relative risk of a patient having uncontrolled asthma and making an ‘insufficient inspiratory effort’ error – these data were applied to the transition probabilities. All other DPI-related errors assessed were not statistically significantly associated with asthma control. The analysis assumed the breath-triggered device lacked this critical handling error and had the same price as each comparator. Indirect costs were explored. Base-case analysis included direct costs: emergency room visits (£138), physician visits (£36) and hospitalisation/day (£401.63). RESULTS: The breath-triggered device dominated both budesonide/formoterol and fluticasone/salmeterol over one-year and resulted in direct cost savings of...
£98 and £142 with 0.0117 and 0.0169 additional QALYs, respectively. The breath-triggered device had the highest probability (100%) of being cost-effective at a £20,000/QALY threshold. One-way sensitivity analyses showed that the key factor driving variance was the relative risk of patients moving to an uncontrolled state for each comparator. **Conclusions:** The analysis demonstrated the economic and societal costs of ‘insufficient inspiratory effort’ and the potential benefit of introducing an effective intervention to eliminate this error.

**PMD81: COST EFFECTIVENESS OF UNIVERSAL NEONATAL HEARING SCREENING WITHOTOACOUSTIC EMISSIONS AND/OR AUTOMATED AUDITORY BRAINSTEM RESPONSE, FOR THE DETECTION OF BILATERAL CONGENITAL HEARING LOSS AND EARLY TREATMENT, IN NEWBORNSWITHOUT RISK FACTORS, IN COLOMBIA**

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**Objectives:** To evaluate the cost-effectiveness of neonatal hearing screening with otoacoustic emissions (OAEs), automated auditory brainstem response (AABR) and OAEs+AABR, compared among themselves and with the absence of a hearing screening program, for the early detection and treatment of moderate, severe, or profound bilateral congenital deafness in newborns with no risk factors, from the Colombian National Health System perspective. **Methods:** For the cost-effectiveness analyses, a decision tree was developed to represent the process of detection, diagnosis and treatment of congenital hearing loss. The operational characteristics of tests were obtained and estimated by Heidari et al. (2015), and effectiveness of early treatment was obtained from Fulcher (2012) and Yang (2015); these studies were identified through systematic literature searches. The costs were derived from tariff manuals and expert consultation. Outcome included was DALYs averted. An expectation of lifetime horizon was used and costs and benefits were discounted at 5%. Deterministic and probabilistic sensitivity analysis were performed. **Results:** Universal neonatal hearing screening is more costly; however, prevents a greater number of DALYs in the population compared to the absence of a screening program. The cost per DALY averted/person with each test compared with the non-screening was COP $28,612,500 with AABR, COP 34,077,391.30 with OAEs+AABR and COP 77,995,774.65 with OAEs. Comparing the two dominant strategies (AABR versus OAEs+AABR), the AABR was cost-effective using the threshold of willingness to pay of three times GDP/capita. **Conclusions:** AABR is a cost-effective strategy for universal neonatal hearing screening in Colombia. However, with a willingness to pay ≥COP 30,000.000, the probability that the OAEs+AABR strategy will be cost effective compared to AABR, is 50-80%. Results are maintained in the sensitivity analysis. The DALYs discount rate, the prevalence of congenital hearing loss in neonates without risk factors, and the prevalence of profound hearing loss generated greater uncertainty in the results.

**PMD82: COST-EFFECTIVENESS OF INSULIN PUMPS VERSUS MULTIPLE DAILY INSULIN (MDI) INJECTION IN TYPE 1 DIABETES IN INDIA FROM SOCIETAL PERSPECTIVE**

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**Objectives:** Each year 3-5% of Indians develop Type 1 diabetes mellitus (T1DM). Intensified insulin therapy using insulin pumps or MDI are recommended methods. However, insulin pumps are expensive for patients living in middle income countries like India who have to bear high out-of-pocket expense. We conducted a cost-effectiveness analysis to assess the value for money of insulin pumps in Indian settings. **Methods:** Analysis was conducted from societal perspective using a Markov model with time horizon of 8 years. India specific data, wherever available, were extracted, else adopted from comparable economies. Costs and quality-adjusted life years (QALYs) were discounted at a rate of 3.5% annually. Probabilistic sensitivity analysis was performed to assess the robustness of analysis. Model outcomes were reported as incremental cost-effectiveness ratio (ICERs) and cost-effectiveness acceptability curve was constructed. **Results:** Insulin pumps had high cost (INR 1286215.08) and high benefit (INR 1,7787). Insulin pump incurred an additional cost of INR 9,78,114.74 to gain an additional year of perfect health. The ICER was greater than three times of India’s Gross Domestic Product (GDP) per capita (INR 1,10,368.91). **Conclusions:** Insulin pumps were associated with better outcomes and higher costs. Insulin pump could be an effective and useful technique provided the patients have lower out-of-pocket expense. Scarcity of India specific data, especially efficacy estimates could have compromised the robustness of analysis.

**PMD83: COST-EFFECTIVENESS ANALYSIS OF NEONATAL SCREENING WITH PULSE OXIMETRY FOR THE DETECTION OF CRITICAL CONGENITAL HEART DISEASE IN COLOMBIA, 2017.**

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OBJECTIVES: Critical congenital heart diseases, such as late postnatal diagnosis, are associated with the prognosis of surgical treatment or catheterization before the first year of life, as well as with more hospital admissions, more hospital days, and more hospital costs during childhood. This research aims to establish the incremental cost-effectiveness ratio of cutaneous pulse oxymetry at 24 hours after birth, in addition to the general examination of the newborn, in the early detection of critical congenital heart disease in Colombia. METHODS: A full cost-effectiveness analysis was conducted from a societal perspective using a decision tree that compares general examination plus pulse oximetry versus the general examination only to detect critical congenital heart disease. Sensitivity and specificity of the test were taken from the best evidence available through a systematic review; costs were estimated using official sources and local rates. For non-dominated alternatives we calculated the incremental cost-effectiveness ratio and we performed a deterministic sensitivity analysis to assess the effect of uncertainty. RESULTS: The cost of screening with pulse oximetry and general examination was USD 124, USD 30 more than the general examination alone; the effectiveness of pulse oximetry and general examination was 0.99, 0.01 more than general examination alone. The incremental cost-effectiveness ratio was estimated at USD 3,008 per correctly diagnosed cases, that is, if we want to increase the number of correctly diagnosed cases by 1%, that amount will have to be invested. Willingness to pay was defined at USD 5,138.42 per case correctly diagnosed. Results were sensitive to changes in specificity of the tests and prevalence of critical congenital heart disease. CONCLUSIONS: From the societal point of view and at current prices, 24-hour pulse oximetry screening in addition to general newborn screening may be a cost-effective strategy for the early detection of critical congenital heart disease in Colombia.

PMD84: COST EFFECTIVENESS OF DURAGRAFT AS A VEIN GRAFT TREATMENT IN CORONARY ARTERY BYPASS GRAFTING IN TURKEY

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Objectives: Following revascularization procedures, Vein Graft Failure (VGF) can generate complications such as repeat revascularization, myocardial infarction (MI), mortality, hospital readmission, quality of life and co-morbidities. VGF is the most common complication of Coronary Artery Bypass Grafting (CABG). Storage and flushing of the vein graft is the most critical stage of the surgery. DuraGraft is one-time intraoperative vein graft treatments that prevents VGF and reduces repeat revascularization and MI by 48% and 53% respectively. The main objective of this study is to analyze the cost effectiveness of DuraGraft in CABG in Turkey. Methods: A simple decision model was used in the study. Analyses were made from the Turkish Social Security Institution’s (SSI/SGK) perspective. Literature research and expert opinions were used to estimate the cost of CABG and complications as revascularization and myocardial infarction. The comparison was made with use and nonuse of DuraGraft. Outcome measures were taken from literature, cost data were obtained from expert views of use of resources in both CABG and treatment of complications. The results were presented as incremental cost per averted complication. Results: There were 46,956 CABG procedures performed in Turkey in 2016. Revascularization after CABG was 4.59% and experts stated that 35% of these patients undergo another CABG, with and balloon+stent applied to the other patients. MI rate after CABG was 4.44%. Cost of treatment per patient was 6,430 TRY for CABG, 1,865 TRY for balloon+stent and 8,277 TRY for MI. The incremental number of averted complications was 2,724. In terms of incremental cost effectiveness ratio, use of DuraGraft as a vein graft treatment dominated non-use and achieved better outcomes with lower cost. Conclusions: The results showed that use of DuraGraft as a vein graft treatment in CABG is a cost effective option for the Turkish SSI/SGK.

PMD85: COST EFFECTIVENESS OF ULTRASOUND SCREENING, CANCER PATIENTS, TO DETECT ASYMPTOMATIC THROMBOSIS

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OBJECTIVES: Cancer patients are at high risk to develop thrombosis with an even distribution between symptomatic and asymptomatic. The objective was to evaluate the cost-effectiveness of screening with ultrasound (US) cancer patients for asymptomatic deep vein thrombosis (DVT) at the time of cancer diagnosis. METHODS: A decision tree was developed to compare two approaches for detecting DVT in high-risk cancer patients without symptomatic DVT at the time of cancer diagnosis: (a) screening all patients by US and subsequent treatment, and (b) clinical surveillance for signs or symptoms of DVT and treatment after clinical confirmation of DVT or pulmonary embolism (PE). To increase US specificity all patients with a positive US were subjected to a second one. Prevalence of symptomatic and asymptomatic DVT, sensitivity and specificity of US, incidence of PE and DVT in those receiving or
OBJECTIVES: Regular glucose monitoring is important for T2DM patients receiving intensive insulin, with lower HbA1c observed in patients testing glucose more frequently (Schutt 2006). A novel, factory-calibrated flash glucose monitoring ("FM") system (the FreeStyle Libre™ system) continuously measures glucose levels from interstitial fluid without requiring routine self-monitoring of blood glucose (SMGB). Data is then transferred to a handheld reader from the wearable arm sensor. Real-world data collected from a cohort of 50,831 readers indicates FM users scan more often on average than SMGB users (16 scans/day vs 2.7 tests/day (Schutt 2006)), and confirms lower HbA1c associated with more frequent testing. This analysis evaluates potential clinical and economic benefits of more frequent testing associated with FM compared to SMGB in T2DM patients using intensive insulin. METHODS: The QuintilesIMS Core Diabetes Model was run for 40 years, modelling a population reflecting the REPLACE study (Haak 2017). Intervention effects include: HbA1c intervention benefit (0.94%) based on number of tests/day; REPLACE study-based reductions in hypoglycaemic events (27.7% reduction in glucose <70 mg/dL); and a 0.03 utility benefit (Matza 2017). Costs were reported in 2016 SEK. Disaggregated costs and effects were estimated, with sensitivity analyses conducted on the frequency interquartile range, as well as exploration of scan frequency impact on major hypoglycaemic event rates. RESULTS: In base case analysis FM dominated SMGB, with 0.906 more QALYs (6.444 vs 5.538) and SEK84,586 in combined (direct and indirect) cost savings (FM: SEK1,966,052 vs SMGB: SEK2,050,638). Explored scenarios also showed that FM dominated, with incremental savings: SEK34,808 to SEK154,809 and incremental QALYs: 0.829 to 0.988. CONCLUSIONS: Real-world data indicate a high testing frequency among FM users compared to SMGB use. Given that higher test frequency is associated with lower HbA1c and hypoglycaemia, FM may be considered dominant for T2DM patients receiving intensive insulin in Sweden.

OBJECTIVES: Chest pain is the most common reason for emergency hospital admission yet only a minority of patients admitted to hospital ultimately have acute coronary syndrome (ACS). The Manchester Coronary Acute Syndromes (MACs) model is a validated clinical decision model that ‘rules in’ and ‘rules out’ ACS at admission using one blood test. MACs can potentially release economic benefits by preventing unnecessary admission and discharging patients home early. This feasibility study aimed to evaluate whether MACs represents a potentially cost-effective use of resources. METHODS: An economic evaluation integrated into a randomised controlled trial compared (i) MACs guided care pathway (n=67) to (ii) ‘standard care’ pathway (n=65) with delayed (12 hour) troponin testing. Patients presenting to the emergency department at two hospitals with suspected ACS were included. In the MACs arm, clinicians were given patient’s risk of ACS and individualised treatment recommendations. An NHS perspective was used with a 6-month time horizon. Resource-use within hospital and follow-up was collected. Health status using the EQ-5D-3L was collected (baseline, 1, 3 and 6 months) and quality-adjusted life-years (QALYs) were calculated. Unit costs were collected from national sources (price year: 2016). Missing data were accounted for using multiple imputation (n=10 imputations). RESULTS: Compared to SC, the MACs guided care pathway did not lead to a statistically significant increase in costs or QALYs. Incremental costs for MACs was £75 (95%CI: £248.96 to £98.75) versus SC and incremental QALYs was -0.0025 (95% CI: -0.0183 to 0.0235) versus SC. CONCLUSIONS: This feasibility study provides evidence on the use of MACs to guide clinical decision-making within the emergency department. There was no evidence of a change in QALYs or costs.
associated with MACS. Due to the small sample size, results on costs were sensitive to assumptions regarding missing data. Robust estimates on cost-effectiveness requires a larger trial.

**PMD88: COST-EFFECTIVENESS OF HIGH-THROUGHPUT, NON-INVASIVE PRENATAL TESTING FOR FETAL RHESUS D STATUS**

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**OBJECTIVES:** To assess the cost-effectiveness of high-throughput non-invasive prenatal testing (HT-NIPT) for fetal rhesus D (RhD) status in avoiding unnecessary prophylactic anti-D immunoglobulin treatment in RhD-negative women found to be carrying an RhD-negative fetus. **METHODS:** A probabilistic cohort model was used to describe the antenatal care pathway and the long-term consequences of sensitisation events (e.g., miscarriage). The performance of HT-NIPT was derived from a systematic review and bivariate meta-analysis of 3 UK studies. Estimates of other relevant parameters were derived from literature sources. Five alternative strategies in which the use of HT-NIPT may impact on the existing post-partum care pathway were considered. A UK health service perspective was used and lifetime costs and effects were discounted at an annual rate of 3.5%. Sensitivity analysis was performed to key model parameters. **RESULTS:** The results indicated that HT-NIPT appeared cost saving but also less effective than current practice, irrespective of the post-partum scenario evaluated. Potential cost-savings with HT-NIPT appeared sufficient to outweigh the QALY loss associated with the small increase in sensitisations. A post-partum strategy, in which inconclusive test results are distinguished from positive results, was considered the optimal strategy. The results were also sensitive to the cost of the HT-NIPT. **CONCLUSIONS:** HT-NIPT would reduce unnecessary treatment with anti-D immunoglobulin and appears cost saving when compared to current practice of providing prophylactic anti-D immunoglobulin to all RhD-negative pregnant women. The extent of any savings is highly sensitive to the additional cost that introduction of HT-NIPT would impose on the antenatal care pathway.

**PMD89: COST EFFICIENCY ANALYSIS OF A NEW ARRHYTHMIA DETECTION ALGORITHM IN A MINIATURIZED INSERTABLE CARDIAC MONITOR**

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**OBJECTIVES:** Insertable cardiac monitors (ICMs) have proven high sensitivity to detect arrhythmias. However, subsets of detected episodes are false. Adjudication of these episodes requires clinician time to review and results in additional costs. False positive episodes of a new ICM algorithm were reduced for Bradycardia (95%), Asystole (47%), and Atrial Fibrillation (32%). The purpose of this analysis is to estimate savings in episode review time and costs by comparing false transmissions and episodes between the current and the new ICM algorithms. **METHODS:** This analysis evaluated transmissions and episode in a de-identified ICM database from 2014–2016. Nightly automatic and manual transmissions with 1 or ≥ 1 ECGs were evaluated. Mathematical model was developed to simulate 174 patients during 1 and 3 years of follow-up in order to quantify time and costs saved by using the new ICM algorithm from a US hospital perspective. Assumptions included that nurses reviewed all ECGs, and physicians reviewed difficult to interpret rhythms (8.2%). **RESULTS:** In total, 1,603,318 nightly transmissions with 1 or ≥ 1 ECGs generated alerts. There were 833,725 with 1 ECG reviewed by a nurse, of which 68,365 were difficult rhythms also evaluated by a physician. The other 769,593 had alerts with ≥ 1 ECG, and required a manual download to be evaluated by clinicians. The new algorithm resulted in a 55% relative reduction in time expended by clinicians in reviewing false transmissions (Per patient per 1 yr: 1.15h was reduced to .52h, 3 yr: 3.46h to 1.56h; Clinic wide: 1 yr: 200.72h to 90.48h, 3 yr: 602.20h to 271.50h all). This was associated with a reduction in costs of $63.55 and $190.66 per patient and of $11,058.29 and $33,174.90 for all patients in clinic (1 and 3 years of follow-up), respectively. **CONCLUSIONS:** The new algorithm significantly reduces clinician review time and costs required for monitoring ICM patients.

**PMD90: COST-MINIMIZATION ANALYSIS OF HPV 16/18 GENOTYPING TEST VERSUS HPV REFLEX GENOTYPING FOR CERVICAL CANCER SCREENING**

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**OBJECTIVES:** The clinical superiority of HPV testing for cervical cancer (CC) screening is steering the international society to lean in its favor. However, the choice between the different HPV testing methods is crucial, as it can determine the efficiency of the screening programs. Simultaneous 16/18 genotyping testing offers the potential to save resources by avoiding retesting for the respective oncogenic HPV types. Aim of this study was to compare the
The economic impact of HPV 16/18 genotyping to HPV reflex genotyping in Greece. **METHODS:** Given that the two methods have been proved equally effective, a cost-minimization analysis was performed to compare HPV 16/18 genotyping test versus HPV reflex genotyping as primary screening methods every 3 years for women 25-65 years old. The time horizon was two screening cycles. A decision tree and a Markov model were developed to simulate the screening algorithm and the natural history of CC. Clinical inputs were drawn from the HERMES study and cost inputs from the official price list and the international literature. Both one way and probabilistic sensitivity analysis were conducted. **RESULTS:** The two methods were proved of equal effectiveness detecting 94.1% and 88.7% of Cervical Intraepithelial Neoplasia 2+ (CIN2+) and CCs, respectively. However, the HPV 16/18 genotyping strategy was found to save 14.8 million € (41%) annually for the social insurance (21.4 million € vs 36.2 million €). The total cost per screened patient/year (screening, diagnostic and treatment cost) was estimated at 24€ and 40€ for the 16/18 and the reflex genotyping methods, respectively. The cost per case of CIN2+ was found 69.2% higher for the reflex genotyping algorithm (21,127€ vs 12,482€). **CONCLUSIONS:** According to the above the efficiency of an HPV CC screening program is maximized by choosing the method with simultaneous 16/18 genotyping as it can provide the same outcomes with substantially less cost.

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**PMD91:** **INSERTABLE CARDIAC MONITOR VERSUS STANDARD OF CARE FOR DETECTION OF ATRIAL FIBRILLATION IN PATIENTS FOLLOWING CRYPTOGENIC STROKE: A DUTCH COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** Documentation of atrial fibrillation (AF) is required to initiate oral anticoagulation therapy for recurrent stroke prevention. The cause of ischemic stroke remains uncertain despite a complete diagnostic evaluation in 20-40% of cases (cryptogenic stroke), and conventional standard of care (SoC) often fails to diagnose AF. An insertable cardiac monitor (ICM) is a diagnostic device which has been shown to improve detection of AF in this patient population. We evaluated the cost-effectiveness of ICM versus SoC, in patients with a cryptogenic stroke, from a Dutch payer perspective. **METHODS:** A lifetime Markov model was developed to assign patients to health states according to the presence and detection of AF, the occurrence of cerebrovascular and bleeding events, and death. Utilities and costs were applied to each state according to occurrence of stroke, AF diagnosis and drug therapy use. The model used 3-month cycle length for state transitions and a lifetime horizon. Costs and QALYs were discounted at 4% and 1.5% per year, respectively. Probabilistic sensitivity analysis was undertaken to explore the effect of parameter uncertainty. **RESULTS:** In the base-case analysis, the model predicted an incremental cost-effectiveness ratio (ICER) of €24,715 per QALY gained. Amongst the CHADS2 sub-group analyses, the ICER ranged from €22,011 (CHADS2 score 4 to 6) to €29,795 (CHADS2 score 2). Probabilistic sensitivity analysis suggested that ICM had a probability of 91% of being cost-effective at a threshold of €80,000 per QALY gained. **CONCLUSIONS:** The results suggest that ICM is a cost-effective intervention in patients following cryptogenic stroke, leading to improved health outcomes at acceptable additional cost via improved detection of AF and subsequent strokes avoided. The ICER was within the cost-effectiveness threshold used in the Netherlands and the probabilistic analysis showed a high probability of cost-effectiveness, indicating that the model is robust to variability in the input parameters.

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**PMD92:** **THE COST-EFFECTIVENESS OF TAVI IN INTERMEDIATE RISK PATIENTS IN FRANCE**

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**OBJECTIVES:** TAVI (Transcatheter Aortic Valve Implantation) is a minimally invasive alternative to surgical replacement of the aortic valve (sAVR). It has recently received European regulatory approval to treat intermediate risk (IR) patients. We present here the results of a cost-effectiveness analysis of TAVI versus sAVR in France. **METHODS:** An Excel based Markov model was used to evaluate economic and clinical outcomes in French IR patients undergoing TAVI or sAVR over a 15 year time horizon. Clinical inputs to 2 years were derived from the PARTNER 2 clinical trial and quality of life (QoL) utilities were derived from study data and transformed into French values. Mortality beyond the trial period was projected from Kaplan Meier survival estimates. All costs including index admissions, complications, rehabilitation, etc. were derived from French sources. An annual discount rate of 4.0% was applied to health and cost outcomes. Sensitivity and scenario analyses were used to investigate the robustness of the analyses and identity key drivers. **RESULTS:** TAVI was associated with increased quality of life, providing an additional 0.58 quality-adjusted life years (QALYs) per patient compared with sAVR (4.55 vs. 3.97). At currently reimbursed costs for TAVI, total costs were slightly higher over patient lifetimes for TAVI versus sAVR (€32805 vs. €30971, respectively) yielding an ICER per QALY gained of €3141. Deterministic and probabilistic sensitivity analyses showed the results were generally robust and impacted most by changes in assumptions to procedural costs and mortality. **CONCLUSIONS:** For IR patients TAVI is associated with beneficial patient outcomes compared...
with sAVR and at the current price would be cost-effective in France given generally accepted willingness-to-pay thresholds. Price threshold analyses show that even at a price increase of almost 25% for TAVI the ICER would only be €10000 per QALY gained.

PMD93: COST-EFFECTIVENESS ANALYSIS OF STEREOTAXIC EEG (SEEG) AS A PREOPERATIVE DIAGNOSTIC PROCEDURE IN EPILEPSY SURGERY.

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OBJECTIVES: The aim of our study was to determine the health gain and the corresponding costs resulted from the introduction of stereotaxic EEG (SEEG) as a preoperative diagnostic procedure in epilepsy surgery for MRI negative refractory epilepsy patients. Furthermore, we analyzed the cost-effectiveness of the intervention compared to medical management as the standard of care in Hungary. METHODS: The incremental health gains and costs of SEEG were determined with a Markov model over a 45 years’ time horizon. Transition probabilities and utilities have been derived from international literature. The intervention has not yet been financed by the National Healthcare Fund in Hungary, therefore the actual cost were determined from provider’s perspective, based on the relevant units costs and resource use at the Department of Neurology and Department of Neurosurgery regarding the intervention. RESULTS: Based on the result of our model the total cost of the SEEG intervention is 10,540 thousand HUF which represents a 4,490 thousand HUF additional cost and 3,086 QALY gain in 45 years compare to the standard medical management. The calculated preliminary incremental cost-effectiveness ratio is 1,455 thousand HUF/QALY. CONCLUSIONS: Based on our preliminary results in the treatment of patients with MR negative refractory epilepsy the preoperative SEEG diagnostic procedure in Hungary was cost-effective compared to the medical management. Based on our result we suggest the SEEG to be introduced into the Hungarian reimbursement system as a new procedure.

PMD94: COST-EFFECTIVENESS OF PET/CT IN PRE-OPERATIVE STAGING OF PANCREATIC CANCER: AN ECONOMIC EVALUATION OF THE PET-PANC COHORT STUDY

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OBJECTIVES: Diagnosis of pancreatic cancer is challenging as patients may be relatively asymptomatic during its early course. PET/CT may improve diagnosis and staging of pancreatic cancer but is not widely used across the UK. There is uncertainty whether PET/CT represents good value for money. This study aimed to model the cost-effectiveness of PET/CT compared with multidetector computed tomography (MDCT) alone in the diagnosis and management of patients with pancreatic cancer, based on data collected from the multi-centre PET-PANC cohort study. METHODS: A decision-analytic model was developed to compare patient pathways following diagnosis with PET/CT compared with MDCT alone. Patient management strategies following PET/CT were taken from PET-PANC. Patient management strategies following MDCT alone were based on clinical interpretation of the initial MDCT diagnosis. Event-based regressions were used associate strategies with cost and QALY data collected during PET-PANC. Analysis was conducted from the perspective of the UK National Health Service (NHS), over a 12-month time-horizon. Uncertainty was considered in univariate and multivariate sensitivity analyses. Subgroup analysis considered the impact of PET/CT on patients with diagnosis of chronic pancreatitis; malignancy; and those who were scheduled for resection surgery. RESULTS: The mean total cost and QALYs of pancreatic cancer service use over 12-months were £13,193 per patient (95% confidence interval (CI): £11,634, £14,802), and 0.5540 (95% CI: 0.5261, 0.5811), respectively. PET/CT dominated MDCT, being both less costly and more effective. The largest cost saving and highest QALY gain were seen for the subgroup scheduled for resection surgery. The probability of cost-effectiveness at a threshold of £20,000/QALY was 82%. CONCLUSIONS: It is likely that use of PET/CT in the diagnosis and staging of pancreatic cancer is cost-effective for the UK NHS, with the most cost-effective use of PET/CT being in patients who are suspected of having pancreatic cancer and are scheduled for resection surgery following MDCT.

PMD95: COST-EFFECTIVENESS ANALYSIS OF MECHANICAL THROMBECTOMY IN ACUTE PHASE OF ISCHEMIC STROKE (AIS)

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OBJECTIVES: To compare cost-effectiveness of mechanical thrombectomy (MT) using a stent retriever added to best standard care treatment (BSC) compared to BSC alone in patients with AIS in Poland. METHODS: Analysis was performed from public payer (public payer + patient) perspective over a lifetime horizon. A Markov state transition model defined by modified Rankin Scale was used. In base case the model is split into two distinct phases: an acute phase (0–90 days) and a rest-of-life phase (>90 days). Data on effectiveness and safety were taken from a meta-
analysis of 5 RCT studies. Utilities and resource utilization were estimated from Polish data sources and clinical expert opinion. Other parameters were in accordance with identified economic analyses. Results were presented for 2 patient’s subgroups: contraindicated to intravenous tissue plasminogen activator (IV rt-PA) and suitable for IV rt-PA. Health outcomes and future costs were discounted respectively at 3.5% and 5.0% following national HTA guidelines. Reliability of estimates was tested in probabilistic (PSA) and one-way (OWSA) sensitivity analyses. RESULTS: Estimated total QALYs were 5.29 for MT + BSC and 3.64 for BSC regardless of patient’s subgroup. In patients contraindicated to IV rt-PA average costs per patient were 67,573 PLN (68,220 PLN) for MT + BSC and 16,889 PLN (17,440 PLN) for BSC alone. In patients available for IV rt-PA average costs per patient were 70,879 PLN (71,525 PLN) for MT + BSC and 23,737 PLN (24,287 PLN) for BSC alone. Estimated differences for QALYs and costs were statistically significant. Incremental cost-utility ratio (ICUR) ranged from 28,566 PLN to 30,771 PLN for acceptability threshold of 125,955 PLN. MT + BSC was also cost-effective in PSA and OWSA. Base case results were confirmed by sensitivity analysis. CONCLUSIONS: Mechanical thrombectomy, using a stent retriever, added to BSC is cost-effective compared with BSC alone.

PMD96: THE COST-EFFECTIVENESS OF TAVI IN INOPERABLE AND HIGH RISK PATIENTS IN FRANCE

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OBJECTIVES: TAVI (Transcatheter Aortic Valve Implantation) is a minimally invasive alternative to surgical replacement of the aortic valve (sAVR) and the only treatment option for those considered at too high risk for surgery. We present here the results of a cost-effectiveness analysis of TAVI in inoperable and high risk patients in France based on the most recent clinical data derived from third generation valves. METHODS: An Excel based Markov model evaluated economic and clinical outcomes in patients undergoing TAVI, sAVR or medical management (MM) over a 15 year time horizon. Clinical inputs were derived from the PARTNER 1 and 2 clinical trials and quality of life (QoL) utilities derived from study data and transformed into French values. Mortality projections were extrapolated from Kaplan Meier survival estimates. All costs including index admissions, complications, rehabilitation, etc. were derived from French sources. All results were discounted annually by 4.0%. Sensitivity and scenario analyses were performed. RESULTS: TAVI was associated with increased quality of life in both inoperable and high risk patients of 1.6162 and 0.5495 quality-adjusted life years (QALYs) compared with sAVR and MM respectively. At currently reimbursed costs for TAVI, the ICER in inoperable patients was €11784 per QALY gained and for high risk patients TAVI was dominant with cost savings of €2003 per patient. Deterministic and probabilistic sensitivity analyses showed the results were generally robust and impacted most by changes in assumptions to procedural costs and mortality. CONCLUSIONS: TAVI delivers substantial clinical benefits in terms of improved life expectancy and quality-adjusted life expectancy in inoperable and high risk patients. For inoperable patients the ICER for TAVI versus sAVR would generally be considered to represent a cost-effective therapy and for high risk patients TAVI is a cost saving option.

PMD97: A COST-UTILITY ANALYSIS OF ARTIFICIAL URINARY SPHINCTER VERSUS ADVANCE MALE SLING IN POST PROSTATECTOMY STRESS URINARY INCONTINENCE: A CANADIAN HEALTHCARE PERSPECTIVE

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OBJECTIVES: The artificial urinary sphincter (AUS) remains the "gold standard" for the treatment of post prostatectomy stress urinary incontinence (PPSUI). However, in recent years, minimally invasive, less expensive sling device (Advance) are offered as potential alternative treatments. We sought to investigate the long-term cost-utility of the AUS compared with Transobturator Retroluminal Repositioning Sling (Advance sling) in the treatment of severe PPSUI. METHODS: A Markov model with Monte-Carlo simulation was developed to estimate the incremental cost-utility ratio (ICUR) of AUS vs. Advance sling from a provincial payer perspective over a 10-year period. Probability estimates, success rates, healthcare resources and utilities were obtained from published literature when available or by expert opinion. The Markov model included 4 states (wet, post-wet, dry and death). Costs for disease management and devices included in this model were obtained from provincial databases in Quebec, Canada and hospital database. Uncertainty was analyzed using deterministic and probabilistic sensitivity analysis. RESULTS: AUS Implantation had a 10-year mean total cost of $14,300 (SD±3,509) for 7.64 QALYs. On the other hand, Advance sling had a mean total cost of $17,042 (SD±12435) for 6.53 QALYs. The cost-utility analysis showed that AUS becomes a dominant strategy when compared to Advance sling over 10 years. The incremental cost savings of AUS was $2,742 with an added effectiveness of 1.11 QALYs. The probability of becoming wet after an Advance sling as well as the probability of going through AUS after an initial surgery with Advance sling demonstrate the most variability compared to base-case ICUR in one-way sensitivity analyses. (751,16$ and 437,07$, respectively). CONCLUSIONS: Although the initial cost of sling is attractive, superior long-term outcomes are
demonstrated with durable high success rate of AUS in men with severe PPSUI. Hence, the AUS implementation strategy over a 10-year period time is estimated to be more economical to our health care system.

PMD98: INTEGRATING NOVEL SCREENING METHODS FOR PROSTATE CANCER, COST-UTILITY INTERVENTIONS

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OBJECTIVES: The most common method today of prostate cancer diagnosis is screening for Prostate Specific Antigen (PSA) followed by a Transrectal Ultrasound Guided-Biopsy (TRUSGB). Magnetic Resonance Imaging-Guided Biopsy (MRGB) is an available method that has shown potential in previous studies. The available screening methods showing potential to reduce unnecessary biopsies are 4Kscore, Prostate Health Index (PHI) and Prostarix. The aim of this study was to evaluate the cost-effectiveness of introducing these tests compared to the use of only TRUSGB or MRGB. METHODS: To calculate the cost-effectiveness for the screening tests, a Markov model was developed to integrate new screening tests for prostate cancer. Quality-adjusted life years gained (QALY) and costs for the tests were estimated over a time horizon of 5, 10, 15 and 20 years. The model includes probabilities of not getting an initial biopsy due to the tests, getting a positive result on the biopsy and stratification in low and intermediate/high risk cancer. The rate of missed cancers of the test is also a part of the model, as well as direct medical costs. RESULTS: Data for Prostarix was insufficient and more clinical utility studies are needed to model this without big uncertainties. Costs and cumulative effects in QALY were calculated for 10, 15 and 20 years for 4Kscore and PHI. The costs for 4Kscore were $8300, $10389 and $11995 for the different time spans and for PHI $11164, $14700 and $17419 respectively. The cumulative effects for 4Kscore were 4.38, 7.42, 9.42 and 10.59 QALY and for PHI they were 7.28, 9.18 and 10.25 respectively. Compared to the TRUSGB and MRGB strategies, the 4Kscore strategy was the dominating strategy, yet the PHI strategy demonstrated similar costs and QALYs as the TRUSGB strategy. CONCLUSIONS: The new screening methods show potential in complementing the existing screening process for prostate cancer.

PMD99: COMPARISON OF UTILITY COST IN THREE COMMERCIALLY AVAILABLE PRECISION MEDICINE APPROACHES IN ONCOLOGY

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OBJECTIVES: The introduction of molecular profiling as standard of care in cancer has led to the launch of a number of commercial precision medicine services, which differ largely in their approaches. It can be difficult for payers, physicians, and patients to distinguish between these services and determine which testing is most appropriate for an individual case. An understanding of the clinical utility and the utility cost (cost of finding one patient with clinical benefit) of the different approaches can help to set expectations for all stakeholders involved. The aim of this study is to define the utility cost of three leading commercially available oncology precision medicine approaches, Caris Molecular Intelligence® (CMI), FoundationOne® and PCdx™. METHODS: A systematic review of all published clinical evidence for the three services was performed, to determine the number of patients treated in line with the profiling results and the clinical benefit resulting from these treatment choices. Utility cost was defined as the list price divided by the fraction of patients treated based upon the profiling results and the clinical benefit in treated patients. RESULTS: Based on the number of profiled patients treated and the corresponding number of patients with clinical benefit, 34% of CMI-profiled patients had clinical benefit (184 of 534 profiled patients), compared to 6% of those profiled with FoundationOne® (166 of 2,675 profiled patients) and 11% profiled using PCdx™ (19 of 168 profiled patients). Utility cost was calculated as $19,118 for CMI, $43,636 for PCdx™ and $96,667 for FoundationOne®. CONCLUSIONS: The results of this study shows that the multiplatform approach of CMI brings the highest clinical utility, based on the use of conventional chemotherapies in the majority of patients profiled. A low clinical utility means that almost 20 cases of FoundationOne® must be purchased to find one patient who benefits.

PMD100: COST-UTILITY OF NOVEL TESTS AFTER A NEGATIVE PROSTATE BIOPSY

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OBJECTIVES: Transrectal Ultrasound-Guided Biopsies (TRUSGB) are today the main approach of diagnosing prostate cancer but overdiagnosis and sampling errors are major limitations. Magnetic Resonance Imaging-Guided Biopsies (MRGB) have been researched and previously published as an alternative approach. In this study, five tests for use after an initial negative biopsy for better patient stratification were assessed: PCA3, ConfirmMDx, Prostate
Core Mitomic Test (PCMT), Prostate Health Index (PHI) and the 4Kscore. The resulting costs and QALY were compared to the use of TRUSGB and MRGB. METHODS: A Markov model was used over 5, 10, 15 and 20 years. All tests were performed on patients referred to a second biopsy due to a remaining suspicion of prostate cancer after an initial negative biopsy. The Markov model considers the probability of harboring prostate cancer, diagnostic accuracy of the tests, the stratification of patients after performing the tests and probabilities of being assigned to different treatments. The included costs were direct cost in the Quebec health care system perspective. RESULTS: Introducing PCA3 resulted in cumulative effects at 7.24, 9.12 and 10.21 QALY after 10, 15 and 20 years. The corresponding values for ConfirmMDx were 7.24, 9.13 and 10.21. PCMT, PHI and 4Kscore were excluded during the systematic literature review due to lack of data. The cumulative costs using PCA3 after 10, 15 and 20 years were $11525, $14951 and $17480. The corresponding costs for ConfirmMDx were $11706, $15092 and $17598. The costs and QALY were compared to the approach used today, TRUSGB, and the incorporation of MRGB. Both strategies, PCA3 and ConfirmMDx, demonstrated similar costs and QALYs as the standard strategy TRUSGB. CONCLUSIONS: Introducing the new tests showed potential of use in clinical practice, demonstrating similar clinical and economic outcomes when compared to TRUSGB.

**PMD101: COST-UTILITY OF LIQUID CHROMATOGRAPHY -TANDEM MASS SPECTROMETRY (LC-MS/MS)- BASED URINE ANALYSES TO IMPROVE ADHERENCE TO ANTIHYPERTENSIVE TREATMENT**

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OBJECTIVES: In the UK, over 28% of the population are estimated to suffer from hypertension. A high systolic blood pressure (SBP) increases the risk for cardiovascular disease (CVD). While antihypertensive medications, along with lifestyle changes, are deemed effective in combating hypertension, adherence to drug treatment may not be optimal. Data from UK patient samples show that discussion of the results from LC-MS/MS-based urine analyses with patients can improve adherence significantly. The objective of this study was to determine whether performing LC-MS/MS-based urine analyses is cost-effective by improving adherence in hypertensive patients. METHODS: Cost-utility analysis was performed from a UK healthcare payer perspective over a lifetime horizon. A Markov model was adapted from an existing published model in a UK setting. Hypertensive patients entered the model event-free, but at risk for cardiovascular events. Effectiveness of urine analysis was modelled by lowering the probability of having an event, as a consequence of lowered SBP by improved adherence to drug treatment, as found in the empirical study. Cost and utilities were derived from literature. The base case cohort consisted of males aged 65. Further analysis varied sex and age of the population. Subgroup analysis concerned those with resistant hypertension, and univariate and probabilistic sensitivity analyses were also performed. RESULTS: The intervention resulted in an incremental health benefit of 0.020 quality-adjusted life-years (QALYs) per patient, and incremental cost was £867 per patient, i.e. the intervention strategy is dominant compared to care as usual. Sensitivity analyses showed that targeting younger patients (aged 45) or only patients with resistant hypertension would increase cost savings and QALY gains. CONCLUSIONS: Using LC-MS/MS-based urine analyses to improve adherence in hypertensive patients is an effective and cost-saving strategy, especially in patients with resistant hypertension, since non-adherence is found to be higher in this population.

**PMD102: PATTERNS IN WORKING DAYS LOST BY PARENTS OF CHILDREN NEWLY-DIAGNOSED WITH TYPE 1 DIABETES (T1D).**

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OBJECTIVES: Continuous subcutaneous insulin infusions (CSII) are an alternative to multiple daily injections (MDI) for glycaemic control and reducing the risk of developing long term microvascular and macrovascular complications in type 1 diabetes (T1D). The objective of this study as part of a randomised clinical trial (SCIPI, ISRCTN29255275) was to assess patterns of work-related absences, and whether a difference was apparent between treatment groups. METHODS: Patients between 7 months and 15 years of age, newly diagnosed with T1D were eligible to participate in this pragmatic, open, multicentre, parallel group, randomised, controlled trial. Parental work-related absences in days from the preceding 3-months were measured by parental interview at randomisation, 3, 6, 9 and 12 month intervals. RESULTS: Actual time taken off work was reported by parents and/or guardians for 78% of participants (CSII=113, MDI=117). Absence from work between randomisation and 12-month follow-up in parents of patients in the CSII group was 3.6 days (95% CI 2.3, 4.9) compared to 2.7 days (1.9 to 3.4) in the MDI group [difference in means of 0.9 days (95% CI -0.6, 2.5)]. In the 3-month period prior to randomisation, however, absence from work in parents of patients in the CSII group was 5.5 days (95% CI 4.7, 6.3) compared to 4.9 days (4.1 to 5.7) in the MDI group [difference in means of 0.6 days (95% CI -0.5, 1.7)]. CONCLUSIONS: T1D diagnosis for a child can
have a temporary disruptive influence on parental work commitments. However, there is no evidence to suggest that one treatment is associated with any more or less work-related absences than the other.

PMD103: IMPACT OF ADENOMA SURVEILLANCE GUIDELINES ON THE FUTURE DEMAND OF COLONOSCOPIES ASSOCIATED TO A POPULATION-BASED COLORECTAL CANCER SCREENING PROGRAM

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OBJECTIVES: Recent European guidelines recommend colorectal cancer screening of average-risk population. Besides colorectal cancer, adenomas are found. Adenomas deserve surveillance through colonoscopy, but there is no clear recommendation on its frequency and several guidelines are proposed. Our objective was to estimate the demand of colonoscopies to undergo recommended surveillance of adenomas found under a population-based colorectal cancer screening program following three different guidelines. METHODS: A previous discrete-event simulation representing a colorectal cancer screening program for a target population of 100,000 women and men aged 50 to 69 years was used to account for resources at the follow-up phase after screening. The underlying conceptual model was based on the European Guidelines for the screening process. For follow-up after adenoma removal, three guidelines were implemented and compared: that of the Catalan Society of Gastroenterology, that of the European Society of Gastrointestinal Endoscopy and that of the US Multi-Society Task Force. Parameters were estimated from the Colorectal Cancer Screening Program of Barcelona and follow-up colonoscopy results from the literature. A 10-year horizon starting in 2015 was simulated. The model included the population ageing and projections. RESULTS: The predicted 10-year cumulative number of colonoscopies was 16,180 for the Catalan, 15,415 for the European and 15,266 for the US guidelines, representing the Catalan guideline 5% and 6% more colonoscopies than the European and the US guidelines, respectively. The number of colonoscopies after a positive FIT was similar, while the number of adenoma surveillance colonoscopies was higher for the Catalan guideline: 26.1% and 35.6% higher than the European and the US guidelines, respectively, while the European guideline presented a 7.5% more surveillance colonoscopies than the US guideline. CONCLUSIONS: The choice of the surveillance guidelines for follow-up of adenomas found under a population-based colorectal cancer screening program is relevant in terms of its impact on the demand of colonoscopies.

MEDICAL DEVICES/DIAGNOSTICS - Patient-Reported Outcomes & Patient Preference Studies

PMD104: PATIENT INSIGHTS IN COPD MEDICATION ADHERENCE FROM PHARMACY DATA

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OBJECTIVES: Over half of patients with chronic obstructive pulmonary disease (COPD) struggle to use a metered dose inhaler correctly. Strikingly, therapies seem to vary from country to country. For instance, the three strengths of a specific dry powder inhaler prescribed in Germany are consistently 20%/25% lower for their two active ingredients than the corresponding three strengths dispensed in the UK. This study attempts to quantify the impact of this difference on patient behaviour. METHODS: To quantify adherence we used two comprehensive anonymised patient level datasets comprising 13,337 and 20,252 unique patient IDs for the UK and Germany, respectively. Each patient was followed for 365 days and a Medication Possession Ratio (MPR) trend calculated using the FMPR methodology. We then compare the two patient groups applying different filters. RESULTS: This study indicates that patients in the UK exhibit a significantly higher adherence than patients in Germany. However, general adherence patterns are the same with men exhibiting a higher adherence than women and a positive correlation between adherence and age groups. In contrast the pattern between product strength and adherence is not shared between the two datasets. While the strongest product in the German market (320/9 mcg) shows the best adherence the weakest product (80/4.5 mcg) shows the worst adherence in the dataset for Germany. In contrast, the strongest product in the UK market (400/12 mcg) shows the worst adherence in the UK dataset while the medium strength (200/6 mcg) shows the best adherence. CONCLUSIONS: Given that the correlation between product’s strength and adherence is the only striking difference between the two datasets working hypotheses can be drawn from this. For example, one hypothesis may be formulated where 200/6 mcg is the ‘sweet spot’ for this combination inhaler, with all strengths above or below this having an adverse effect on patient adherence.

PMD105: PATIENT PREFERENCES IN ITALY: HEALTH STATE UTILITIES ASSOCIATED WITH ATTRIBUTES OF WEEKLY INJECTION DEVICES FOR TREATMENT OF TYPE 2 DIABETES
OBJECTIVES: Several GLP-1 receptor agonists are administered as weekly injections for treatment of type 2 diabetes (T2D). These medications vary in their injection processes, and these differences could impact quality of life and patient preference. The purpose of this study was to examine patient preferences in Italy and estimate utilities associated with injection processes for these weekly therapies. METHODS: Participants diagnosed with T2D in Italy (Milan, Rome) valued health states in time trade-off interviews. The health states (drafted based on literature, device instructions for use, and clinician interviews) had identical descriptions of T2D, but differed in description of the treatment process. One health state described an oral only treatment regimen, while six health states described oral treatment plus a weekly injection. The injection health states differed in the treatment administration process (e.g., requirements for reconstituting the medication, waiting during medication preparation, and needle handling). RESULTS: A total of 238 participants completed interviews (58.8% male; mean age = 60.2y; 118 from Milan; 120 from Rome). The mean (SD) utility of the oral treatment health state was 0.90 (0.10), and all injection health states had significantly (all p < 0.0001) lower utilities ranging from 0.87 (reconstitution, waiting, and handling) to 0.89 (weekly injection without any of the three treatment administration requirements). Utility differences among the injection health states suggest that each administration requirement had a small but measureable disutility (i.e., negative utility difference). Disutility values include -0.006 (reconstitution), -0.006 (needle handling), -0.011 (reconstitution, needle handling), and -0.022 (reconstitution, waiting, needle handling). CONCLUSIONS: Findings provide insight into patient preferences among attributes of weekly T2D treatment processes in this Italian sample. Results suggest that injection device attributes may be important to some patients, and it may be useful for clinicians to consider these attributes when choosing medication for patients initiating these weekly treatments.

PMD106: THE HEALTH-RELATED QUALITY OF LIFE (HRQOL) ASSOCIATED WITH OSTOMY APPLIANCES AND FEATURES

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OBJECTIVES: Differences between ostomy appliances have until now only been documented using condition-specific tools. However, these results are not applicable in standard economic evaluations which require a common metric for measuring outcomes, such as QALY-values. This study, therefore, aimed to investigate the incremental health-related quality of life (HRQoL) associated with different ostomy appliances and features using a time trade-off (TTO) internet experiment. METHODS: The HRQoL associated with the ostomy appliances and features were investigated in a TTO internet experiment. Respondents traded off life expectancy for improved quality of life following the standard bisection methodology. The health states were described using evidence relating to function, appearance, waterproofness, comfort and fit, confidence, skin problems and ballooning. Two populations were included in the study: 1013 respondents from a British general population (BGP) and 237 respondents from a Swedish ostomate population (SOP) consisting of ostomates with either a colostomy or an ileostomy. Confidence intervals were determined using bootstrapping with resampling, and 5% outliers were excluded from the main analysis. A sensitivity analysis was conducted to investigate the impact of outliers on the incremental HRQoL. RESULTS: All health states showed statistically significant improvements in HRQoL, at the 0.05 significance level. The health states for ostomy appliances showed an incremental utility ranging from 0.017-0.036 in the BGP and 0.015-0.038 in the SOP. Only minor differences were observed in the incremental utility values between the two populations. The sensitivity analysis showed that the BGP outliers had little impact on the incremental utility values, while the SOP outliers added to the incremental utility values. CONCLUSIONS: The study confirmed that the TTO method can be used to measure HRQoL related to ostomy appliances and found statistically significant differences in HRQoL associated with improvements in ostomy appliance attributes and features.

PMD107: PREDICTING QUALITY ADJUSTED LIFE YEARS USING ST. GEORGE RESPIRATORY RESULTS IN PATIENTS WITH SEVERE EMPHYSEMA TREATED WITH ENDOBRONCHIAL COILS IN ADDITION TO STANDARD OF CARE COMPARED TO STANDARD OF CARE ALONE

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OBJECTIVES: Endobronchial coils (“coils”) are a minimally invasive treatment option for severe emphysema. Health Related Quality of Life (HRQoL) is important for assessing disease severity and treatment efficacy. St George’s Respiratory Questionnaire (SGRQ) is commonly used to measure HRQoL in pulmonary clinical trials. The efficacy of coils + Standard of Care (“SoC”) compared to SoC alone on HRQoL was evaluated in a recently published RCT.
(RENEW, NCT01608490). To make cross-disease reimbursement decisions payers increasingly require benefit to be quantified using Quality-Adjusted Life Years (QALYs). To aid such decisions, we mapped SGRQ data onto EQ-5D values and generated prognostic statistical models to quantify the impact of coils on HRQoL and estimate indicative long-term QALY gains over a range of clinically plausible scenarios. METHODS: Patient level SGRQ data from RENEW and the National Emphysema Treatment Trial (NETT) were combined into a master dataset and mapped to EQSD values using a published algorithm. Multilevel statistical models were developed using treatment, time, response, and baseline characteristics (EQ-5D, age, gender, FEV1, lung RV >220%, Emphysema status) to predict EQ-5D over time. Lifetime QALY estimates were generated using published long-term Kaplan-Meier all-cause mortality data from NETT (assuming no impact of treatment on mortality) and four clinically plausible hypothetical response profiles (variations on constant and time varying values). Each response profile was combined with assumptions around the impact of treatment (constant or time varying). RESULTS: After controlling for baseline characteristics both treatment and response had a statistically significant impact (p<0.001) on utility (+0.101 and +0.061, respectively). When combined with selected baseline characteristics and time, Coils+SoC generated more QALYs than SoC alone in all eight scenarios, with generated incremental lifetime benefit ranging from 0.29 to 0.55 QALYs. CONCLUSIONS: In patients with severe emphysema, Coils+SoC resulted in statistically significant improvements in HRQoL compared to SoC alone.

PMD108: PATIENT PERCEPTION WITH RESPECT TO THE OVERALL EXPERIENCE TO A PATIENT-FRIENDLY EQUIPMENT DESIGN AND THE IMPACT OF PATIENT-ASSISTED COMPRESSION FEATURE DURING A MAMMOGRAPHY EXAM

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OBJECTIVES: Patient experience is an important factor in mammography. Participation rates for repeat mammography remain low. The objective of this research was to understand patient perception to a patient-friendly equipment design and the effect of a patient-assisted compression device designed to change the mammography experience METHODS: A questionnaire was developed with IPSOS Healthcare to collect responses from patients who were attending mammography in two clinics in France and Italy. Approval from hospital’s ethical committee was received. This study was conducted during February/March 2017. All respondents were interviewed immediately after having a mammography exam using the new equipment with the new patient-assisted compression device. RESULTS: The survey included patients of varying experience with mammography. On an average the patients have had 6 previous mammograms (N=272). A majority (83%) of patients had a better overall experience than with previous systems (N=296). In this study, 50% of patients were not at all anxious (N=310) during the exam and 37% were less anxious as compared to their previous exams (N=298). Of those who used the patient-assisted compression feature (N=159), 80% responded that it made the exam more comfortable. 54% of the respondents said that the patient-assisted compression device led to less anxiety (N=156). CONCLUSIONS: Patient-assisted compression may be a valuable feature in mammography. Previous study showed that patient-controlled compression was associated with reduced pain perception than technologist-controlled compression. To improve patient adherence to screening exams all such factors should be considered. In this study, the patient-assisted compression contributed to improving patient comfort and experience that may also contribute to increasing the participation rate of screening. Note: Patient-assisted compression feature on this equipment is currently CE marked and commercially available in Europe

PMD109: PATIENT-PREFERRED DESIGN FEATURES OF TNF INHIBITOR SELF-INJECTION DEVICES: INSIGHTS FROM A RHEUMATOID ARTHRITIS AUTO-INJECTOR PREFERENCE STUDY

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OBJECTIVES: To determine which tumor necrosis factor inhibitor (TNFi) auto-injector design features are most important to rheumatoid arthritis (RA) patients. METHODS: Auto-injector-naïve patients with moderate to severe RA performed multiple simulated self-injections with unbranded certolizumab pegol (CZP), adalimumab, golimumab, and etanercept auto-injectors to determine device preferences. 1 Patients were then asked to define 5 key design features that best supported their needs. Each patient ranked their 5 features from the most important (awarded 5 points) to least important (1 point); patients could rank multiple features equally. Individual rank scores were summed into an overall patient preference score per feature. RESULTS: 76 patients were enrolled; 20 had previous experience with self-injecting RA medication using a syringe and vial or pre-filled syringe; 9 had previously self-injected non-RA medication. After testing the 4 auto-injectors, 23 features were suggested by ≥1 patient as of key importance. The 5 most commonly preferred features of an RA self-injection device were identified as an easy-to-use handle width (selected by n=59 patients [51.3%]; total score 169 points), an easy and comfortable grip (n=37 [48.7%]; 155 points), reassurance of injection completion (n=48 [63.2%]; 150 points), an easy-to-activate injection such as button-
free/single-handed use (n=38 [50.0%]; 140 points), and an easy-to-remove cap (n=27 [35.5%]; 95 points). Other features cited by >25% of patients included: confidence in control and safety (n=21 [27.6%]; 91 points), ease of use (n=21 [27.6%]; 84 points), and a non-slip grip (n=20 [26.3%]; 76 points). **CONCLUSIONS:** Defining features of key importance to RA patients is crucial when designing auto-injector devices to address patient-reported needs. Incorporating patient-preferred features, such as a wide handle, comfortable grip and reassurance of injection completion, could enhance the patient treatment experience, promote compliance and persistence, and improve clinical outcomes. 


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**PMD110:** CAPTURING PATIENT PERSPECTIVES IN THE EVALUATION OF MEDICAL DEVICES: THE CASE OF CENTRAL VENOUS ACCESS DEVICES IN CHEMOTHERAPY

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**OBJECTIVES:** The primary objective of this research was to incorporate patient perspectives into a large-scale trial (Cancer and Venous Access; CAVA) comparing the safety and effectiveness of three venous access devices for the delivery of chemotherapy (Hickman type device, PICC, implantable chest-wall Port). Secondary objectives included the assessment and development of a quality of life measure for patients using these devices, and to inform the education of clinicians caring for these patients. **METHODS:** Semi-structured focus group discussions were conducted with patients at six sites in England and Scotland participating in CAVA. Focus groups were audio-recorded, transcribed, and data were analysed using thematic analysis. A range of experiences with different devices were sampled. **RESULTS:** Four key themes were identified. (i) Patient adaptability: Overall, patients found that the devices had limited impact on their daily lives. However, the minimisation of impact depended on patients making adaptations and adjustments to behaviour and routines. (ii) Positive psychological aspects of Ports: Patients had positive perspectives on all devices. Patients with Port devices discussed additional social and psychological benefits. (iii) Staff capabilities influence patient experiences: Patients’ concerns about their devices were tied to perceptions regarding staff confidence/competence. Patients with Ports described playing a role in educating staff unfamiliar with the device. (iv) Measurement of quality of life: Patients provided feedback on an original questionnaire developed for the purposes of CAVA which was felt to capture experiences more adequately than a standardised measure (i.e., EQ-5D). **CONCLUSIONS:** This research identifies several challenges facing patients who need CVADs for the administration of chemotherapy, and offers novel insights regarding some potential benefits of Ports. It also suggests that conventional approaches using EQ-5D alone to capture the impact of medical devices on patient quality of life may not be sufficient; the incorporation of technology-specific measures should be considered.

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**PMD111:** SURVEY OF LIFE QUALITY AMONG PATIENTS WITH INSULIN DEPENDANT DIABETES MELLITUS MANAGED BY INSULIN PUMP

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**OBJECTIVES:** The incidence of Type 1 Diabetes Mellitus is increasing consistently (3 percent per year). The insulin pump and the PEN also maintains the glycemic control and improves the life quality, but still there is the question which is the better choice. The aim of the study was to measure the life quality and therapeutic satisfaction of patients with pump and compare the results with the datas of patients with PEN. **METHODS:** A quantitative, retrospective research was taken in the hospital of Pecs and Veszprem between November, 2016 and March, 2017 using standard questionnaires. Altogether 101 patients’ datas were evaluated (n-pump=43; n-PEN=58) with descriptive statistics, t-test, ANOVA and linear regression (p<0.05). **RESULTS:** The therapeutic satisfaction of the patients with pump is significantly higher than the patients with PEN (p=0.01). Patients with pump are more confident of handling compliance, but not significantly (p=0.49). We found no significant difference between the two groups’ life quality (p=0.55). Hypoglycaemia occured in more cases with patients using insulin pump (p=0.73). **CONCLUSIONS:** Compare to previous researches the patients with insulin pump also are more satisfied with their therapy than the patients with PEN but their life quality is almost equal.

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**PMD112:** WOMEN’S PREFERENCES: A DISCRETE-CHOICE EXPERIMENT FOR TREATMENT OF MENORRHAGIA WITH UTERUS-PRESERVING THERAPY

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**OBJECTIVES:** This study aimed to validate women’s preferences between radiofrequency treatment and loop resection (gold standard) as uterus-preserving therapy alternatives for treatment of Menorrhagia in Germany.
Therefore, first aim of the study was to find the relevant attributes for decision making between both therapy alternatives. Second, to qualify the relative importance of this attributes between radiofrequency treatment compared with loop resection from a women’s perspective. Third, to evaluate the willingness to pay (out of pocket) to avoid relevant side-effects based on woman’s perspective confronted with this choice set. METHODS: A Discrete Choice Experiment (DCE) was conducted. The following attributes were found in a systematic literature review: amenorrhoea chance, regular use of hormone medication, post surgery pain, hysterectomy rate, re-surgery rate. The study included women in the age from 35 to 55. After a pre test, the DCE was conducted in an online survey from December 1 to January 31, 2017. The willingness to pay was also obtained from the survey. The data was analysed using a multivariate mixed logit model. RESULTS: In sum, 228 woman started the survey and there was 108 complete replies. Therefore, the response rate was 47%. The following attributes had a significant (p<0.05) impact on women’s choices: hormone medication (standardized beta = 0.39), hysterectomy rate (sb = 0.22), re-surgery rate (sb = 0.22), amenorrhoea chance (sb = 0.14). The average willingness to pay for women in this study is 10-times higher than the regular co-payment in Germany for a hospital stay. So women in this study are willing to pay up to 250 € for the preferred choice set. Model fit (Pseudo-R²) was 0.2141. CONCLUSIONS: Consequently, taking into account women’s preferences, the loop resection cannot be seen as the gold standard in treatment with ablation technique. In the Netherlands and UK this standard has already been replaced.

PMD113: HEALTH-RELATED QUALITY-OF-LIFE AND UTILITY MEASURES IMPACT IN A RANDOMIZED CONTROLLED STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY (FNAC) VERSUS WATCHFUL OBSERVATION IN PATIENTS WITH INCIDENTAL SYMPTOMATIC THYROID NODULES

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OBJECTIVES: To present the impact of treatment on health-related quality-of-life (HRQOL) and health utility measures from the randomized controlled trial (ClinicalTrials.gov Identifier: NCT02398721) that investigated the FNAC versus watchful observation in patients with symptomatic benign thyroid nodules. METHODS: Health utility and HRQOL were evaluated using the EuroQoL 5-dimension 5-level (EQ-5D-5L), 6-item Short Form Health Survey (SF-6D), cancer-specific Functional Assessment of Cancer Therapy-general (FACT-G) and generic 12-item Short Form Health Survey (SF-12v2) at baseline, 3-month, 6-month and 12-month assessments. A repeated measure analysis of variance (ANOVA) evaluated differences in HRQOL scores between treatment groups over time. Multiple imputation was used to impute missing data at each time point. RESULTS: HRQOL data completion rates were 99.7% at baseline, 92.7% at 3-month, 93.9% at 6-month and 92.7% at 12-month after baseline. There were significant mean differences in SF-6D, EQ-5D-5L, FACT-G and SF-12v2 over time except PWB, EWB of FACT-G and mental health of SF-12v2. Mean change of utility scores from baseline between groups did not exceed minimal important difference. No significant treatment group by time interactions were found in all HRQOL and utility scores except in the vitality domain and PCS of SF-12v2 (p-value = 0.033; 0.024). CONCLUSIONS: When compared to watchful observation, FNAC intervention was associated with better vitality and physical-related HRQOL scores but did not provide better preservation of utility score improvement over the 12-month period.

PMD114: COST-EFFECTIVENESS OF REPERFUSION STRATEGIES FOR ST-ELEVATION MYOCARDIAL INFARCTION. REAL-WORLD DATA FROM THE STENT FOR LIFE INITIATIVE IN ITALY

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OBJECTIVES: To evaluate the one-year cost-effectiveness of different reperfusion strategies for ST-elevation acute myocardial infarction (STEMI) using real-world data from a prospective survey endorsed by the Stent For Life (SFL) Initiative in Italy. METHODS: Outcome and resources data were collected on 212 consecutive patients treated for STEMI in May 2012 at all public hospitals in Sicily, one of the target regions within the SFL Initiative in Italy. RESULTS: 69.3% of patients underwent primary angioplasty (pPCI) and 20.3% non-primary PCI (i.e., secondary PCI, rescue PCI and pharmaco-invasive strategy); 2.4% was treated with thrombolysis (TBL); 8% did not receive any reperfusion treatment. The economic analysis was performed adopting a societal perspective. On average, patients treated with pPCI costed €1,963 less than non-primary PCI (€18,371 vs. €20,334, p=0.26). This was mainly due to lower costs of index hospitalisation (€10,034 vs. €10,918, p=0.03), one-year follow-up hospitalisations (€3,574 vs. €4,307, p=0.577), transportation (€184 vs. €272, p=0.05) and productivity losses (€2,774 vs. €3,243, p=0.65). Quality-adjusted survival (QALY) was more favourable in case of pPCI (0.72 QALYs vs 0.69, p=.45). Based on one-year follow-up, pPCI was dominant compared with non-primary PCI. The treatment with TBL costed €6,382 less than pPCI (€11,989 vs. €18,371, p=0.13), mainly due to lower costs for index hospitalisation (€5,373 vs. €10,034, p<0.001) and productivity losses (€6 vs. €2,774, p=0.30), but has a much lower level of outcomes (0.48 vs. 0.72 QALYs, p=.03). Compared with TBL, pPCI has an incremental cost-effectiveness ratio of €26,485. Therefore, pPCI is cost-effective with respect to commonly accepted threshold values. CONCLUSIONS: The cost of pPCI does not significantly differ
from other reperfusion strategies for STEMI. Anyhow, the economic analysis at one-year follow-up highlighted that pPCI is dominant compared with non-primary PCI and cost-effective compared with TBL. The results, reflecting real-world clinical practice, confirmed that pPCI represents the gold standard treatment for STEMI.

**PMD115: PUBLIC PERCEPTIONS, ATTITUDES AND WILLINGNESS TO PAY TOWARDS A MEDICAL DEVICE FOR DETECTING FOOT ULCERATION IN PEOPLE WITH DIABETES**

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**OBJECTIVES:** Diabetic foot ulceration (DFU) is a common and serious complication among diabetic patients. A medical device has been developed to prevent the occurrence of DFU. The aim of this study was to investigate the willingness to pay (WTP) for this device among the general public in the UK. **METHODS:** A contingent valuation survey was administered to 1051 participants through an online survey including questions on socio-demographic characteristics, self-reported health, knowledge of diabetes and similar medical devices, and WTP. **RESULTS:** More than half of the participants (55.9%) expressed a positive WTP. The annual mean (standard deviation [SD]) and median (interquartile range [IQR]) WTP values were £76.9 (69.1) and £50 (80), respectively. Older age, middle-level education, good/excellent self-reported health, visiting doctors once/2-5 times, diabetes experience, medical device experience, and more than average self-perceived likelihood of using similar devices were associated with higher likelihood of willingness to pay. Younger age, male gender and higher household income were associated with higher WTP values, conditional on willingness to pay. **CONCLUSIONS:** We found that more than half of people are willing to pay for this diabetes device and they tend to contribute when they have experience of diabetes or similar devices and perceive self-benefit. These results highlight the strong public preference and provide an important component to the economic business model for this device.

**MEDICAL DEVICES/DIAGNOSTICS - Health Care Use & Policy Studies**

**PMD116: IMPACT OF GENOMIC TESTING BILLING PRACTICES ON UTILIZATION IN ACADEMIC HYBRID ONCOLOGY PRACTICE**

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**OBJECTIVES:** Molecular testing is often used to guide practitioners and patients to select treatment or clinical trials. Payment coverage for molecular testing varies by technology and vendor. We examined the impact of billing practice changes for genomic testing (GT) on utilization in an academic hybrid, multi-site community-based cancer institute. **METHODS:** In June 2015, Levine Cancer Institute (LCI) standardized the availability and use of GT across its 26 sites. GT consisted of a commercially produced, tissue-based ~600 gene panel (Panel A) which guided treatment and clinical trial selection with a maximum cost to patient of $550. In June 2017, vendor-negotiated rates with public/private insurers were implemented increasing patient out-of-pocket (OOP) costs between 45% and 518% (insurance provider and cancer type dependent). LCI instituted financial consents in order to test samples to ensure patients understood OOP costs. A liquid biopsy panel (B; ~40 genes) was added in October 2016 for no charge to insurance provider and cancer type dependent). LCI institu

**RESULTS:** Since its peak in April 2016 (n=122, 32 ordering physicians), Panel A’s utilization has decreased (May 2017, n=36, 28 ordering physicians), Panel B’s utilization remained constant until February 2017 when test volume increased (n=22, 3 ordering physicians) and continued increasing (May 2017, n=44, 6 ordering physicians; Feb-Jun 2017 mean=32). In June 2017, orders for Panel A decreased (n=18, 10 ordering physicians). Nine financial consents were returned and specimens shipped for analysis. Panel B orders remained constant (n=30, 9 ordering physicians) in June 2017. **CONCLUSIONS:** Preliminary data suggest billing practice changes could impact physician’s willingness-to-order and patient’s willingness-to-pay for genomic tests. While Panels A and B are imperfect substitutes, these data provide real-world evidence of how GT can be impacted by billing practices.

**PMD117: ASSESSMENT OF INNOVATIVE MEDICAL DEVICES: PROVING THE BENEFIT FOR THE PATIENT – BEST PRACTICES FROM GERMANY AND FRANCE**

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OBJECTIVES: While uniform rules apply for market entry of medical devices in the EU, coverage decisions by Social Health Insurance fall within national competence according to diverse procedures and criteria. Therefore objectives of this analysis are to define what are the key concepts for assessment of innovative devices and how do they reflect inherent characteristics of medical devices. METHODS: Due to the inherent characteristics of medical devices in terms of complexity, learning curve, life-cycle and regulation, determining the benefit of an innovative technology for patient care at the earliest stages might be difficult. Methodology for evaluating innovative medical devices by Institute for Quality and Economic Efficiency (IQWiG) in Germany and the medical devices evaluation committee (CNEDIMTS) in France has been analyzed in a comparative way taking into account key concepts of "innovation", "benefit", and "efficiency". RESULTS: Both countries developed different approaches to bypass the evidence gap inherent to early developmental stage of a device in order to ensure patients fast access to safe and effective medical innovation. In Germany a testing regulation and early dialogue framework have been progressively developed to generate evidence along with the device manufacturer. In France, a fast-track for innovative devices has been designed to accelerate their market access and gain reliable technical data on added benefit for patients. Establishing an innovation pathway at European level based on patient registries to collect uniform data would make valuable contributions to the evaluation and monitoring of such disruptive innovation at early stage. CONCLUSIONS: Development of medical devices is an iterative process and differs from pharmaceuticals. Assessment of innovative technologies should take these specificities into account when assessing added benefit for patients. On that basis, both countries progressively strengthened their legal framework. However in practice it still takes time for innovation to reach the market and be reimbursed.

PMD118: F-CALPROTECTIN USE IN INFLAMMATORY BOWEL DISEASE IS CHARACTERISED BY IMPROVED DIAGNOSTIC ACCURACY, LESS PATIENT HARM AND DECREASED COSTS, COMPARED WITH CONVENTIONAL SEROLOGICAL MARKERS AND COLONOSCOPY. A SIMULATION STUDY IN THE NETHERLANDS AND IN THE UNITED KINGDOM.


OBJECTIVES: Gastrointestinal disorders may exhibit overlapping symptoms making diagnosis difficult in primary care. Inflammatory bowel disease (IBD - prevalence <0.5%) is a chronic inflammation of the gastrointestinal tract. Irritable bowel syndrome (IBS) is a functional disorder without gastrointestinal inflammation (prevalence of 10-20%). Endoscopy is the gold standard to diagnose IBD vs. IBS, but due to IBD’s low prevalence is negative in most of cases. Furthermore, colonoscopy is invasive, expensive, and uncomfortable for the patient and not without risks. F-Calprotectin (FC) is a fecal marker of intestinal inflammation. IBD patients exhibit FC levels significantly higher than the general population whereas IBS patients have FC levels higher than healthy controls, but significantly lower than IBD patients. Therefore, FC can be used as a pre-endoscopic test to differentiate between IBD and IBS. The present study evaluates the cost-effectiveness of a) FC compared to b) CRP+ESR, and c) colonoscopy to distinguish IBD from IBS in the UK and NL. METHODS: A Markov model was developed for each diagnostic strategy; using data from the published literature. 1.6% of the colonoscopies brought about complications, resulting in Emergency Room visits/surgery. Inadequate colon preparation (23%) and consequent repeated colonoscopies (30.3%) were also considered. Outcomes include cost savings, cost-per-corrected-IBD diagnosed, and colonoscopy reduction. Uncertainty was addressed with sensitivity analysis. RESULTS: In NL/UK, FC results in a lower price (average cost/patient: FC =751€/350£; CRP+ESR=1095€/561£; Colonoscopy=1022€/562£), and it reduces the number of unnecessary endoscopies (FC=736 colonoscopies avoided; CRP+ESR=722) and minimizes the associated complication costs, increasing the number of correctly diagnosed IBD (N=63) and IBS (N=26) patients. CONCLUSIONS: Results show that the usage of FC as pre-endoscopic diagnostic tool is associated with fewer colonoscopies and correctly identifies more disease while decreasing costs compared to the alternatives. Consequently, FC demonstrates superior value both from patient and payer perspective, while simultaneously increasing diagnostic efficacy.

PMD119: SPIROMETRY COMPARISON OF LUNG FUNCTION BETWEEN COALMINERS AND NON-COALMINERS

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OBJECTIVES: The study was conducted to assess the lung function of coalminers and non-coalminers by using Spirometer. METHODS: This was case-control study. Total 120 male coalminers and non-coalminers group, 15-40 years of age over than one year of experience. Study was conducted in the tehsil Hernai, district Ziarat, Baluchistan, Pakistan. Self-designed questionnaire and Spirometer were used. The interview was conducted on coalminers and non-miners and facts was documented in the questionnaire and Spirometry was implemented for coalminers and non-coalminers individually. The FVC, FEV1, FEVI/ FVC, FEF25-75% and PEFR were recognized and calculated.
The frequency, percentage, Friedman’s two-way analysis was applied and (P<0.05) detected via SPSS 22 for both groups, coalminers and non-coalminers. **RESULTS:** The mean value of FVC in coalminers was (57.91%) and the mean value in non-coalminers was (66.14%), the FEV1 mean value in coalminers was (63.16%) and the mean value in non-coalminers was (73.09%). The mean value for PEFR in coalminers was (71.89%) and in non-coalminers was (84.61%). The mean value for FEV1/FVC in coalminers was (112.95%) and in non-coalminers was (113.87%), the mean value for FEV25-75% in coalminers was (92.34%) and in non-coalminers was (97.57%). **CONCLUSIONS:** This study determined that no significant difference found between coalminers and non-coalminers. The both group’s values shows typically similar result, but the lung function of non-coal miners was better than the coalminers. The mean value of PEFR, FVC and FEV1 were clearly decreased in coal miners than non-coal miners which should be noticed and if it decreased to 50% or lesser should be hospitalized in time.

**PMD120: WHAT STROKE IMAGE DO WE WANT? EUROPEAN CLINICIAN SURVEY ON ACUTE STROKE IMAGING AND REVASCULARISATION TREATMENT**

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**OBJECTIVES:** The cost-effectiveness of clinical interventions is often assessed using current care as a comparator. However, various imaging and treatment options are available in current stroke care and evidence suggests clinical practice variation in acute stroke imaging across European countries. This research aims to describe the patterns of stroke imaging and acute revascularisation therapy, examine variations across countries and obtain results reflecting current care that will be used in future cost-effectiveness analyses. **METHODS:** A web-based clinician survey was circulated through email distribution lists and websites of European professional societies. The survey focused on stroke imaging and revascularisation treatments. Statistical comparisons were performed in Excel and SPSS, and confidence intervals were estimated using bootstrapping. **RESULTS:** We received responses from Sweden (21), the UK (16), Hungary (15), Germany (12) and elsewhere in Europe (47). Large variations are observed in revascularisation treatment: German respondents report that 81% of their ischaemic stroke patients diagnosed with a large vessel occlusion within 4.5 hours receive intravenous thrombolysis and thrombectomy, while UK respondents report a very low percentage (12%). For patients diagnosed with an extensive ischaemic stroke within 2 hours from onset, 75% of UK-respondents state thrombectomy as their preferred revascularisation treatment, but only 13% report using it. Computed Tomography (CT) is indicated as the most widely used first imaging test (81-93% of patients across geographic areas), while Magnetic Resonance Imaging (MRI) is a distant second (6-26%). Wide variations in terms of proportion of patients and modality used are observed during the second-line imaging test. **CONCLUSIONS:** Revascularisation treatments given to stroke patients vary considerably across Europe, mainly because of barriers to thrombectomy. This study reinforces the need to compare the quality of stroke care in terms of process and outcomes between countries and to improve it. Research is also needed to investigate the cost-effectiveness of second-line imaging strategies.

**PMD121: WHAT ARE THE IMAGES USED TO DIAGNOSE AND ASSESS SUSPECTED STROKES?: A SYSTEMATIC LITERATURE REVIEW OF CARE IN FOUR EUROPEAN COUNTRIES**

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**OBJECTIVES:** The cost-effectiveness of clinical interventions is often assessed using current care as a comparator. However, various imaging options are available in current stroke care and evidence suggests clinical practice variation in acute stroke imaging across European countries. This research aims to describe the patterns of stroke imaging, examine variations across four selected countries and obtain results that will be used in future cost-effectiveness analyses of imaging strategies. **METHODS:** A systematic literature review was conducted. Embase, Medline, Web of Science, the Cochrane Library and Google Scholar were researched in August 2016. The search strategy focused on the current imaging workup used in acute stroke care in clinical practice in Hungary, Germany, Sweden and the UK. Characteristics extracted from these studies included the type and number of health centres and patients, the study design and goal and information about the data found. Information regarding the type and frequency of imaging techniques used was extracted and analysed. **RESULTS:** The literature search yielded 3616 records. Sixteen eligible studies were identified for final analysis. The complete imaging methods used to diagnose stroke patients were poorly documented. Computed Tomography (CT) appeared to be the main diagnostic imaging used in stroke care (for 78 to 98% of patient profiles across the 3 countries over different periods). Magnetic Resonance Imaging (MRI) was reported to be substantially less used. Studies performed in the UK revealed dramatic variations in the proportion of scanned patients and timing of imaging. **CONCLUSIONS:** The imaging strategy...
documentation, the proportion of patients scanned and the timing of imaging is insufficiently described in the literature. The heterogeneity in stroke imaging observed in this study reinforces the need to compare the quality of care in terms of process and outcomes within and between countries. Research is also needed to investigate the cost-effectiveness of different imaging strategies.

PMD122: BOOSTING HOME DIALYSIS UPTAKE BY SETTING FIXED MODALITY CEILINGS: IS IT AN EVIDENCE-BASED POLICY APPROACH?

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OBJECTIVES: There is a global payer tendency to foster the share of home dialysis modalities (HDM) for cost saving purposes, with some countries, e.g. the Netherlands, proposing to set fixed modality ceilings. The aim was to analyse whether this is an evidence-based policy approach considering cost-effectiveness as well as patient preferences and healthcare professionals (HCP) perspectives towards HDM. METHODS: In order to assess current evidence, two systematic literature reviews (SR) were conducted to identify economic evaluations of home vs. ambulatory or hospital dialysis (SR 1) and to explore patient preferences and HCP perspectives (SR 2). To match global with local evidence, we additionally performed qualitative in-depth semi-structured interviews with Dutch dialysis patients and HCP. RESULTS: Of 1056 initial identified studies, twelve economic evaluations (SR 1) were included. The majority of studies reported positive effects on quality-adjusted life years and cost savings associated with HDM. The consecutive patient and HCP HDM preference analysis (SR 2) identified 22 studies revealing (1) patient characteristics and demographics, (2) family situation, (3) patient motivation, and (4) dialysis reimbursement to influence HDM uptake. Interviews generally supported these findings and stressed financial disincentives for providers as a main barrier for increasing patient access to HDM. CONCLUSIONS: Available economic evaluations fail to reflect the complex nature and course of End-Stage Renal Disease. Today’s cost assessments are carried out “situative” and do not incorporate all relevant cost categories. Modality preferences depend on a large variety of factors and thus differ substantially among patients and HCP. Therefore, we conclude that the current evidence only allows limited informed decision-making for policymakers on setting fixed dialysis modality ceilings. Future studies need to crucially consider the patient journey, incorporating the medical/social necessity of modality switch and patient preferences. Further, all associated costs need to be analysed, including informal caregiver burden.

PMD123: CENTRALIZED PROCUREMENT OF MEDICAL DEVICES IN ITALY: A METHODOLOGY TOWARDS STANDARDIZED TENDER DOSSIER

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BACKGROUND: Despite the ongoing trend towards centralized procurement for Medical Devices (MDs) in Italy, the lack of national guidelines translates into heterogeneity of tender specifications and lack of comparability and governability of MDs purchasing processes. OBJECTIVES: To develop a methodology for comparative analysis of tenders for MDs procurement, with the ultimate goal of drafting a national standardized tender dossier. METHODS: The work focused on sanitary gloves. We performed a systematic search and collected documents related to all awarded, expired and ongoing Italian regional tenders from 2015 onwards. We developed an ad hoc extraction protocol of relevant information and performed comprehensive analyses at both dossier and lot level. RESULTS: 13 regional tenders were implemented in 12 out of the 21 Italian Regions during the analyzed period. Both structure and contents of the retrieved documents were highly heterogeneous among the contracting authorities. The characteristics used in lot description were more detailed than those included in the Italian National Classification System of MDs (CND). Consequently, the groups of MDs in the CND include heterogeneous devices. This should be considered in comparative analysis of MDs unit price. Finally, awarding criteria of lots differed substantially among tenders, with quality weighting varying between 30 and 60%. CONCLUSIONS: Tender specifications and criteria should be harmonized among contracting authorities. A higher adherence between classification system and characteristics of the purchased goods is recommended. Finally, technical aspects and quality should have a higher importance in awarding public contracts. Our analysis contributed to the implementation of the procurement of MDs in Italy in several ways. First, the Italian Ministry of Health (MoH) has started a revision of the CND. Second, the authors supported the Italian MoH and Regions in drafting national guidelines for procurement of MDs and a standardized tender dossier for sanitary gloves, aimed at overcoming the current fragmentation in public procurement documents.

PMD124: VALUE OF NEEDLELESS SAFETY DEVICES FOR IV VORICONAZOLE IN PREVENTION OF NEEDLESTICK INJURY (NSI)
OBJECTIVES: In 2010, the European Union (EU) adopted the Framework Agreement on Prevention from Sharp Injuries in the Hospital and Healthcare Sector. Needleless IV infusion technologies to improve healthcare worker safety may be particularly useful. To assess this, we developed an economic analysis of potential impact of needleless prefilled IV voriconazole on reduction of NSI among healthcare workers caring for hospitalised patients treated for fungal infections.

METHODS: A cost-of-treatment analysis was conducted, from an EU hospital perspective, based on literature review and standard publicly available tariffs. Cost data were derived from the literature and included direct costs to manage the prophylaxis and treatment of healthcare workers after an NSI from a high-risk patient, as well as indirect costs associated with the NSI (including work loss). All costs were adjusted to 2016 Euros. Sensitivity analyses were conducted. RESULTS: Rates of NSI were 26–39 per 100,000 exposures. Transmission rates of blood-borne viruses from an infected patient after NSI ranged from 30% with hepatitis B to <1% with HIV. The average direct cost of an NSI was €989, including testing, administration, post-exposure prophylaxis, and treatment costs, with the key direct cost driver being post-exposure prophylaxis costs. Average indirect cost of an NSI was €879, including counselling, work loss and legal fees. Assuming a hospital treats 250 patients annually with two doses per day of IV voriconazole for an average of 10 days, switching to needless prefilled IV voriconazole could potentially prevent 1.30–1.95 cases of NSIs in healthcare workers per year, translating to annual average cost-savings of €2,428–3,642 per 250-patient cohort. CONCLUSIONS: Use of needless technologies helps hospitals protect healthcare workers and comply with NSI prevention laws. This analysis suggests that the reduced risk of NSI with the needleless prefilled IV voriconazole infusion may provide cost-offsets and potential cost-savings to hospitals.

PMD125: NEW EUROPEAN MEDICAL DEVICE DIRECTIVE (MDD) COMES INTO EFFECT IN 2020: CHANCES AND CONSEQUENCES FOR STAKEHOLDERS

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OBJECTIVES: Despite high requirements for approval of medical devices (MDs), several serious and avoidable complications caused by product specific quality deficiencies were observed during the past years. To ensure that all MDs (all classes ranging from heart valves to sticking plasters) are safe, the EU commission proposed in 2012 new regulations on medical and in-vitro diagnostic MDs (e.g. extending the market surveillance, verifying scientific and technological evidence). To assess the effect of the new MDD on four different stakeholders (i.e. manufacturers, regulatory bodies, physicians, and patients) a decision analytical framework has been used. METHODS: Based on a structured analysis the strengths, weaknesses, opportunities and threats of the new MDD have been identified and a qualitative analysis of their occurrence rates was performed. RESULTS: The most often expected consequences by implementing the new MDD are the increased workload and higher product development costs for manufactures, but also an enhanced product safety for patients, higher quality of medical evidence to the attention of regulatory bodies and physicians. Outcomes occurring less often as a consequence of the implementation of the new MDD are a decline of new and innovative products for diseases with a limited profitability or a reduction of small and mid-size manufacturers of MDs either due to buy up by bigger companies or by abandoning the business area. CONCLUSIONS: Overall, the implementation of the new MDD results in a benefit for all stakeholders. Nevertheless, an extended regulation causes also unfavorable consequences. Even though the implementation of the new rule will come into effect in 2020, it is important that all stakeholders anticipate the wide range of potential consequences as early as possible. Therefore, the findings of the decision analytical framework may help to identify areas with a high impact and to develop strategic decisions.

PMD126: REPORTING CLINICAL OUTCOMES IN TAVI REGISTRIES

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OBJECTIVES: Transcatheter aortic valve implantation (TAVI) has been demonstrated to be an alternative treatment for high surgical risk patients with severe aortic stenosis. However, the fast growth of TAVI has created difficulties in cross-study result comparison. In 2011 and 2013, Valve Academic Research Consortium (VARC) published standardized definitions on reporting endpoints in TAVI studies. The objective of this study is to provide an overview of TAVI registries and the reporting of clinical outcomes based on VARC-2 definitions. METHODS: A systematic review of TAVI registries reporting VARC-2 definitions has been performed in line with PRISMA guidelines in PubMed, ScienceDirect, Scopus databases and EMBASE. Based on VARC-2, patients’ characteristics and procedure characteristics, 30-day clinical outcomes, 1-year mortality and composited endpoints were extracted from each registry’s publications. No publication time restriction was used. RESULTS: 20 TAVI registries were identified in our review with an overall sample size of 12,583 patients. 20 TAVI registries used either EuroScore or Society of Thoracic Surgery Risk Score (STS) or both to record patients’ baseline characteristics and case selection. The 30-
day all-cause mortality ranged from 0 to 12.7%. 14 registries reported 30-day cardiovascular mortality, and only 11 registries reported 1-year mortality. Myocardial infarction (MI) should be differentiating into periprocedural MI and spontaneous MI, the author only can identify 11 registries who reported periprocedural MI. The majority of registries have reported complications such as bleeding, vascular complications and new pacemaker implantation. Of all 20 TAVI registries, 30% reported 9 of 9 complications, and 55% missed 1-2 complications. CONCLUSIONS: VARC and VARC-2 definitions are more and more widely used by TAVI registries. Reporting VARC-2 definitions makes cross-registry comparisons more feasible. Since the introduction of VARC, the number of systematic-review and meta-analysis is dramatically increasing. This transparence will provide better evidence to patients and decision makers such as regulatory bodies, payers and HTA agencies.

PMD127: THE EVOLUTION OF NICE MEDTECH INNOVATION BRIEFINGS AND THEIR ASSOCIATED TECHNOLOGIES

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OBJECTIVES: A MedTech Innovation Briefing (MIB) is a document produced by the National Institute for Health and Care Excellence (NICE) designed to help NHS commissioners, patients and clinicians make informed decisions about new medical technologies. Our objective was to establish how MIBs have evolved over time since the publication of the first briefing in February 2014, and to identify trends in the technologies evaluated by this process. METHODS: Structured desk research was conducted. The number of MIBs produced per month was quantified and an analysis on the types of technologies included in the briefings was performed. Areas of interest included regulatory details, contributions from patient groups and specialists, and device cost. RESULTS: The study showed that the number of MIBs produced each year has steadily increased between 2014 and 2016 from 17 to 42. Across all years, devices with a Class IIa or IIb CE mark remained the most common technologies selected for evaluation, as did technologies with a purchasing price between £1,000 and £10,000. Our analysis also revealed that across this timeframe, the majority of MIBs (78%) did not contain comment from patient organisations or carers, however, all briefings contained contributions from three or more specialists. CONCLUSIONS: Whilst the number of MIBs produced each year is increasing, there remains limited patient group involvement in the development process. Due to the absence of a NICE recommendation and NHS funding mandate, MIBs are typically perceived as low profile assessments. This may contribute to the observed limited patient engagement. With the development of MedTechScan to identify technologies suitable for NICE evaluation, the quantity and diversity of MIBs is likely to increase. Implementing the Government’s Accelerated Access Review recommendations to provide funding for medical technologies approved by NICE is expected to raise the status of MIBs.

PMD128: HTA REPORTS IN GENE AND CELL THERAPY PRODUCTS: A SCOPING REVIEW

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OBJECTIVES: The approval of Strimvelis from GlaxoSmithKline (GSK) for treatment of “bubble boy syndrome” raised questions in field of gene and cell therapy products (GCT), whether new models of modified HTA assessment methodologies are needed. The objective of our study is to overview HTA reports in GCTs in Europe and United States (US). METHODS: A scoping review was performed on HTA reports in GCTs from exiting HTA agencies in Europe and US. The assessment reports planned to identify limited within 8 approved advanced therapy medicinal products (ATMPs) from European Medicines Agency (EMA) and 13 approved gene and cellular therapy products (GCTs) from US Food and Drug Administration (US FDA). The Language is limited in English and German. RESULTS: 12 HTA reports have been identified, five from NICE, three from IQWIG, three from HAS and one from LBI. Two reports based on systematic review of clinical studies, which assessed MACI from LBI and NICE. The other assessment reports used methods of experts or committee’s comments on the dossier submitted by the company. Compare to focusing points on safety and efficacy from regulatory bodies, HTA agencies focus on added value and actual benefit comparing to the comparator for current treatment. For example, for assessing a cancer treatment for melanoma called “Imlygic”, both IQWIG and NICE criticized on its comparator, IQWIG needed the company to submit additional three RCTs to prove their added value, NICE also needed one RCT to prove actual benefit, because they suggested the current comparator used in pivotal study is ineffective. CONCLUSIONS: The assessment process for GCTs is similar to other medical products but with more flexibility. For safety concerns, a long-term follow-up observation in a registry is recommended from different agencies. To assess cost-effectiveness, make appropriate health economic model, early involving payers and HTA in the development of GCTs is necessary.

PMD129: ECONOMIC OUTCOMES OF THE ATTUNE® KNEE SYSTEM: ANALYSIS OF REAL WORLD LENGTH OF STAY IN AN ITALIAN HOSPITAL

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OBJECTIVES: Total Knee Arthroplasty (TKA) is a successful, widely-used procedure that provides pain relief and improved function for osteoarthritic patients. Given the increased demand for TKAs, there is a need for meaningful innovation that improves clinical outcomes and optimises resource utilisation. The DePuy Synthes (DS) ATTUNE® Knee System has been designed to improve patient function and satisfaction. The objective of this study was to compare the length of stay (LOS) for TKA patients who received ATTUNE versus the DS SIGMA® Knee System. METHODS: A single center, retrospective analysis was conducted between 2013 and 2015 at a private Italian hospital. 200 consecutive patients from a single surgeon underwent TKA, representing the last 100 SIGMA cases and first 100 ATTUNE cases (post 20 learning curve cases). The primary endpoint was LOS. Electronic medical records were used to collect patient characteristics: age, gender, marital status, ASA grade, prior TKA, and pre-operative Oxford Knee Scores (OKS). Bivariate analyses to compare patient characteristics by implant were generated and a linear regression model was constructed to evaluate LOS as a function of demographic and clinical variables. RESULTS: Patients implanted with ATTUNE demonstrated a 4-day reduction in mean LOS (95% CI 3.5 – 4.5 p<0.0001): ATTUNE: 9.7 (SD: 1.2); SIGMA: 13.7(SD: 1.9). There were no significant differences in reported characteristics between the two groups. The proportion of females (71%) was similar; there were no significant age differences with most patients between 61 and 70. Most patients were married (ATTUNE: 92%, SIGMA: 85%). All patients (100%) had severe preoperative OKS (ATTUNE: mean=9.5 (SD: 3.7); SIGMA: mean=9.4 (SD4.1)), and 22.5% patients had previous contralateral TKA (ATTUNE: 23%, SIGMA: 22%). CONCLUSIONS: Statistically significant differences were noted in the LOS between the two groups. This Real World study demonstrates how the adoption of ATTUNE could potentially benefit providers, payors and patients by reducing LOS.

PMD130: COMPETENCY ANALYSIS OF COMMUNITY PHARMACISTS ABOUT CORRECT USE OF METERED DOSE INHALER

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OBJECTIVES: Asthma is one of major respiratory disorders, requiring the use of corticosteroids and bronchodilators for its treatment. These drugs, in the form of inhaler device, provide quick and prompt relief due to the increased bioavailability. It is the integral responsibility of the community pharmacists to guide the patients about the correct technique of using an inhaler device. The present study evaluated the competency of community pharmacists about the rational use of metered dose inhaler (MDI). METHODS: A cross-sectional study was conducted to assess correct use of MDI by utilizing a 10-items criteria after validation in Lahore, Pakistan. A pseudo-patient approach was used in which one person acted as a patient of asthma requiring inhaler device and the second as the first's caretaker. A total of 100 community pharmacies were targeted by convenient sampling technique. Scoring system was designed based on the critical and noncritical steps. RESULTS: A total of 60 (60%) community pharmacists agreed to participate in this study. Male was the dominant gender (95%) and most practicing community pharmacists (92%) were bachelor in Pharmacy. Nearly 43% community pharmacists were able to counsel the pseudo-patients about how to exhale completely before using MDI. The instruction that patient should wait for 5 to 10 seconds before second puff was skipped by 60% of the community pharmacists. Majority of the pharmacists (37%) counseled only 6 critical steps correctly. Only 3% of the community pharmacists were able to demonstrate all the selected critical steps of the rational use of MDI. CONCLUSIONS: Community pharmacists are not competent enough to demonstrate correct use of inhaler device. The regular training programs by government is needed to be launched for the rational use of drug delivery devices. This will not merely increase the prognosis rate of disease but also the prestige of pharmacists.

PMD131: COST AND OPERATIONAL EFFICIENCY COMPARISON OF AN INTEGRATED VS. A MULTI-STEP SYSTEM FOR EXTRACORPOREAL PHOTOPHERESIS IN GERMANY

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OBJECTIVES: Extracorporeal photopheresis (ECP) is a treatment in which the mononuclear cells of a patient are ex vivo exposed to 8-methoxypsoralen, irradiated with ultraviolet A, and then reinfused into the patient. Two approaches exist for delivering ECP: 1) integrated ECP systems, where all procedure steps are fully integrated and the patient remains connected to the system and 2) multi-step procedures, where separate devices are used for cell separation and photoactivation. Aim of this model was to compare the budget impact of delivering photopheresis with both approaches. METHODS: A decision analytic model was developed in Excel to compare the budget impact of an
integrated with a multi-step ECP system in different scenarios. Scenarios were adjustable by procedure step times, cost parameters, weekly available time and time horizon. Sensitivity analyses were conducted to assess the results. RESULTS: Over one year, the application of one unit of each system results in 780 (integrated) vs. 260 (multi-step) treatments with total costs of €1,152,992 (integrated) vs. €356,612 (multi-step). One treatment cycle of the integrated system costs €1,478 compared with €1,372 for the multi-step system. With an average DRG reimbursement of €3,492 per treatment cycle, the operating costs would constitute 42% (integrated) and 39% (multi-step) of the compensation. Due to higher treatment volume of the integrated system the budget impact presented with +€1,019,461 in net earnings compared to the multi-step system. Varying the cost parameters and procedure step times by +20% (integrated) and -20% (multi-step), the budget impact of the integrated system remained beneficial compared to the multi-step system with +€197,439. CONCLUSIONS: Due to shorter procedure times, integrated ECP systems can achieve more treatments and higher net earnings per year. By applying these fully integrated systems, hospitals could increase efficiency in healthcare delivery for the relevant patient populations. Sensitivity analysis showed robustness of the model.

PMD132: BUDGET IMPACT ANALYSIS OF INCISIONAL HERNIA REPAIRS CONSIDERING POLY-4-HYDROXYBUTYRATE RESORBABLE MESHES

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OBJECTIVES: With the development of newer prosthetics for hernia repair, it is nowadays difficult to understand the total cost of management of patients treated with these advanced medical devices. The aim of this study was to develop knowledge about the economic implications to support “stakeholders” in hospitals in the choices of prostheses offered to patients undergoing abdominal wall repair. METHODS: A budget impact analysis (BIA) model was developed to evaluate the economic consequences of the management of patients undergoing incisional hernia repair (Ventral Hernia Working Group grade 2-3) through synthetic, biologic and poly-4-hydroxybutyrate (P4HB) resorbable meshes, from the hospital perspective in Italy. The model was populated with annual complication rates (recurrence, infected mesh removal, infection, seroma) retrieved from the literature and integrated with epidemiological data (40,000 incisional hernia repairs/year). Hospital costs (€, 2017) for the different complications were estimated on the basis of healthcare resource consumption derived from an e-survey completed by key opinion leaders (KOLs) in 8 Italian Hospitals. The current scenario (60% synthetic, 10% P4HB, 30% biologic meshes) was compared to future hypothetical scenarios considering increasing utilization rates of P4HB meshes in the next 5 years, as estimated by KOLs. RESULTS: A future scenario with utilization rates of P4HB meshes of 25%, 38% and 44% in the next 1, 3 and 5 years would lead to a decrease of the total Italian hospital budget of about 140,000,000€ in the next 5 years, with a saving per patient of about 710€. CONCLUSIONS: Our findings support the use of P4HB resorbable meshes for complex abdominal wall repairs, showing a decrease in the Italian hospital budget after the diffusion of these new biosynthetic prostheses. Further studies and real world data will be able to provide additional information to increase the understanding of the economic sustainability of these advanced devices.

PMD133: HEALTHCARE RESOURCE UTILIZATION AND COSTS FOR TOTAL HIP ARTHROPLASTY: BENCHMARKING THE ANTERIOR APPROACH IN THE MEDICARE POPULATION

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OBJECTIVES: The anterior approach (AA) for total hip arthroplasty (THA) is associated with more rapid recovery when compared to traditional approaches. This may result in economic benefits for patients and the healthcare system. The purpose of this study was to benchmark healthcare resource utilization and costs for patients with THA via AA relative to matched patients. METHODS: We queried Medicare claims data (2012-2014) to identify patients who received THA via an anterior approach from experienced surgeons, and matched these patients to a control cohort (all THA hip approaches/techniques). Direct and propensity-score matching were employed to maximize similarity between patients and hospitals in the two cohorts. Hospital length of stay (LOS), the proportion of patients discharged to home or home health, and post-acute care was assessed. Generalized estimating equations were applied to control for imbalances between the cohorts and clustering of outcomes within hospitals. RESULTS: A total of 1,794 patients (897 per group) were included after patient matching. Patients who received AA had significantly lower mean hospital LOS versus patients in the control group (2.06 ± 1.36 vs. 2.98 ± 1.58 days, p<0.0001). The adjusted proportion of patients discharged to home was nearly 20 percentage points higher in the AA cohort versus the control cohort (87.3% vs. 68.7%, p<0.001). Post-acute claim payments for AA patients were nearly 50% lower than those for control patients ($4,139 vs. $7,465, p<0.0001). CONCLUSIONS: AA patients had significantly lower in-hospital length of stay and post-acute care
biologic grafts (xenograft tissue) are used to provide early reinforcement and remodel over time and rarely need to

OBJECTIVES: Several studies show that targeting factors that constrain efficiency in the operating room can provide important benefits to surgical staff and hospitals. Shorter procedure time with Echo PS™ Positioning System may shorten anesthesia time. Shorter anesthesia duration is associated with reduced length of stay, reduced pulmonary complications, and reduced postoperative infection, nausea and vomiting. Hemia repair with the Echo PS™ Positioning System does not require patients to have pre-placed orientation sutures or an additional trocar for mesh for placement and fixation, avoiding complications related to suturing and additional incisions or trocar use. The primary goal of this study is to compare Echo PS™ positioning system used with Ventralight™ ST vs Flat mesh in Laparoscopic Hernia repair procedures. METHODS: A retrospective analysis of laparoscopic hernia repair procedures using large, medium or small sizes of either Echo PSTM with Ventralight™ ST or mesh without a positioning system for treatment of Ventral Hernia from the Premier Hospital Database in the Outpatient surgical setting was conducted. Laparoscopic hernias (ICD-9 53.62 & 53.63) for patients with a procedure between July 1, 2013 to December 31, 2016 were evaluated. RESULTS: Propensity Score Matching resulted in differences in surgery time by size for Ventralight™ ST with Echo vs Flat Mesh without Echo: Small: 107.9 (N=120) vs 123.5 (N=120), 15.6 minutes, p=0.039; Medium: 105.2 (N=172) vs 106.4 (N=172), 1.26 minutes, p=0.820; Large: 91.7 (N=77) vs 107.0 (N=77), 23.4 minutes, p<0.001. CONCLUSIONS: In this analysis, Ventralight™ ST with the use of Echo PS™ Positioning System has demonstrated reduced procedure time variability in the outpatient surgery setting for all mesh sizes. Reductions in procedure time and variability in procedure time may lead to greater operating efficiencies, start time efficiencies, avoided staffing costs and improved patient satisfaction which may ultimately result in lower healthcare resource use.

PMD135: COST EFFECTIVENESS OF CONTOUR CURVED CUTTER STAPLER IN LOW ANTERIOR RESECTION IN TURKEY

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Objectives: Contour Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device is used for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic and thoracic surgical procedures. The objective of this study is to assess the cost effectiveness of Contour in low anterior resection (LAR) in Turkey. Methods: A simple decision making model was used in assessing the cost effectiveness of Contour. Use of our Contour was compared with non-use. The ICER was calculated as additional cost per avoided complication. The analyses were made from the perspective of the Social Insurance Institution. Cost data regarding the type and frequency of resources used before, during and after LAR and in treatment of complications with and without Contour were obtained from expert views. Complications were listed as recurrence, colostomy, anastomose leakage and wound infection. Epidemiologic data and complication rates were obtained from literature and expert views. Results: Total cost per patient of LAR with Contour stapler was found as 2,894 TRY. Total number of LAR patients for 2017 was estimated as 13,694. Of these patients 8,379 had complications if Contour is not used whereas 1,676 patients had complications when Contour is used. The total annual costs of operations including cost of complications were 54,569,305 TRY and 97,775,068 TRY for LAR with Contour and LAR without Contour respectively. With these results, LAR with Contour dominated LAR without Contour. Conclusions: These results showed that Contour is a cost-effective option LAR in Turkey

PMD136: A RETROSPECTIVE PREMIER DATABASE STUDY TO COMPARE REPAIR OF VENTRAL HERNIA WITH PHASIXTM VS STRATTICETM IN THE INPATIENT HOSPITAL SURGICAL SETTING

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OBJECTIVES: There is no standard treatment for complex hernias or abdominal wall defects. In the United States, biologic grafts (xenograft tissue) are used to provide early reinforcement and remodel over time and rarely need to be
removed for a post-operative infection. The challenge with biologic graft is the cost. They range from $300 - $30,000 depending on size. In recent years Phasix™ Mesh, a fully absorbable synthetic mesh, was introduced into the market to address some limitations associated with biologic mesh. Phasix™ Mesh handles like synthetic mesh, retains its strength throughout the critical initial healing phase and remodels over time. The purpose of the study is to compare the clinical and cost-effectiveness of Phasix™ mesh vs the Strattice™ Tissue Matrix in the inpatient hospital surgical setting. METHODS: A retrospective analysis of inpatient hospital procedures using either Phasix or Strattice for treatment of Ventral Hernia from the Premier Hospital Database was conducted. Rates of post-operative infection, reported as a count and percent of discharges in Adult patients (>18) with a procedure between Q3 2013 to Q4 2016 were evaluated. Total costs for the procedure, re-operations and clinical complications were collected. RESULTS: The analysis produced cohorts of 1,020 for Strattice and 818 for Phasix. Average Length of Hospital Stay (LOS) for Strattice was 11.8 days, SD 18.2 and for Phasix was 7.9 days, SD 12.9. Average Cost of procedure with Phasix was associated with a lower all-cause cost of $9,683 (Strattice: $41,086, SD $80,010 vs Phasix: $31,403, SD $48,392). CONCLUSIONS: Ventral and Incisional hernia repair in patients with underlying comorbid conditions, can result in frequent complications. Lower healthcare utilization and inpatient hospital cost was found to be associated with the use of Phasix compared to Strattice. The research shows that Phasix can be more cost-effective than biologic grafts, such as Strattice.

PMD137: FEASIBILITY ASSESSMENT: THE IMPACT OF A REDUCED OPERATING ROOM FOOTPRINT SYSTEM ON THE RESOURCES REQUIRED FOR INSTRUMENT MANAGEMENT IN DEFORMITY SURGERY FROM AN ITALIAN HOSPITAL PERSPECTIVE


OBJECTIVES: The improvement of intra- and perioperative efficiency has been identified as a focus area for hospital providers as it is related to the potential release and re-allocation of resources. This can be particularly relevant in orthopedics, where procedures can be long and a quick turnover of the instruments may be required. The EXPEDIUM VERSE® Spinal System was designed to enhance operating room efficiency by delivering the functionality of multiple implants in one versatile implant and by reducing the number of instruments to address reprocessing and sterilization costs. The primary objective of this study is to quantify resource utilization related to instrument management for Adolescent Idiopathic Scoliosis procedures with EXPEDIUM VERSE in comparison to currently used traditional pedicle screw systems. METHODS: A single-center, non-interventional feasibility assessment in Italy measured resource utilization related to surgical instrument management for EXPIMUM VERSE and traditional pedicle screw systems in the treatment of Adolescent Idiopathic Scoliosis. Data was prospectively collected. Endpoints included number of instrument units for sterilization, operating room staff time performing set up and clean down, and the total duration of procedure. RESULTS: Use of EXPIMUM VERSE led to a 29% reduction in the number of units sent for sterilization, driven by a 50% reduction in instrument trays required for EXPIMUM VERSE compared to the traditional pedicle screw system. Operating room staff time performing set up and clean down was reduced by over 40%. The total duration of the procedure from first incision to last suture was also reduced. CONCLUSIONS: Use of EXPIMUM VERSE in the treatment of Adolescent Idiopathic Scoliosis leads to efficiency improvements in terms of sterilization and operating room staff time. These benefits could translate into financial efficiencies for hospital providers through operational efficiency. Further research is required to quantify the cost savings on a national level.

PMD138: BUDGET IMPACT ANALYSIS OF P4HB VS PERMANENT SYNTHETIC MESHES IN COMPLEX ABDOMINAL WALL REPAIR IN SPAIN

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OBJECTIVES: Despite advances in surgical technique and prosthetic technologies, the risks for recurrence and infection are high following the repair of incisional ventral hernias. The current standard for reinforced herna repair is synthetic mesh, which may reduce the risk for recurrence in many patients. Patients with comorbidities, contaminated wounds or previous wound infections experience higher rates of surgical site occurrences/infections (SSO/SSI). Mesh choice in Complex Abdominal Wall Repair (CAWR) under the perspective of the Spanish National Health System METHODS: A dynamic excel-based decision-analytic model was developed to assess the Budget Impact of P4HB Mesh use versus Permanent Synthetic Meshes in CAWR, under the perspective of the Spanish National Health System. RESULTS: The analysis covered a 12 month time horizon and assumed 100% use for each
technology. Public databases, as well as published and grey literature were used to estimate model input data. In the base case, a price difference of +1,500€ for P4HB mesh was considered. A tornado analysis was conducted for verification. RESULTS: Compared to Permanent Synthetic meshes, use of P4HB mesh in CAWR resulted in cost savings of 364€ per procedure in Spain. The sensitivity analysis showed robust results for P4HB mesh, even in the most complex scenarios. CONCLUSIONS: Compared to Permanent Synthetic meshes, use of P4HB mesh may lead to potential cost savings in CAWR, under the perspective of the Spanish Health System. Further research is needed in order to better assess rates of clinical complications, as well as the appropriate patient groups where P4HB technology would be most beneficial for patients and health systems.

**PMD139: LENGTH OF HOSPITALISATION AFTER ATTUNE® KNEE JOINT ARTHROPLASTY (TKA) - RESULTS OF A GERMAN RETROSPECTIVE DATABASE ANALYSIS**

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**OBJECTIVES:** Total Knee Arthroplasty (TKA) is increasingly performed and novel designs need to address clinical improvements and cost savings. It was hypothesized that a new knee system – the Attune knee – may result in reduced length of stay (LOS). This study was thus conducted in a real-world setting in a German private clinic to determine LOS of patients with Attune vs LCS implants. **METHODS:** A retrospective chart review from July 2008 to June 2016 was conducted and included all consecutive patients treated with LCS (from July 2008 to October 2013) and Attune (from November 2013 to June 2016). No organizational change took place during the study period and all patients were treated by the same surgical team. Data capture for all patients included sex, age group (41-50, 51-60, 61-70, 71-80), availability of home support, prior contralateral TKA, ASA score and length of stay. Statistical analyses included chi-squared test for differences in patient demographics and presentation, and difference in LOS was evaluated using an ANOVA test. **RESULTS:** A total of 170 consecutive patients were included (85 Attune, 85 LCS), age distribution included 5%, 13%, 30%, 44% and 8% patients in the 41-50, 51-60, 61-70, 71-80 and >80 years age categories, respectively. 18% of patients had previous TKA in the contralateral knee, 68% had support at home and 56% were ASA Grade 3 at time of surgery. There were no significant differences in any of these variables between Attune and LCS cohorts. However, average LOS was significantly lower in the Attune group, from average 10.4 (SD:1.91) for the LCS group to 8.3 (SD:1.79) in the Attune cohort (p<0.001), a difference of 2.1 days (95% CI 2.7 - 1.6). **CONCLUSIONS:** Comparing two cohorts with similar demographic factors, patients implanted with Attune had a LOS on average 2.1 days shorter than patients treated with LCS.

**PMD140: COST IMPACT ANALYSIS OF NEEDLESTICK INJURIES IN INDIA**

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**OBJECTIVES:** Needlestick injuries (NSIs) constitute a serious occupational health hazard because they can expose healthcare workers to infections by bloodborne pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) for the health care workers (HCWs). **METHODS:** MEDLINE was systematically searched, pairing keywords for NSI with outcomes, to identify English-language articles for India. Conference proceedings from past four years were also reviewed. Studies evaluating clinical, patient-centered, economic, and epidemiologic outcomes in NSI were included. Subsequently, a decision tree was developed to estimate and compare the yearly costs incurred while using safety engineered device needle devices (SED) compared to non-SED. For this cost impact analysis, we quantified the annual total direct medical cost per HCW per NSI. **RESULTS:** The prevalence and frequency of NSI in India ranged from 61% to 79.5% and 2.3 to 4.5 per HCW per year respectively. Incidence density was 228.57 per 100 person days. 79.5% to 90.5% HCWs reported having at least one NSI in their career. In a hypothetical cohort of 100 HCWs, costs per HCW per year per NSI episode avoided was ₹ (Indian Rupee) 47,861($744). The components comprising this cost element were costs incurred due to injecting needle, suturing needle, cannula, and other needles, respectively as per the literature. Hence, the breakdown of ₹ 47,861 were estimated as ₹ 23,930 ($370), ₹ 15,794 ($244), ₹ 6,221 ($96), and ₹ 1,914 ($29) due to injuries inflicted by injecting needle, suturing needle, cannula, and other needles, respectively. This is close to the international estimate of median of means for aggregate (direct + indirect) costs $747 (range, $199–$1,691) of one NSI injury episode. **CONCLUSIONS:** The use of SED would surely produce cost savings for hospitals. Government of India initiatives are needed to protect healthcare workers from risk of bloodborne pathogen infections due to NSIs.

**PMD141: COST-EFFECTIVENESS OF PLUROGEL® - A NEW MICELLE-MATRIX-BASED DRESSING WITH 1% SILVER SULPHADIAZINE – IN THE MANAGEMENT OF NON-HEALING WOUNDS**

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OBJECTIVES: Complex wounds present a substantial economic burden on healthcare systems, costing billions of dollars in Europe and the US. The prevalence of complex wounds is a significant patient and societal healthcare concern and cost-effective wound-care management remains unclear. The model compares the following strategies for the wound-types venous, diabetic, arterialized and mixed: PluroGel vs. Silver-dressings, Hydrogel-dressings, Medical-honey, Impregnated-dressings and Good-wound-care (GWC). All reimbursed products, corresponding to the reimbursement rule, were considered. METHODS: Markov-modeling techniques were used to estimate wound healing (=wound closure) according to wound types. The three Markov states included unhealed, healed and death. The model considers treatment changes and relapse. According to treatment specific healing-rates patients may move weekly from the health state “Unhealed” to the “Healed” state. This research utilized the outcomes data of a published 1,036 patient, 10-center clinical-study. A 1-year time horizon was used to determine the number of ulcer-free-weeks and the expected costs of therapies. Healing-rates were derived from a systematic literature review from the medical literature for all wound types and comparators. Cost data represent direct medical costs (2017€) for Austria. The payer’s perspective was adopted and only direct costs of care were considered. Sensitivity analyses were performed to gauge model parameter uncertainty. RESULTS: In all wound types PluroGel is associated with the lowest costs. In venous wounds PluroGel costs amount to 3,771€ (silver-dressings: 4,644€; hydrogel-dressings: 4,538€; medical-honey: 4,676€; impregnated-dressings: 4,324€; GWC: 6,764€). With PluroGel, patients reach the median healing-rate after 17 weeks. All comparators need prolonged healing-time (silver-dressings: 21 weeks; hydrogel-dressings: 21 weeks; medical-honey: 19 weeks; impregnated-dressings: 21 weeks; GWC: 22 weeks). Ulcer-free-weeks of PluroGel account for 31 weeks. All treatment alternatives show significantly fewer ulcer-free weeks (24.5 to 27.5 weeks). CONCLUSIONS: From the Austrian health-care-systems perspective PluroGel is the most cost-effective wound care product and yield potential cost-savings.

PMD142: COST EFFECTIVENESS OF INTELIGENT LIVER FUNCTION TEST(ILFT) FOR INVESTIGATING PATIENTS WITH ABNORMAL LIVER FUNCTION TEST

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OBJECTIVES: Liver function tests are widely used by GPs in UK. Abnormal results from these tests(ALFTs) are common, and are either left uninvestigated further-- potentially overlooking curable liver disease which would otherwise be fatal, or associated with a lengthy process of retesting, referral, costing both the patient and the health services time and resources. iLFT is a semi-automated liver test cascading system with a structured diagnostic algorithm to maximise the efficiency of requesting LFTs. This study undertook a cost-effectiveness analysis of the iLFT decision tool compared to routine practice in Scotland, UK. METHODS: An economic evaluation alongside the trial, and lifetime model undertaken from the perspective of NHS of Scotland. A step wedge design trial was carried out which compared effect before and after intervention. Within trial outcomes are reported as incremental cost per adjusted life years gained in each arm, to account for early detection of Alcoholic Liver Disease(ALD) and Non-Alcoholic Liver Fatty liver Disease(NAFLD). RESULTS: The within trial analysis found costs to be £ 198.99 (95%CI 180.05, 217.94) and £260.14 (95%CI 190.93, 329.35) in routine practice and iLFT arms respectively. Probability of correct liver diagnosis was 0.41 (95%CI 0.37,0.46) in routine and 0.94 (95%CI 0.88,0.99) in iLFT, resulting in an ICER of £17.59 (95%CI 88,126). The lifetime model found an incremental QALY gain of 0.99(95%CI .0843, .115) and a decreased cost of -3127.6(95%CI -3165.53 , -30957.55at) , resulting in an ICER of £-312872. CONCLUSIONS: iLFT has a higher correct diagnosis rate and cost in short-term, in life-time model it dominates.

PMD143: ESTIMATE EUROPEAN CANDIDATES FOR BRONCHOSCOPIC LUNG VOLUME REDUCTION (BLVR) TECHNOLOGIES IN THE TREATMENT OF SEVERE EMPHYSEMA

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OBJECTIVES: Since CE mark was granted to BLVR technologies valves and coils, respectively in 2003 and 2010, procedure volumes grew significantly in Germany which was among the first country to adopt these techniques. Objectives of this research are exploring trend of adoption and estimating the number of candidates for BLVR in 9 European countries. METHODS: we used data from the German Federal Statistics Office databases for the period 2010-2015. This is the only database available in Europe differentiating BLVR procedures to retrospectively draw therapy uptake. Having valves two different indications, we excluded codes associated to the implant of 1-2 valves being mainly used to treat air leak. For coils we computed code-specific volume and we approximated the number of patients treated per year using average number of units per procedure from literature. RESULTS: Our analysis
suggests a pronounced growth in BLVR treatments in the study period, reaching an adoption rate of 23 patients per million inhabitants in 2015 in Germany across 146 different clinics with 73 clinics performing less than 10 procedures; by excluding outliers clinics (<3 and >100 procedures) the average number of procedures per clinic per year is 17 . Under the indication of severe emphysema, nearly 10,000 patients per year can be considered for BLVR in the 9 selected European countries by applying a scenario similar to the German one. CONCLUSIONS: Since CE mark several new trials and Health Technology Assessments were published helping physicians optimise patient selection and driving the inclusion of BLVR technologies in the clinical guidelines. The reality is that with few exceptions the adoption of BLVR techniques outside Germany is still on its infancy. Many factors can influence diffusion: guideline adoption, physicians’ awareness, capacity, organisational factors, referral pathways, socio-economic indicators and coverage recommendations.

PMD144: COST-EFFECTIVENESS ANALYSIS OF A POINT-OF-CARE TEST FOR RENAL FUNCTION MEASUREMENT IN COMMUNITY PHARMACIES IN THE NETHERLANDS TO PREVENT ANTIBIOTIC-RELATED HOSPITALIZATIONS

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OBJECTIVES: Medication errors that lead to adverse drug effects are an important source of unintentional patient harm and economic burden. A decreased kidney function is one of the risk factors for (preventable) drug-related hospital admissions. The incidence of renal impairment is increasing, thus medication monitoring will become more important. However, within public pharmacies, there is large number of unknown or outdated kidney function values, that can lead to an overload of signals from medication monitoring, which leads to alert fatigue. To reduce this problem, Point-of-Care tests can be introduced in public pharmacies. The objective of this study was to estimate the cost-effectiveness of a POCT creatinine meter for renal function measurement in community pharmacies in the Netherlands, to prevent antibiotic-related hospitalizations. METHODS: The introduction of the POCT was compared with the standard of care in public pharmacies according to antibiotic prescriptions in case of impaired kidney functions. A decision tree was used to assess the process of an antibiotic prescription in public pharmacies and the possible consequences, based on real-life patient data. Direct costs of renal function screening, antibiotic treatments and medical care due to antibiotic-related hospitalization were included. For completeness, univariate and probabilistic sensitivity analysis were performed. RESULTS: The intervention is deemed cost-saving and provides healthcare gains, with the probability of being cost-effective of 81.1% for every threshold willingness to pay. The budget-impact analysis shows that the introduction of the POCT in community pharmacies will save €95.38/patient each year. CONCLUSIONS: The results indicate that the introduction of the POCT in public pharmacies in the Netherlands is cost-saving. In addition, we estimate a positive budget impact due to anticipated cost-savings per patient.

PMD145: COST-SAVINGS IN PROCESS INNOVATIONS; A CASE EXAMPLE IN MYOCARDIAL INFARCTION PATIENTS

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OBJECTIVES: In the recent New England Journal of Medicine published COMPARE-ACUTE trial it was demonstrated that full revascularization, a process innovation, for patients with ST-elevation myocardial infarction (STEMI) results in less revascularisations compared to a conservative approach, treatment of the infarct-artery only. The primary objective of our analysis was to explore whether this complete revascularization in the acute setting of STEMI treatment is cost saving compared to the infarct-artery only treatment strategy from a health care payer perspective. METHODS: We analyzed all health care consumption regarding procedures and complications from the previous COMPARE-ACUTE trial. This health care consumption was directly linked to the respective reimbursement approaches and unit costs from five different countries. Average costs per patient and per treatment arm were calculated. A hypothetical scenario analysis was performed in which costs of the index procedure were increased with 15% to account for the increased number of stents, and additional procedure time. RESULTS: In all of the countries included in this study full revascularisation reduces average costs of patients identified with STEMI. Total cost savings varied between €1.022 (21%) in Germany up to savings of €4.148 (23%) in the US. With the hypothetical increase of 15% for a PCI we continue to see savings of up to €2.146 (12% per patient in the US). CONCLUSIONS: Complete revascularisation in STEMI patients is a cost saving strategy from a health care payer perspective as it decreases the total number of PCI’s in hospitals per patient. Although this strategy is cost saving, it is assumed that there is a reluctance to implement in countries with Diagnosis Related Group systems.
Therefore, financial disincentives should be addressed or removed before society and patients will benefit from such so-called process innovations.

**PMD146: HOW TO AGGREGATE VARIOUS VALUES OF MEDICAL DEVICES INNOVATION?; A REVIEW OF EMPIRICAL WORK**

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**OBJECTIVES:** Value Appraisal Standard (VAS) system was introduced to recognize the premium value of innovative medical devices in Korea since 2006. To better innovation value recognition, VAS was revised and placed into official regulation effective in January 2015. The purpose of this review was to analyze how VAS contributes to value-based decision making in Korea. **METHODS:** VAS is evaluated by clinical usefulness, cost effectiveness, and technology innovation. Two tracks exist for the VAS based on the evidence requirement for appraisal. Track A is for ones that have submitted clinical study literature and its maximum premium rate is 100%. Track B is for ones that have submitted technical file. Premium rate is calculated by multiplying weight and score in each category and summate total scores. All results of VAS from 2015 to March 2016 were reviewed and classified per appraisal track. The results were further assessed per the category and how the value for each category contributed to the decision-making. **RESULTS:** The total applied for VAS was 34, but 11 of them were excluded and 23 were appraised by HIRA (Health Insurance Review and Assessment Service). Only 6 of them were granted 10~30% premium rate. Classifying the applied products by the type of Tracks, the appraised rate was much higher for Track A. Track A was appraised by 78%, while Track B was appraised by 29%. Also, looking at the number of products which were granted premium rates, only 1 product in Track B got a 10% premium rate. Considering the type of sources accepted as evidence, most of them were Clinical Study Report and Expert Opinion. **CONCLUSIONS:** Currently, VAS has lots of area to improve since decision is made by clinical evidence rather than value in technical innovation of Medical Devices. The holistic approach in decision-making is required for better patient access.

**PMD147: OPEN TIBIAL FRACTURES WITH SEGMENTAL DEFECTS: A U.S. RETROSPECTIVE DATABASE ANALYSIS EXAMINING 12-MONTH POST-OPERATIVE PATIENT OUTCOMES AND COSTS**

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**OBJECTIVES:** Segmental bone defects may result from trauma, infection, and malignancy. For bone defects >3cm, treatment typically involves a masquelet within a two-stage surgical technique. This study evaluates postoperative outcomes, costs, and risk factors associated with this procedure. **METHODS:** A retrospective database analysis using the Truven Commercial Claims and Encounters database was designed to include patients with open tibial and/or fibular fractures (“index”) from 2007 to 2016 and ≥ 12-months continuous enrollment post-index. Patients were categorized as “Severe” if they had saucerization and/or insertion of a non-biodegradable drug delivery implant (CPT-4 codes 26540, 11981). All other patients were identified as “Other”. The Severe and Other cohorts were tracked longitudinally for non-union, malunion, infection and post-index amputation. All healthcare encounters with orthopedic diagnoses were identified and cost of care was estimated for each patient over 12 months. **RESULTS:** 4,522 patients were included in the study, (n=416 “Severe”; n=4106 “Other”). Rates of obesity, diabetes, smoking, and osteoporosis was 14%, 14%, 17% and 7%, respectively. Twelve-month rates of nonunion, malunion, infection and amputation reached 74.7%, 19.5%, 58.0% and 16.2%, respectively, in the Severe cohort vs. 29.8%, 7.2%, 16.0% and 3.5%, respectively, in the Other cohort (p<0.05 for all outcomes). Index admission costs reached $116,115 (SD $196,473) in the Severe cohort vs. $66,985 (SD $117,183) in the Other cohort, and mean post-index costs were $101,912 (SD $103,901) for Severe vs. $23,553 (SD $52,046) for Other. Across both cohorts, smoking, osteoporosis and obesity were associated with greater odds of nonunion. All risk factors were associated with greater odds of infection, the greatest being smoking and osteoporosis. **CONCLUSIONS:** Open tibial fractures are associated with high complication rates and significant post-operative costs. Complications are significantly associated with pre-existing diagnoses of smoking and osteoporosis. Further understanding risk factors is important to provide targeted, value-based care.

**PMD148: RETROSPECTIVE ANALYSIS OF PATIENTS TREATED WITH COMPUTER-ASSISTED EXTERNAL RING FIXATORS: A DESCRIPTIVE ANALYSIS OF PATIENT DEMOGRAPHICS, HEALTHCARE UTILIZATION, AND COSTS IN THE U.S.**

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OBJECTIVES: Computer-assisted (CA) circular ring fixators are often used in complex long-bone procedures. Postoperative complications include, nonunion, infection, re-fracture, implant failure, pain, and post-traumatic arthritis and may result in residual deformities requiring repeat procedures. Rates of residual deformity range from 15%-45% in the literature. Significant variability in patient outcomes are reported often due to small patient cohorts. This study provides a descriptive analysis of patient demographics and healthcare resource utilization (HRU). METHODS: A retrospective analysis was conducted using the Truven Commercial Claims and Encounters database (2007 to 2013). Patients had an index procedure requiring application of multiplane, external fixation system (CPT-4 20692,20696) in the inpatient setting and at least 12-months continuous enrollment post-procedure. This analysis includes patient demographics, primary diagnoses, HRU, and costs. HRU and costs were evaluated in the perioperative and 12-month post-operative time periods. All costs were adjusted for inflation to 2015 price index. RESULTS: 1,542 patients were included in the study. Index surgery cost was estimated at $42,909 (SD $59,117) for adults and $50,180 (SD $52,162) for pediatric cases. The most common reasons for unplanned readmissions were surgical complications (78%), nonunion (58%), and fracture (58%). Mean costs of readmissions ranged from $28,000-$68,000 per readmission for adults, and $12,000-$37,000 for pediatrics. Post-index procedures were defined as visits and/or encounters or tests with distinct dates (“events”) and ranged from 32.6 events in patients with no complications to 40.7 events for patients with non-union. Post-operative outpatient care resulted in significant costs, ranging from an average of $18,378 (SD: $18,869) to $30,426 (SD: $32,162). Total 12-month costs per patient reached an average of $98,194 for adults (SD: $100,355) and $88,987 for pediatric cases (SD: $79,250). CONCLUSIONS: Using CA circular ring fixation is complex and costly. Further research to understand risk factors may help reduce costs while increasing quality of care.

PMD149: FEASIBILITY AND ACCEPTABILITY OF ATRIAL FIBRILLATION SCREENING USING A HAND-HELD ECG DEVICE IN GENERAL PRACTICE SETTING IN HONG KONG

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OBJECTIVES: General practitioners (GPs) can play an important role in atrial fibrillation (AF) screening but 12-lead ECG is not ready available in most GP clinics in Hong Kong. We evaluated the acceptability of AF screening using a handheld ECG device with automated AF diagnostics in GP setting in Hong Kong. METHODS: Patients aged ≥65 years underwent AF screening in 9 GP clinics using a handheld single-lead ECG device (AliveCor) between March 2015 and June 2016. All ECGs were over-read by a cardiologist. Primary outcome was the prevalence of newly diagnosed AF. Patient and GP’s awareness and acceptability of AF screening was assessed. RESULTS: A total of 1041 patients age ≥65 years were screened. Overall AF prevalence was 2.6% (n=26) and newly identified AF 1.5% (n=15). Mean age of newly diagnosed AF patients was 77±6.7 years with mean CHA2DS2-VASc score of 3.9±1.6. Among patients with known AF, 45.5% were prescribedoral anticoagulants (OAC) (18.2% warfarin, 27.3% NOAC) and 54.5% antiplatelet therapy. Patient awareness of AF was low with 36.4% unfamiliar with AF and 63.6% unaware of the risk of AF related stroke (even in patients on OAC). All patients agreed handheld ECG was easy to operate and willing to undergo repeated screening in future GP visits. 86% of GPs considered handheld ECG was useful for AF screening and would use it in their daily practice. At baseline, 47% of GPs used CHA2DS2-VASc score to assess AF related stroke risk which increased to 71% at the end of the study. CONCLUSIONS: AF screening using handheld ECG was feasible in a GP setting and acceptable to both GPs and patients. A significant number of newly diagnosed AF and known AF but undertreated patients were identified who would be suitable for OAC therapy for stroke prevention. Improvement in AF awareness may promote the benefits of AF screening.

PMD150: REDETS. 10 YEARS OF FULL ECONOMIC HEALTH TECHNOLOGIES ASSESSMENTS (MEDICAL DEVICES) IN SPAIN (2006-2016)

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OBJECTIVES: RedETS, created in 2006, is the Spanish network of health technology assessment agencies. The objective of this work is to describe and assess the quality of the full economic evaluation reports carried out by RedETS on medical devices (FEEMD). METHODS: The FEEMD were identified through the RedETS website publications database. Assessments about screening technologies were not included. The characteristics of FEEMD were analysed using a formal RedETS HTA quality checklist. The characteristics extracted were analysed through a descriptive univariate analysis. RESULTS: 26 FEEMD were found. The publication years were distributed quite uniformly over time (approximately 2/year), although 7 were published in 2008 and 7 in 2013. 13 studies analysed
cost-utility, 10 cost-effectiveness but not utility and 3 both. The most frequent Medical Devices (MD) class analysed were "In vitro diagnosis MD" (n = 8) and Class III products (8). The most frequent sources to analyse effectiveness were literature (22) and data collected through ad-hoc studies (6). The main unit costs sources were official public tariffs (14), manufacturers direct values (10) analytical accounting of one/more centres or regions (11) and DRGs (7). In relation to the modelling used, 14 evaluations performed Markov models and 7 decision trees. The perspective of 23 studies was that of the National Health System (NHS), and the rest corresponded to the perspective of a specific region (2) or social perspective (1). All studies analysing time horizons greater than 1.5 years, except for 1, applied discount rates in the modelling. All studies included a sensitivity analysis. CONCLUSIONS: The economic evaluations of MD published by the RedETS accomplish most of the quality checklist aspects and are therefore exhaustive. These FEEMD have been used in the framework of decision making for an efficient management of the NHS basic portfolio.

**PMD151: THE ROLE OF MEDICAL TECHNOLOGIES IN REVOLUTIONISING THE NHS IN ENGLAND: A REVIEW OF SUSTAINABILITY AND TRANSFORMATION PLANS (STPs)**

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**OBJECTIVES:** Local health and social care organisations across England have been tasked by UK Government to collaboratively design "place-based plans" to ensure the sustainability of health and care services in their area. Our objective was to establish the ambitions of the 44 "footprint" areas regarding the increased use of technology to establish the importance of medical technologies in transforming the future NHS. **METHODS:** A review of the proposed use of technology in each of the 44 STPs was undertaken. Data was collected on the key priorities for digital transformation, the types of technology included in the plans and the provider sectors highlighted as candidates for technological advancement. Mention of local digital roadmaps, which are 65 separate area plans for digital transformation in the NHS, were also noted. **RESULTS:** Local digital roadmaps were included in 39 (89%) STPs, however, only five STPs referenced the “Personalised Health and Care 2020” framework which outlines the Government’s commitments to data and technology transformation. Telehealth and remote monitoring, particularly for the management of chronic conditions, were among the most popular areas selected for advancement and over half of the STPs (61%) included plans to integrate mobile applications into care delivery. Only one STP proposed collaboration with NHS Digital. **CONCLUSIONS:** Whilst the scope of STPs is broad, the motives for increasing the use of technology were limited, with many STPs focusing on technological advancements solely as a means of improving care planning and co-ordination. Despite this, a recurring theme throughout the plans was that sharing patient data between provider sectors has the potential to offer both time and cost savings across the NHS. Future challenges in delivering technological transformation include unifying local digital roadmaps within a single footprint area, and collaboration across footprint areas to reduce variations in quality of care.

**PMD152: EXAMINING GLOBAL OCCURRENCE OF COMPLICATIONS RELATED TO PERIPHERAL IV CATHETERS USING A FOCUSED LITERATURE REVIEW**

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**OBJECTIVES:** The peripheral intravenous catheter (PIVC) is one of the world’s most frequently used medical devices, with an estimated annual volume of 2 billion units sold globally. This study aimed at acquiring a holistic understanding of publications investigating PIVC-related complications worldwide by conducting a literature review and preliminary data analysis. **METHODS:** A systematic literature review, using key terminologies in the PubMed advanced search engine, was executed with timeframe set to 2005 onwards. Key articles outside the analytical framework were added by clinical experts in the Becton Dickinson (BD) catheter team. Complications examined in this review included catheter-related bloodstream infection (CRBSI), catheter-related infections, bacteremia, occlusion, thrombosis, phlebitis, infiltration, extravasation, and dislodgement. **RESULTS:** The initial review identified 13,251 articles written in English and 11 additional articles were contributed by the BD internal repository. 985 articles were excluded before full-text examination with key outcomes other than PIVC-related complications, and/or with nonhuman subjects. Ultimately, 84 articles met inclusion criteria with data available for extraction, while the remaining 12,277 did not. PIVC-related complication rate was described under three units: % of catheters, % of patients, and per 1,000 catheter days. Complication rate in the same unit were weighted with study sample size and reported as weighted averages and are as follows: CRBSI: 4.33%, catheter related infections: 4.12%, bacteremia: 9.32%, occlusion: 6.87%, thrombosis: 7.00%, phlebitis: 13.60%, infiltration: 31.49%, extravasation: 5.30%, and dislodgement: 5.70%. Outliers include the neonatal population and a healthcare facility inside a developing nation. Complication rates under % patients and per 1,000 catheter days also showed similar burden. **CONCLUSIONS:** Given the widespread use of PIVCs, magnitude and implications of PIVC-related complications might be understated. As use of PIVCs continues to increase due to aging populations and prevalence of chronic diseases, more in-depth analyses and real-world studies are needed to understand and confirm actual burden.
**PMD154: COMPARISON OF CATHETER-RELATED COMPLICATIONS BETWEEN MANUALLY-PREPARED SALINE FLUSH SYRINGES AND COMMERCIAL AVAILABLE PRE-FILLED SALINE FLUSH SYRINGES**

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**OBJECTIVES:** Intravenous catheterization in hospitals are extremely common, and though necessary, can put patients at risk of developing catheter-related complications, such as catheter related blood stream infections (CRBSI), occlusions, and extravasation. Flushing and locking are the primary interventions used to reduce these complications. The objective of this study was to analyze differences in catheter complications using manually-prepared and pre filled saline syringes. **METHODS:** A comprehensive literature search was conducted using PubMed, Embase, Ovid Medline, Cochrane library and conference presentations, with a timeframe of 2005 and beyond. Inclusion and exclusion criteria were applied, studies reporting the outcomes of interest after flushing central vascular access devices (CVADs) and peripheral intravenous catheters (PIVC) were analyzed. Burden was reported as % catheters, and % patients. All pre-filled saline flush syringes used in the studies were BD PosiFlush.TM **RESULTS:** Over 18,000 studies from the literature review were analyzed. 45 articles were included in the final analysis after checking for duplication, and relevance. 27 articles were related to CVAD, while 18 were PIVC focused. In the CVAD setting, pre-filled saline flush syringes showed reduction in CRBSI rate / % catheters (3.01% vs 2.70%) and CRBSI rate/ % patient (2.92% vs 1.67%) as well as reduced occlusion rate (4.7% vs. 5.8%) per % catheters when compared to manually-prepared saline flush syringes. In the PIVC setting, pre-filled saline flush syringes showed better outcomes than manually-prepared flush syringes for occlusion rate/ % patient (6.05% vs. 15.40%) and extravasation rate/ % patients (2.5% vs. 34%). **CONCLUSIONS:** The analysis shows that BD PosiFlushTM syringes improve serious outcomes such as occlusion, extravasation, and CRBSI complications compared to manually-prepared saline flush syringes in both CVAD and PIVC settings. This helps maintain better catheter patency and continuity in therapy in catheterized patients.

**PMD155: A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS IN ROBOT-ASSISTED HYSTERECTOMY USE FOR CERVICAL CANCER COMPARED WITH OPEN AND LAPAROSCOPIC SURGERY**

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**OBJECTIVES:** To systemically assemble the evidence on the cost-effectiveness of robot-assisted hysterectomy (RAH). **METHODS:** Scope research at the electronic databases for PubMed, MEDLINE, EMBASE, NHS EED, NHS HTA, CNKI and WanFang from 2012 to 2016 in both English and Chinese. The reviewing for the papers were retrieved by certain inclusion and exclusion criteria. Quality of the included studies was assessed against a critical appraisal checklist for economic evaluation. Methods and results of identified studies were assessed to reveal the deficiencies in current evidence and present areas need to explore. Cost of intervention, determinants of cost (including length of hospital stay, operating time and cases per annum), quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratio (ICER) were extracted. Costs were discounted into 2017 US dollars. **RESULTS:** Eleven eligible studies were identified (health technology assessment report n = 1, systematic review n=2 and primary study n = 8). The total cost of RAH was recognized consistently higher than the alternatives, when included the purchasing robot and maintenance fee. It also varied from US$2,872 to over US$13,000 in different health system context, in which costs were considered differentially. Additionally, one of the key determinants of the costs in differences were the capital cost of the robotic system, its life span, and number of times of the surgical equipment. One unpublished multi-center survey study from China shown the estimate the cost should between US$6,311 and US$ 6,898 per person with 200 cases per annum as assumption. **CONCLUSIONS:** The available clinical evidence for long-term effectiveness of RAH is limited. RAH costs were consistently higher than open and laparoscopic surgery and varied substantially between health systems. Therefore, the health decision makers need to take into account the cost-effectiveness of RAH by adaption and trying to benchmark the results for international comparisons.

**PMD156: DOES THE NICE DIAGNOSTICS ASSESSMENT PROGRAMME USE AN EMPirical ICER THRESHOLD?**

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**OBJECTIVES:** Technologies used for diagnosis, monitoring, risk stratification and screening are an integral part of efficient healthcare systems. The NICE diagnostics assessment programme (DAP) was established in 2009 to promote consistent adoption of innovative and cost-effective diagnostics in the UK NHS. The objective of this study
was to establish the empirical cost-effectiveness threshold for diagnostics evaluated by the DAP and to assess the importance of the ICER in decision-making. METHODS: All NICE DAP assessments published before June 2017 were included; the guidance document and diagnostics assessment report (DAR) were reviewed. The type of technology, disease area, adoption decision, rationale for decision, ICER and research recommendations were extracted. RESULTS: Based on the 27 DAP assessments reviewed, there were 17 positive, 9 negative and 11 neutral recommendations (insufficient evidence). Multiple technologies were often evaluated within the same DAP assessment, and separate recommendations were sometimes given for different technologies or indications. Approved technologies were dominant, associated with QALY gains at costs of up to £85,300/QALY or associated with QALY losses at cost-savings from £4,324/QALY lost. Low ICERs, cost-savings and non-health related benefits were quoted as reasons for approval. Rejected technologies had on average higher ICERs (median: £1,468,175, range: £4,148–£15,000,000) compared to approved technologies (median: £21,127, range: £319–£85,300), but could also be dominant. Rejection decisions were often due to high ICERs, insufficient evidence or poor robustness of the model; the latter two reasons were grounds for rejection despite a cost-effective ICER. CONCLUSIONS: The DAP assessments reviewed were often limited by insufficient evidence and high levels of decision uncertainty. The ICER threshold of £20,000–£30,000 seemed to be mostly adhered to when recommending diagnostic technologies. However, the ICER was not the only determining factor, as non-health related benefits, including patient preferences, convenience and anxiety, were also considered by the committee when approving technologies despite high ICERs.

**PMD157: HOW SHOULD WE TEST FOR PRE-TERM LABOUR? AN ECONOMIC MODEL AND COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** Develop a prognostic model including quantitative fetal Fibronectin for predicting pre-term labour and assess its cost-effectiveness. METHODS: Based on data derived from four European studies comprising 1,835 women and 171 events of preterm delivery in the QUIDS IPD meta-analysis, a decision analytic model assessed the cost-effectiveness of alternative prognostic strategies. Costs and probability of correct diagnosis were calculated for each strategy, and expressed as net monetary benefit (NMB). Strategies included (i) clinical risk factors alone (CR) (ii) CR plus fetal-fibronectin (fFN), (iii) CR plus quantitative fetal-fibronectin (qfFN), (iv) CR plus transvaginal ultrasound of cervical length (TUCL), (v) CR plus fFN plus TUCL, and (vi) CR plus qfFN plus TUCL. The cost-effectiveness of each strategy is modelled over three gestation periods: extremely premature (<28 weeks), very premature (28-32 weeks), and premature (32-37 weeks). RESULTS: qfFN testing dominated fFN in all three gestational periods with a lower mean cost per patient and greater probability of correct diagnosis at 7 days. qfFN had the greatest NMB for the Extremely Premature model (£17,301 (95% CI: £16,818 – £17,7750) per correct diagnosis), while in the Very Premature model TUCL had the greatest NMB (£16,375 (95% CI: £15,670 – £17,028) per correct diagnosis), while qfFN + TUCL had the highest NMB in the Premature model (£17,199 (95% CI: £16,236 – £17,965) per correct diagnosis). CONCLUSIONS: Current NICE clinical guidelines support the use of TUCL for predicting pre-term labour in women ≥30 weeks pregnant. Our findings support this recommendation in Very Premature women, however, the optimal choice between qfFN and TUCL varies across the three gestation periods.

**PMD158: POCT COST EFFECTIVENESS CASE STUDY ON THE WAY TO A HB-HTA UNIT**

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**OBJECTIVES:** In Motol University Hospital in Prague, POCT, point-of-care testing, was selected to test the possibilities and limits of HB-HTA. POCT producers usually adapt the technical solution to the fact that the devices are operated by staff without special laboratory skills; they make operation simpler and the device design more user-friendly. All maintenance of POCT is usually left to the producer or supplier, and the only requirement from the payer’s part is a participation in external quality control, while the hospital’s biochemistry laboratory is responsible for quality management. A POCT acid base balance analysis system was implemented in the Hospital some years ago. The study was initialized as the system requires some changes in laboratory, technical and economic processes. The task of the HB-HTA study was to assess the cost-effectiveness of POCT after several years of implementation. METHODS: The survey was done in 18 hospital departments, where the acid base balance analysers have been operated. Patient data (without identification of particular patients) were collected retrospectively from January 2012 through November 2014, completed with interviews with ward sisters from all 18 departments. Effects and costs were analysed using Saitty’s matrix. RESULTS: The total financial balance was positive in all years; hence, the analysers (as a whole) can be labelled as profitable. Analysing each department individually, nine departments showed negative results at least in one year of the study, above all due to purchase of reagents and
consumables. A frequent reason was also that some checks were not reimbursed by insurance companies due to non-observation of negotiated limits. **CONCLUSIONS:** The survey pointed at a non-controlled and insufficiently regulated operation of the analysers. The HTA study showed that the acid base balance POCT process must be modified and better controlled. The study is encouraging establishment of a HB-HTA unit in the Hospital.

**DISEASE-SPECIFIC STUDIES**

**CARDIOVASCULAR DISORDERS - Clinical Outcomes Studies**

**PCV1:** **STATIN INDUCED CATARACT IN CARDIOVASCULAR PATIENTS: A RETROSPECTIVE COHORT STUDY OF A TERTIARY HEALTHCARE FACILITY**

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**OBJECTIVES:** To assess the effect of statins on cataract development when used for secondary prevention. **METHODS:** Retrospective cohort study based on the hospital database of patients aged ≥ 30 years, without any previous statin prescription and admitted in the Department of Cardiology for a major cardiovascular events or procedure between 1st January 2009 and 31st December 2013. Two cohorts were constructed for the analysis of the study: one for study cohort (newly prescribed statin users) and another for a reference cohort (without statin users). Among 561 patients met study criteria, we identified 429 were as statin users and 132 were non-users. We took the date of entry into study cohort as the date of first statin prescription (index date) and the date of exit as the date of subsequent admission/diagnosis for cataract, date of death or ending date of the study, whichever will be the earliest. We calculated incidence rate and relative risk of cataract in the cohorts. **RESULTS:** The incidence of cataract among statin users and statin non-users are 16.8% and 4.5% respectively. Risk of developing cataract in statin users is 3.692 times more than statin non-users. There is a positive relation between duration of statin use and development of cataract. The relative risk of development of cataract among patients treated with rosuvastatin was found to be 0.972 times more than atorvastatin users. **CONCLUSIONS:** There is a higher incidence of cataract among statin users in cardiovascular patients. The risk of development of cataract is more among statin users than non-users. There is a relation between the duration of statin use and development of cataract. Rosuvastatin has higher risk of causing cataract than atorvastatin. We calculated number needed to harm (NNH). On average, 8.1 patients would have to receive statin for one additional patient to develop cataract.

**PCV2:** **LONG-TERM HEALTH BENEFITS OF TREATING NON-VALVULAR ATRIAL FIBRILLATION WITH APIXABAN VERSUS VITAMIN K ANTAGONISTS IN GERMANY: A POPULATION-BASED MODELLING STUDY**

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**OBJECTIVES:** Patients with non-valvular atrial fibrillation (NVAF) are five times more likely to suffer a stroke, resulting in enormous personal, social and economic costs. For more than 50 years, vitamin K antagonists (VKAs) have been the primary medication for stroke prevention. Nevertheless, VKA therapy requires frequent monitoring, is limited by a narrow therapeutic window and is associated with an increased risk of bleeding. Apixaban, a non-vitamin K oral anticoagulant (NOAC), has shown superior efficacy and reduced risk of major bleeding compared to VKA in the ARISTOTLE trial. In this study we extrapolate the health benefits of apixaban compared to VKA therapy to the German NVAF population to quantify the potential societal effects of apixaban from 2017 through 2030. **METHODS:** We estimated the size of the apixaban population according to a claims-data based analysis in Germany and the predicted market share of apixaban. A Markov model based on the ARISTOTLE trial comparing apixaban and VKA for anticoagulation was applied to the German social health insurance (SHI) data to calculate the occurrence of strokes and systemic embolisms (SE), major bleeds and deaths on the patient level. To extrapolate the results of the Markov model to the entire German NVAF population, we created a dynamic population model. It links population forecast with epidemiological data and uses the event risks from the Markov model to quantify the potential for reducing mortality and morbidity. **RESULTS:** In comparison to VKA therapy the administration of apixaban prevents 52,185 additional major clinical events in the assumed German NVAF population from 2017 through 2030. This includes 15,383 non-fatal strokes or SEs, 22,483 non-fatal major bleeds, and 14,319 deaths, corresponding to 109,887 gained life years. **CONCLUSIONS:** We showed that utilization of apixaban instead of VKA for stroke prevention can lead to considerable reduction of mortality and morbidity in the German NVAF patient population.
PCV3: NO EVIDENCE FOR AN ASSOCIATION BETWEEN RENAL FUNCTION AND BLEEDING EVENTS IN PATIENTS ON COUMARIN THERAPY: A POPULATION-BASED STUDY

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**OBJECTIVES:** Although anticoagulation therapy is closely monitored by regional anticoagulation clinics in the Netherlands, coumarin induced over-anticoagulation is still observed and associated with serious bleeding events. Current literature suggests that these medication-related hospital admissions might be due to renal impairment. The objective was to explore the association between renal function and bleeding events in patients on coumarin therapy. **METHODS:** A nested case-control study was conducted using data from the PHARMO Database Network, a population-based network in the Netherlands combining data from different healthcare settings. Patients hospitalised for bleeding events during coumarin therapy were selected as cases and matched to up to 2 controls using coumarins without hospitalisation for bleeding. The hospitalisation date of the cases was set as index date and controls were assigned the index date of their matched case. As a proxy for renal function, all values of estimated glomerular filtration rates (eGFR) calculated from serum creatinine laboratory test results were selected in the 12 months before the index date. These were compared between cases and controls using logistic regression analyses. **RESULTS:** In total, 2,066 cases cases hospitalised for bleeding events during coumarin therapy (60% male, mean±SD age 74±11 years) were matched to 4,082 controls without hospitalisation for bleeding (60% male, mean±SD age 78±11 years). No association was found between the mean eGFR value in the 12 months before index and bleeding events (mean±SD 65.9±22.8 vs. 65.0±20.9 ml/min/1.73m²; OR 1.01, 95% CI 1.00-1.011). Overall, the availability of eGFR values was higher among cases in the 12 months before index (mean±SD 4.4±6.9 vs. 3.3±5.4 eGFR values), reflected in the significantly shorter time since last eGFR value (at index date) (mean±SD 2.6±2.9 vs. 3.7±3.1 months; OR 0.91, 95% CI 0.89-0.93). **CONCLUSIONS:** No association between renal function and bleeding events during coumarin therapy was observed.

PCV4: INAPPROPRIATE PRESCRIBING OF ANTITHROMBOTICS CAUSES POOR DISCHARGE OUTCOMES IN HOSPITALIZED ELDERLY PATIENTS USING STOPP/START CRITERIA 2015, A RETROSPECTIVE COHORT STUDY

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**OBJECTIVES:** The aim of this study was to assess the impact of IP of antithrombotic therapy (AT) on patient discharge outcomes of elderly patients. **METHODS:** This was a retrospective cohort study done in Internal Medicine ward of Gondar University Hospital (GUH) between May 1, 2013 – April 30, 2014. **RESULTS:** Of 156 patients, 100 patients had a good (improved) prognosis and the remaining participants (56) had a poor (no change, worsened or dead) prognosis. Patients who had worsening of medical conditions (91.67%) and dead (69.23%) had higher IP. Based on the Kaplan Meier survival curves (Figure1), there was a significant difference in survival between patients with IP and those with appropriate prescriptions (Log Rank test, P = <0.001). Multivariate Cox regression analysis showed that absence of both antiplatelet and anticoagulant medications (HR = 0.019, CI (0.001–0.322), P = 0.006) and presence of PIM (HR = 5.391, CI (1.203 – 24.156), P = 0.028) independently predicted mortality in all patients. Presence of stroke on admission (AHR = 8.368, CI (2.117 – 33.081), P = 0.002) and presence of IP (P = 0.001) like PIM (AHR = 3.093, CI (1.302 – 7.347), P = 0.011), PPO (HR = 4.203, CI (1.615 – 10.943), P = 0.003) and having both PIM and PPO (AHR = 6.908, CI (1.981 – 24.089), P = 0.002) independently predicted poor discharge conditions. **CONCLUSIONS:** Poor discharge outcomes were high among hospitalized elderly patients who have been exposed to at least one IP of AT during hospitalization. Admission due to stroke and IP of antithrombotics (under/over prescription or both) were found to be risk factors for poor discharge outcomes. Appropriate strategies to optimize antithrombotics therapy should be sought by physicians.

PCV6: THE IMPACT OF CO-MORBIDITY ON THE DISEASE BURDEN OF VTE

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OBJECTIVES: Deep-vein thrombosis (DVT) and pulmonary embolism (PE); collectively termed venous thromboembolism (VTE) are major healthcare burdens in Europe. VTE is often accompanied by other diseases and co-morbidities. This complicates the interpretation of data about mortality, costs and quality of life as being related to VTE. The aim of this study was to assess the contribution of co-morbidities to the disease burden of PE and DVT patients, focusing on mortality and health-related quality of life. METHODS: The PREFER in VTE registry, a non-interventional disease registry, was conducted between 2013 and 2014 in primary and secondary care across seven European countries. Consecutive patients with acute VTE were documented and followed up over 12 months. Patients having co-morbidities were grouped in 9 co-morbidity groups: cancer, cardiovascular (CV) disease, CV risks, venous disease, renal disease, liver disease, respiratory disease, bone and joint disease, and lower extremity paralysis. Various types of regression analyses were performed to determine the impact of co-morbidities on mortality at 12 months and health-related quality of life (using the EQ-5D-5L index score). RESULTS: PE and DVT patients without co-morbidities were relatively uncommon, representing 13% and 16% of the total cohorts. VTE patients without any co-morbidity had a 0.9% and 0.2% higher mortality rate and a 0.068 and 0.049 point lower EQ-5D-5L index score, compared to the age-adjusted UK general population (for PE and DVT patients respectively). Those with more than one co-morbidity had substantially increased mortality rates and decreased quality of life scores. Cancer had the highest negative impact on mortality rates, while lower extremity paralysis had the highest negative impact on EQ-5D-5L index score. CONCLUSIONS: The presence of co-morbidities in VTE patients is relatively common. In those VTE patients without co-morbidities, the data suggest that VTE has a substantial impact on mortality as well as quality of life.

PCV7: GENDER DIFFERENCES IN HEART FAILURE: THE ARNO ITALIAN EXPERIENCE

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OBJECTIVES: to investigate the existence of gender differences between HF patients, in particular related to drug prescriptions, hospitalizations and associated costs. METHODS: An observational retrospective cohort analysis was performed from ARNO Observatory, based on administrative databases of 32 LHU (Local Healthcare Units) in Italy, covering 2.5Mill patients. Patients (≥18) with a hospitalization discharge diagnosis of HF (ICD-9-CM 428.xx; 402.xx) and at least one prescription for specific HF drugs (ACE-inhibitors, angiotensin receptor blockers ARBs, diuretics, digitalics, beta-blockers) from January 1st, 2008 to December 31st, 2012 (inclusion period) were included. The index date (ID) was the first hospitalization for HF during inclusion period. All patients were followed up after the ID for 12 months. RESULTS: A total of 54,059 patients with HF were enrolled in the study, about 51.4% females. Mean age was almost 5 years higher for females. Intra-hospital mortality rates were 10.1% for females and 9.5% for males. Males have a consistently higher risk for all concomitant conditions as compared with females, with the exception of depression (15.5% vs 26.1% for females). Males were more often discharged from Cardiology Units than females, while females were more often discharged from General Medicine Units. A higher percentage of males received beta-blockers and/or ACE inhibitors or (ARBs) as compared with female patients. Total number of hospital re-admissions was 48,549 (2.10 per patient-global; 2.01 per female; 2.14 per male). Mean yearly expenditure was 13,273€ for females and 10,451€ for females. CONCLUSIONS: Our findings highlight that, in the real-world, HF has a strong impact on National Healthcare Service for both genders. Gender seems to influence patient admission unit, pharmacological treatment, comorbidities and costs so it needs to be considered.

PCV8: THE CHANGING TREND OF CARDIOVASCULAR DISEASE AND ITS CLINICAL CHARACTERISTICS IN ETHIOPIA: HOSPITAL-BASED OBSERVATIONAL STUDY

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OBJECTIVES: The aim of this study was to assess the pattern of cardiovascular diseases (CVDs), their clinical characteristics, and associated factors in the outpatient department of the chronic illness clinic of Gondar University Referral Hospital. METHODS: A retrospective cross-sectional study was conducted among patients on follow-up at the outpatient chronic illness clinic of the hospital from October 2010 to October 2015. The source population for the study included patients with a diagnosis of CVD whose medical records have the required socio-demographic information during the study period. The data were collected from August 2015 to December 2015. Chi-square and binary logistic regression tests were performed to test the significance of difference among predictive variables and CVDs. RESULTS: Of 1105 patient medical records, 852 fulfilled the inclusion criteria. The majority of the patients were females (65%) and living in urban areas (62.7%). Hypertension accounted for the majority (62.3%) of CVDs followed by heart failure (HF) (23.9%). Headache was the leading chief complaint among the patients (37.7%) upon diagnosis and was the prominent clinical feature in more than half of the patients during their course of follow-up. Higher proportions of Dyslipidemia (85.7%), hypertension (72.8%), and ischemic heart disease (IHD) (73.2%) were
associated with urban residency (P<0.01). Patients from rural areas (crude odds ratio [COR] =1.306 [95% confidence interval 1.026–2.166], adjusted odds ratio [AOR] =1.272 [95% confidence interval 1.017–2.030]) and those with comorbidity illnesses (COR = 1.813 [1.279–2.782], AOR = 1.551 [95% confidence interval 1.177–2.705]) were more likely to have poor CVD outcome (P<0.05). CONCLUSIONS: Hypertension was found to be the most frequent CVD followed by HF, and hypertensive heart disease was the leading cause of cardiac diseases. Most of the patients had improved assessment in the last follow-up, but patients from rural regions and those with comorbidity had higher likelihood of poor cardiovascular outcome.

**PCV9: SECONDARY PREVENTION CARDIOVASCULAR PATIENTS IN IRELAND - POPULATION CHARACTERISTICS FOR COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** To quantify the patient characteristics of a secondary prevention cardiovascular population in Ireland for use in cost-effectiveness analyses. **METHODS:** Data relating to patients with a history of myocardial infarction (MI) or stroke were extracted from the Irish Longitudinal Study on Aging (TILDA). Patients were weighted to take account of age, gender and education selection bias. Patients were analysed as one single cohort and divided into three mutually exclusive groups: recurrent events, history of single MI and history of single stroke. The TILDA dataset contains variables on relevant patient demographics and self-reported doctor diagnosis of important co-morbidities. For patients who completed as health assessment, objectively measured patient characteristics were analysed and weighted for selection bias. The mean average cohort characteristics were recorded. Median rather than mean age was calculated due to data availability. **RESULTS:** The mean population characteristics derived from the single cohort were as follows: 66.2% Male; 9.7% Congestive Heart Failure; 15.7% Diabetes; 17.7% Abnormal Heart Rhythm; 53.8% Hypertension Treatment; 50.2% Hypercholesterolemia Treatment; 18.7% were current smokers, 53.9% smoked in the past. Median age was 70. The mean BMI of patients in the cohort who completed the health assessment was 29.58. **CONCLUSIONS:** Population characteristics of patients with a history of MI or stroke were presented which may be used in cost-effectiveness analysis of treatments for cardiovascular disease. The presentation of results for mutually exclusive cohorts will allow subgroup analysis to be conducted without double counting the patients at highest risk.

**PCV10: EXPLORING THE ASSOCIATION BETWEEN RISK OF BLEEDING AND COMORBID CONDITIONS FOR PATIENTS WITH WARFARIN TREATMENT**

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**OBJECTIVES:** Warfarin is widely used in Saudi Arabia. Because risk of bleeding is one of the main concerns associated with the use of warfarin, regular warfarin monitoring is an essential part of ensuring that the international normalized ratio for all patients falls within the narrow therapeutic range. Accordingly, this study sought mainly to explore the association between risk of bleeding and diagnosis of different comorbid conditions in patients using warfarin. **METHODS:** This cross-sectional study was conducted at King Abdulaziz Medical City (KAMC) among a sample of patients who were diagnosed with atrial fibrillation and on warfarin treatment between March and April 2014, during ambulatory care visits. With the approval of the King Abdullah International Medical Research Center's Institutional Review Board, a series of descriptive and inferential statistical analyses was conducted comparing patients with and without incidence of bleeding. The R Studio integrated development environment was used to perform statistical analyses such as chi-squared testing and logistic regression. **RESULTS:** A total of 264 patients were eligible and included in the study. About 55% of the patients were females and the majority were 65 years and older. The highest prevalent disease was hypertension (79.5%) followed by diabetes mellitus (54.5%). It was estimated that patients with diabetes were 73% less likely to have major bleeding, compared to patients without diabetes. Also, patients with abnormal renal function were about three times more likely to have major bleeding. Regarding minor bleeding, females and hypertensive patients were more likely to have minor bleeding than others. **CONCLUSIONS:** Careful evaluation of the type of each patient’s comorbid condition could aid prediction of which patients have a high risk of both major and minor bleeding, thereby helping prevent major bleeding incidents.

**PCV11: THE PRESENTATION OF PATIENTS WITH EPISTAXIS SHOWS A MARKED SEASONAL VARIATION IN GERMANY**

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OBJECTIVES: The goal of the present study was to analyze the seasonal variation of epistaxis in ear, nose, and throat (ENT) practices in Germany in 2016. METHODS: The current study sample included patients who received a first epistaxis diagnosis from physicians in 114 ENT practices in Germany between January 2016 and December 2016. The number of epistaxis patients per practice and the number of epistaxis patients as a relative share of all patients who visited each practice were calculated for each month. A logistic regression model, adjusted for age and gender, was used to calculate the association between epistaxis diagnosis and the month. RESULTS: We found a total of 15,523 patients with epistaxis in 114 ENT practices. Of these patients, 55.9% were men and the mean age was 47.8 ± 27.5 years. The highest number of epistaxis patients was found in February (14.89 patients per practice) and the lowest in August (7.22 patients per practice). The highest share of patients with an epistaxis diagnosis was documented in March (2.14%) and the lowest in August (1.27%). The age- and gender-adjusted risk of epistaxis was significantly higher in the months of February (OR=1.32), March (OR=1.37), April (OR=1.34), May (OR=1.35), and December (OR=1.33) compared to August. CONCLUSIONS: The presentation of patients with epistaxis at German ENT practices shows a marked seasonal variation with a low in the summer, an increase in fall and winter, and a peak in February, March, and April.

PCV12: NON-PERSISTENCE RISK AND HEALTH CARE RESOURCE UTILIZATION OF ITALIAN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: to compare discontinuation risk and health care resource utilization between the vitamin K antagonists (VKAs) and the novel oral anticoagulants (NOACs) in newly treated patients with non-valvular atrial fibrillation (NVAF). METHODS: Based on administrative databases of five Italian Local Healthcare Units, all patients with a discharge diagnosis of NVAF between 2011 and 2014 were selected. Among them, the incident users of NOACs and VKAs in 2014 were followed-up from the first prescription date to the occurrence of any of the following events: a 90-days gap in therapy, switch to a different molecule or add-on of a different molecule into the regimen, death, end of follow-up (December 2015). All-causes hospitalizations, outpatient visits and examinations within the persistence period were also evaluated. RESULTS: The final cohort was composed of 2,909 and 765 incident users of VKA and NOACs, respectively. Cox regression to model time to non-persistence within 12 months showed a 62% reduction in risk of drug discontinuation in NOAC patients compared to VKA patients (HR=0.38 [0.33-0.44]). In the adjusted analyses with warfarin as reference, apixaban patients (HR, 0.35 [0.24-0.50]) had the lowest risk of non-persistence, followed by rivaroxaban (HR, 0.42 [0.33-0.54]) and dabigatran users (HR, 0.51 [0.43-0.61]). The mean total numbers of all-cause hospitalizations records in 12-months persistent patients were significantly less in NOACs users compared with VKA users (0.36 vs 0.47, p-value: 0.03). Similarly, the differences in the mean numbers of all-cause visits and examinations were statistically significant between VKA and NOAC patients, who registered on average 2.33 vs 1.84 visits (p-value: 0.01) and 24.4 vs 9.2 exams referrals (p-value: <.0001), respectively. CONCLUSIONS: NOACs showed a better profile in terms of both resource utilization and persistence compared with VKAs. In particular, apixaban presented the lowest risk of discontinuation.

PCV13: BLOOD PRESSURE MEASURING TECHNIQUES, EXAMINATION OF THE BLOOD PRESSURE VALUES IN RELATION WITH THE OPERATING PRINCIPLE OF THE DEVICE

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OBJECTIVES: Oscillometric blood pressure monitors are widely used throughout the world, though they may cause inaccuracies in certain diseases (hypertension, hypotension, cardiac arrhythmia, circulatory insufficiency). The purpose of the research was to examine the values obtained with different techniques and the possible defects in the blood pressure measurement protocol. METHODS: The quantitative cross-sectional examination was performed at the clinics and ambulances of University of Pécs Clinical Center, in two departments between 01.02.2017. – 20.03.2017. In non-random, targeted sampling, patients with atrial fibrillation and untreated hypertension (n = 91) were selected to the target group, while patients with 22-33 cm arm circumference range were excluded from the sample. During document analysis and observation, we performed measurements with mercurial, aneroid, oscillometric devices, and observed the blood pressure measurement protocol (n = 136). Results were gained using SPSS statistical software, descriptive statistics, one-off t-test, correlation, ANOVA and Z2 probe (p <0.05) were used. RESULTS: There is a significant difference in the number of systolic and diastolic values (p <0.05) between the three devices in the case of endemic fibrillation and untreated hypertension. The oscillometric device underestimates blood pressure (p <0.05). In the case of the blood pressure measurement protocol, no satisfactory measurements were made in the case of mercurial measurement, 32% acceptable and 68% inappropriate. For oscillometric measurements 85% of the measurements were acceptable. CONCLUSIONS: The oscillometric blood pressure monitor is reliable in healthy
patients, but in the case of atrial fibrillation and hypertension underestimates blood pressure, which we found different from most international research. In the case of blood pressure measurement protocol, inadequate measurement techniques may result in misdiagnosis.

**PCV14: POSSIBLE MISTAKES DURING BLOOD PRESSURE MEASURING: INAPPROPRIATE POSTURE**

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**OBJECTIVES:** In order to determine the correct blood pressure, it is essential to comply with the measurement protocol. Our goal was to examine the effect of improper posture and speaking during blood pressure measurement on blood pressure values. **METHODS:** Our research was cross-sectional, descriptive, quantitative analysis. The study took place in April 2017 at University of Pécs, Faculty of Health Sciences. Non-randomized, targeted sampling resulted selecting healthy students aged 18 to 30 (N = 22) into the sample. On the first day a 4 error combination, on the second day a 3 error combination was performed. Prior to the measurements the correct blood pressure values measured by the protocol were recorded. Exclusion criteria: cardiovascular disease, pregnancy, paralyzed arm, crevice, acute pain, emotional stress, drug use. We used descriptive statistics, t-tests (p <0.05) using Microsoft Office Excel 2007. **RESULTS:** The average systolic value increased by 10.27 mmHg, the diastolic by 14.23 mmHg and the heart rate increased by 11.82 / min if the participant was talking during measurement, no back support, no legs held on the ground and the arm was lower than the heart level without support (p <0.05). On the second test day, after determining the correct blood pressure values, if the foot was correctly on the floor but the arm was not supported at heart level and the subject was speaking, it caused a significant decrease in systolic value (-4.59 mmHg) while the heart rate increased by 12.36 / min (p <0.05). **CONCLUSIONS:** Blood pressure values are influenced by body posture and speech, so care should be taken to ensure that blood pressure measurement is always based on the currently published protocol. Incorrect measurement technique may induce a misdiagnosis.

**PCV15: LONG-TERM BENEFITS OF LDL CHOLESTEROL LOWERING IN YOUNG ADULTHOOD: A COMPUTER SIMULATION STUDY**

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**OBJECTIVES:** The objective of this study was to predict the benefits associated with controlling elevated LDL-cholesterol (LDL-C) in early adulthood, defined as ages 20-39, compared with commencing control at age 40 or older. Benefit was quantified in terms of reduced coronary heart disease (CHD) events, life year gains, and quality-adjusted life year (QALY) gains. **METHODS:** A microsimulation state-transition model estimated individual-level CHD outcomes for a subset of the US population. A sex-balanced cohort of 40,000 US adults with LDL-C ≥ 160 mg/dL at any time in early adulthood was simulated from ages 20-69. Two treatment scenarios were considered: later life LDL-C control, and early plus later life LCD control. Risk of experiencing a CHD event in the model was dependent on multivariate risk factor exposure and accounted for the competing risks of stroke and non-cardiovascular mortality. Risk of first CHD event after age 40 was conditioned on both time-weighted average LDL-C in early adulthood, and present value LDL-C at age ≥ 40. **RESULTS:** Early plus later adulthood treatment prevented approximately 1,900 and 2,800 primary and total CHD events, respectively, compared with later life treatment alone. Controlling LDL-C in both early adulthood and later life would produce approximately 5,419 life years gains and 9,600 QALY gains. More than 400,000 additional patient years of treatment would be required to achieve these benefits. One-way sensitivity analyses found that these results were most sensitive to changes in follow-up time, treatment eligibility criteria, and treatment efficacy. **CONCLUSIONS:** This study quantifies the benefits associated with treating hypercholesterolaemia identified in young adulthood. It is unclear whether LDL-C control should be achieved by lifestyle or pharmaceutical interventions. This study does not account for screening and other health care-related costs, treatment-related disability, and the discounting of future outcomes. To establish cost-effectiveness, further research should consider these important factors.

**PCV16: A SYSTEMATIC REVIEW ON LIFESTYLE CHANGE INTERVENTIONS PERFORMED BY HEALTH CARE PROFESSIONALS TARGETING BLOOD PRESSURE IN HYPERTENSIVE PATIENTS**

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About 0.9 billion people in the world have hypertension. The annual death rate due to hypertension increased by 51%
from 1990 to 2015. The challenge is to provide an effective pharmacological and nonpharmacological intervention. **OBJECTIVES:** As modifications of lifestyle are essential in decreasing blood pressure and lowering cardiovascular disease risk, the aim of this study was to determine if health care professional-led interventions/recommendations on life style are effective in lowering blood pressure in patients with hypertension. **METHODS:** A systematic literature review following PRISMA guidelines was carried out. We searched PubMed, EMBASE and CINAHL for RCT of life style interventions performed by health care professionals (physician, nurse, pharmacist) targeting blood pressure in hypertensive patients. Papers were reviewed by two reviewers and analyzed using Cochrane software Revman 5.2. Outcomes for the meta-analysis were Systolic blood pressure (SBP), Diastolic blood pressure (DBP) and number of patients under blood pressure (BP) control. **RESULTS:** A total of 32 clinical trials with the recommendation on life style change like diet, smoking cessation, physical activity etc. were included. In the included studies 22,226 patients were randomized (age M=58.2, 49% of them were woman, 69.7% were already using antihypertensive medications. SBP decreased by 4.42 [95% CI -5.56, -3.28] comparing intervention group vs usual care group, DBP by 1.63 [95% CI -2.44, -0.83]. Overall, 56% of patients achieved BP control in intervention group vs 44% in usual care group, OR=1.87 [95% CI 1.51, 2.31]. Data on intervention direct costs was provided in two studies. Third study estimated differences in inpatient utilization, outpatient expenditures and total expenditures between intervention and usual care group. **CONCLUSIONS:** Overall, interventions were effective and achieved almost 5 mmHg decrease of SBP. This may have an impact on preventing cardiovascular disease, morbidity and mortality in hypertensive patients. Yet there is a lack of pharmaco-economic evaluation on life style change interventions.

**PCV17: TREATMENT PATTERNS AND LACK OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) GOAL ATTAINMENT AMONG HIGH-RISK PATIENTS USING HIGH OR MODERATE INTENSITY STATIN THERAPY IN GERMANY**

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**OBJECTIVES:** European Society of Cardiology and European Atherosclerosis Society dyslipidemia guidelines recommend a low-density lipoprotein cholesterol (LDL-C) target of <70 mg/dL for patients at very high cardiovascular (CV) risk. In clinical trials, statins have proven effective for lowering LDL-C levels in patients with hyperlipidemia, but in routine care, statin use varies and most patients do not attain goal. This study describes LDL-C goal attainment among German patients with atherothrombotic CV disease (ASCVD) who exhibit different patterns in their use of high or moderate intensity statins. **METHODS:** This retrospective cohort study used electronic medical records data from the IMS® Disease Analyzer. ASCVD was defined as coronary atherosclerosis, stable/unstable angina, myocardial infarction, ischemic stroke, transient ischemic attack, aneurysm, and peripheral arterial disease. Proportion of ASCVD patients on moderate/high intensity statin with LDL-C <70 mg/dL was determined using the lowest LDL-C value obtained for each patient (index) in each year (2012, 2013, 2014); the LDL-C assessment was required to occur within statin days supply. Treatment patterns were assessed for patients with at least 1-year of post-index follow-up. Results were stratified by year and statin treatment pattern (no change, switch, dose up/dow-titration, discontinuation [≥90 day gap]). **RESULTS:** In the >14,000 patients assessed in each year (mean age 71 years, 35% female, 8-12% taking high intensity statins), 88-93% were included in treatment pattern analysis. In each year, 79 - 81% of patients remained on the same statin regimen throughout follow-up, 1% switched statins, 14-16% discontinued; 1% of moderate intensity users up-titrated, and 3% of all patients down-titrated. LDL-C goal attainment rates in these treatment pattern groups were 20%, 16-24%, 17%, 11-14%, and 17-19%, respectively. **CONCLUSIONS:** Majority of the ASCVD patients did not achieve the LDL-C target with moderate or high intensity statins. Despite this lack of LDL-C goal attainment, few patients changed their treatment regimens.

**PCV18: COMPARATIVE EFFECTIVENESS OF NON-VITAMIN K ANTAGONIST ORAL ANTICOAGULANTS (NOACS) AND WARFARIN IN THE SCOTTISH ATRIAL FIBRILLATION POPULATION: THE VALUE OF REAL WORLD EVIDENCE**

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**OBJECTIVES:** Real world data, compared to randomised controlled trial (RCT) data, provides evidence from real world scenarios. However, the absence of randomisation does not allow for an unbiased comparison between the treatment and the comparator. The objective of this study was to assess the effectiveness and safety of NOACs, and whether RCTs findings are generalizable to clinical practice in Scotland. **METHODS:** National data on prescribing, hospitalisations and death for newly anticoagulated patients, with a diagnosis of atrial fibrillation (AF) were linked. Patients 50 years or older were followed from first oral anticoagulant prescription to first clinical event or death. Censoring was applied to treatment switching. AF related outcomes observed with NOACs were compared with
for a men, 15% had a history of stroke, 95% hypertension, 23% diabetes and 69% heart failure. Apixaban patients had a 9.0 years for apixaban patients and 75.4 years for VKA (p<0.001). Across anticoagulant treatment.

OBJECTIVES: To evaluate the risk of major bleeding among two cohorts of Non-Valvular Atrial Fibrillation (NVAF) patients newly initiating a vitamin K antagonist (VKA) or apixaban in a real-world setting in Italy. METHODS: A retrospective study using a large administrative database of Italian Local Health Units (LHUs) was performed, using data from 5 LHUs. Patients were included from the date of new initiation of apixaban or VKA between January 2012 to June 2015, and followed until treatment discontinuation or switching, death, or end of follow-up. Patient demographics and clinical characteristics were assessed at time of treatment initiation. Risk of major bleeding was calculated using a Cox regression model accounting for the competing risk of mortality, adjusting for age, gender, Charlson Comorbidity Index, CHA2DS2-VASc and HAS-BLED scores, history of stroke risk factors, major bleeding events, gastrointestinal ulceration, liver disease, thromboembolic events and also previous anticoagulant treatment. RESULTS: Of 1,127 patients initiated apixaban and 5,463 VKA. Mean age was 77.6 [SD 9.0] years for apixaban patients and 75.4 [SD 10.3] years for VKA (p<0.001). Across both therapies, 52% were men, 15% had a history of stroke, 95% hypertension, 23% diabetes and 69% heart failure. Apixaban patients had a higher history of major bleeding (6.7% vs 4.4% of VKA). Over a median follow-up of 10 months for VKA and 4 months for apixaban, the incidence rate of major bleeding was 1.54 per 100 person-years among apixaban initiators and 2.30 per 100 person-years among VKA initiators.
per 100 person-years among VKA initiators. Compared with VKA, apixaban had a significantly lower risk of major bleeding (HR=0.42 [95%CI 0.21-0.87]). CONCLUSIONS: In this analysis, apixaban was associated with a lower risk of major bleeding compared with VKA, however there are limitations to the study including the short follow up period for apixaban users.

**PCV21: DECREASING ACEF SCORE IN PATIENTS UNDERWENT MYOCARDIAL INFARCTION AFFECTS PATIENTS’ LIFE YEARS GAINED**

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OBJECTIVES: ACEF score, calculated based on three independent variables, is a significant predictor of major adverse cardiac events for patients who underwent acute myocardial infarction. The long-term implications of decreasing ACEF score is unknown. In the absence of long-term clinical trials, modelling is a useful tool that helps to determine the optimal treatment strategy and predict a long-term impact of treatment. This study aims to predict the life years gained (LYG) in patients with decreased ACEF score over their lifetime by using the Markov modelling. METHODS: Our target cohort consisted of patients with new MI and age of 60. Hypothetical intervention was decreasing ACEF. A markov model was developed based on the previous study assessing cost-effectiveness in patients treated with standard of therapy at risk of vascular event in the UK. The model included six mutually exclusive Markov state: two of vascular event (MI/stroke), two of stable condition (Post MI/stroke) and two of death distinguished by cause (Vascular/Non-vascular). The transition probabilities for each disease state and death were retrieved from previous study, which the vascular rate utilized came from UK observational studies, and 2013 life table of Korean. The trial-based hazard ratio was used as effectiveness parameter to differentiate vascular event rate across levels of ACEF score. The hazard ratio for each x-point decrease of ACEF score was obtained with the following formula: RESULTS: The incremental QALYs and LYG by decreasing 0.1 point of ACEF scores resulted in 0.21 and 0.27, respectively. As the point decrease of ACEF scores became greater, incremental QALYs and LYG would increase significantly. CONCLUSIONS: The strategy of decreasing the ACEF score results in increasing LMG and QALMs. The improvement of ejection fraction would be helpful to improve patients QoL through reducing the 2nd vascular events.

**PCV22: COMPARATIVE EFFECTIVENESS OF RIVAROXABAN VS VITAMIN K ANTAGONIST IN ROUTINE CARE PATIENTS TREATED FOR NON-VALVULAR ATRIAL FIBRILLATION IN GERMANY – A RENAL IMPAIRMENT SUBGROUP ANALYSIS**

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OBJECTIVES: There is a strong relationship between renal function and thromboembolic events for both vitamin-K antagonists and rivaroxaban in patients treated for non-valvular atrial fibrillation (NVAF). Until now, only a few studies showed evidence of effectiveness and safety of anticoagulants in routine clinical practice in Germany where Phenprocoumon is the predominantly prescribed VKA. METHODS: Data from German sickness funds between January 1st, 2012 and March 31st, 2016 were extracted and a new user cohort study comparing patients treated with either rivaroxaban or vitamin K antagonist (phenprocoumon) was conducted. A multivariate Cox-regression was performed to calculate adjusted hazard ratios (HR) for the risk of ischemic stroke as well as intracranial hemorrhage in the overall population as well as in patients with renal impairment. RESULTS: 33,668 newly treated patients were identified and enrolled in the study: 13,155 patients on rivaroxaban (mean CHA2DS2-VASC score: 3.49; median observation time: 275 days) and 20,513 patients on phenprocoumon (mean CHA2DS2-VASC score: 3.78; median observation time: 160 days). Of these, 1,954 patients on rivaroxaban and 3,871 patients on phenprocoumon were coded as renally impaired. A significant risk reduction for ischemic stroke rivaroxaban vs. phenprocoumon was found in the overall population; HR: 0.77 (0.63; 0.99); p<0.05. For renally impaired patients the HR was 0.85 (0.56; 1.28); p=0.428; for intracranial hemorrhage 0.86 (0.54; 1.23); p=0.403 and 0.531 (0.21; 1.33); p=0.176 respectively. CONCLUSIONS: The analysis of the overall population showed a significant reduction in stroke risk for rivaroxaban. Although the number of patients with renal impairment in this study is still low, point estimates indicate a strong protective trend regarding effectiveness and safety of rivaroxaban vs. phenprocoumon. Additionally, the follow-up time on treatment with rivaroxaban was remarkably higher than for phenprocoumon. This study is the first focusing on a renally impaired subgroup of patients with NVAF in Germany.

**PCV23: TARGET ORGAN DAMAGE AND THE LONG TERM EFFECT OF NONADHERENCE TO CLINICAL PRACTICE GUIDELINES IN PATIENTS WITH HYPERTENSION: A RETROSPECTIVE COHORT STUDY.**

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OBJECTIVES: There was limited published data on target organ damage (TOD) and the effect of nonadherence to practice guidelines in Ethiopia. This study determined TOD and the long term effect of nonadherence to clinical guidelines on hypertensive patients. METHODS: An open level retrospective cohort study has been employed at cardiac clinic of Gondar university hospital for a mean follow-up period of 78 months. Multivariable Cox regression was conducted to test associating factors of TOD. Kaplan analysis was done to evaluate the long term effect of nonadherence to practice guidelines on TOD. A person-time method was applied to calculate the incidence rate of TODs RESULTS: Of the total number of 612 patients examined, the overall prevalence of hypertensive TOD was 40.3%. The presence of comorbidities, COR = 1.073 [1.01–1.437], AOR = 1.196 [1.174–1.637], and nonadherence to clinical practice guidelines, COR = 1.537 [1.167–2.024], AOR = 1.636 [1.189–2.251], were found to be predicting factors for TOD. According to Kaplan-Meier analysis patients who were initiated on appropriate medication tended to develop TOD very late: Log Rank [11.975 (p=0.01)] CONCLUSIONS: More than forty percent of patients acquired TOD which is more significant. Presence of comorbidities and nonadherence to practice guidelines were correlated with the incidence of TOD. Appropriate management of hypertension and modification of triggering factors are essential to prevent complications.

PCV24: EFFICACY AND SAFETY OUTCOMES OF RECANALIZATION PROCEDURES IN PATIENTS WITH ACUTE SYMPTOMATIC PULMONARY EMBOLISM: SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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OBJECTIVES: To review the efficacy and safety of the recanalization procedures for the treatment of acute symptomatic pulmonary embolism (PE). METHODS: Searches were performed in PubMed, the Cochrane Library, EMBASE, EBSCO, Web of Science, and CINAHL from inception through July 31, 2015, without language restrictions. Randomized clinical trials that compared the effect of a recanalization procedure vs. each other or anticoagulant therapy in patients diagnosed with acute symptomatic PE were included. Two reviewers independently screened by abstract and full text and extracted data. Disagreements were resolved by consensus. We used network meta-analysis and multivariate random-effects meta-regression to estimate pooled differences between each intervention. The primary outcomes were all-cause mortality and major bleeding. RESULTS: From a total of 930 unique studies identified, 22 studies were included in the analysis (2,494 patients). Of these studies, 16 compared full-dose thrombolysis to no thrombolysis, 1 compared low-dose thrombolysis to no thrombolysis, 1 compared catheter-directed thrombolysis with no thrombolysis, and 4 compared full-dose thrombolysis with low-dose thrombolysis. For all-cause mortality, there were no significant differences in events rates between any of the recanalization procedures and anticoagulant treatment (full-dose thrombolysis: OR, 0.60; 95% confidence interval, 0.36 to 1.01; low-dose thrombolysis: 0.47, 0.14 to 1.59; and catheter-associated thrombolysis: 0.31, 0.01 to 7.96). Full-dose thrombolysis increased the risk of major bleeding (2.00, 1.06 to 3.78) compared with anticoagulant treatment. The adjusted indirect comparison between full-dose thrombolysis, low-dose thrombolysis and catheter-directed thrombolysis did not show superiority of any procedure over the others for all-cause mortality or major bleeding. CONCLUSIONS: When considering the risk–benefit profile of recanalization procedures in the acute treatment of PE, these treatments do not seem to offer a clear advantage compared with standard anticoagulation. Low-dose thrombolysis is probably the best option to consider when a recanalization procedure is indicated.

PCV25: OPTIMAL USAGE OF SACUBITRIL/VALSARTAN FOR HEART FAILURE TREATMENT IN CANADA POTENTIALLY REDUCES MORTALITY, HOSPITALIZATIONS AND EARLY DISCHARGE RE-ADMISSIONS

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OBJECTIVES: Despite multiple evidence-based therapies, HF continues to be characterized by high mortality/hospitalization rates. Sacubitril/valsartan (sac/val), a first-in-class angiotensin receptor neprilysin inhibitor treatment for HF with reduced ejection fraction (HFrEF), provided incremental cardiovascular and overall survival benefit in PARADIGM-HF over the ACE inhibitor enalapril. The objective was to quantify the number of deaths, HF hospitalizations, and 30-day HF re-admissions that potentially could be avoided with optimal usage of sac/val for the treatment of HFrEF patients in Canada. METHODS: Data from Statistics Canada was used to quantify the population above 18 years of age. A literature search was then conducted to determine the HF prevalence in Canada, the proportion of these with NYHA ClassII/III, and the proportion of HFrEF patients. The NNT to avoid one death, hospitalization, and 30-day HF re-admission, standardized to 12 months was derived from the PARADIGM-HF trial. The potential number of deaths/hospitalizations prevented as a result of optimal usage of sac/val as per current Canadian indication was estimated using multiple-way sensitivity analysis and analysis-of-extremes
method. RESULTS: Canadian HF prevalence of 2.31% was applied to determine the number of HF patients; 64% were classified as NYHA ClassII/III with 56% identified as HFrEF. In Canada, ~242,200 patients are affected with HFrEF, NYHA ClassII/III. Based on a NNT of 80, optimal usage of sac/val therapy was estimated to prevent 3,016 deaths and 3,016 hospitalizations/year (range, 1,930–4,331). With a NNT of 61, a total of 3,984 30-day readmissions/year (range, 2,546–5,744) would be prevented. CONCLUSIONS: This analysis suggests that a substantial number of deaths, hospitalizations, and 30-day readmissions in Canada could potentially be avoided by optimal usage of sac/val therapy. It supports the importance of implementing evidence-based therapy into routine clinical practice to improve clinical outcomes for HFrEF patients in Canada as the hospitalization and mortality rates still remain elevated.

PCV27: PRELIMINARY RESULTS OF RESTARTING ORAL ANTICOAGULANT TREATMENT IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION FOLLOWING INTRACRANIAL HEMORRHAGE: A POPULATION-BASED COHORT STUDY

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OBJECTIVES: Patients with non-valvular atrial fibrillation (AF) who survive an intracranial hemorrhage (ICH) have an increased risk of ischemic stroke and thromboembolic events (Stroke/SE). An unanswered question is the efficacy and safety of restarting oral anticoagulant treatment (OAC), relative to not restarting in those patients. Our aim was to investigate if restarting OAC among AF patients with an ICH is linked with a lower risk of Stroke/SE and all-cause mortality, but with a small increase in major bleeding compared to not restarting OAC. METHODS: A cohort study built using administrative data from the Quebec RAMO and Med-Echo databases. We identified older adults using inpatient coding (ICD-9: ICD-10) with AF from 1995 to 2014 who were discharged alive. Patient with subsequent incident ICH were included. After hospital discharge for ICH, patients were categorized as no, partial or full OAC exposure (MPR≥90%). The outcomes were the rate of stroke/SE, mortality, recurrent ICH and major bleeding after a quarantine period of 6 weeks. Crude events rates were done at 1 year of follow-up. Cox models were used to assess aHRs (95%CI). RESULTS: A cohort of 703 AF patients with ICH was identified and aged on average at 83 years with a history of prior Stroke/SE (40%) and major bleeding (9%). The rate (per 100 person-years) of Stroke/SE, mortality, ICH and major bleeding were 2.4, 36.2, 10.6 and 1.9 for no OAC; 4.9, 33.2, 11.5, 11.2 for partial exposure; and 1.1, 3.2, 1.1 and 2.2 for full exposure. The aHR of Stroke/SE and death was 0.11 (0.05-0.28); the aHR for recurrent ICH was 0.09 (0.01-0.63) and major bleeding 0.93 (0.19-4.5) when comparing OAC full exposure to no OAC. CONCLUSIONS: Resuming OAC after ICH seems to be associated with risk reduction of stroke/SE and mortality, supporting It use after ICH. Further analyses are ongoing to optimally control for potential confounders.

PCV28: ANTI-TROMBOTHIC THERAPY FOR PATIENTS WITH VENOUS THROMBOEMBOLISM IN A NATIONWIDE HEALTH PLAN

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OBJECTIVES: To assess the management of anti-thrombotic therapy among patients with provoked or unprovoked venous thromboembolism (VTE) in a real world setting. METHODS: We identified primary VTE events occurring between 2007 and 2013 using computerized databases of a 2-million member health plan. Length of treatment with anti-coagulant therapy (low molecular weight heparins (LMWH), warfarin, and novel oral anticoagulants) and type of initial medication were compared between unprovoked and provoked (active-cancer-associated and other provoked) VTE. RESULTS: Among the study population (n=8,947; mean age=59y, SD=18y), 69.5% initiated anti-coagulant therapy. Median treatment duration with anticoagulation therapy was longer for patients with pulmonary embolism (PE) (415 days) compared with deep vein thrombosis (DVT) patients (206 days). Cancer-associated provoked patients were significantly (P<0.01) more likely to initiate anticoagulation therapy with LMWH (68% for PE and 70% for DVT) compared with patients with other provoked or unprovoked VTE (30% and 47%, respectively). Duration with LMWH among these patients was also significantly (P<0.01) longer (median=129 days) compared to those with other provoked (31 days) and unprovoked VTE (27 days). CONCLUSIONS: A substantial proportion of VTE patients are not treated with anticoagulation therapy within 3 months from event. LMWH are more extensively used in cancer-associated VTE patients. Further study is needed to determine the reasons for this gap in provision of care and whether adherence to therapy improves once NOACs are introduced as first-line therapy.

PCV29: DYSLIPIDEMIA TREATMENT AND CVD RISK IN ADULT RUSSIANS WHO REPORTED DYSLIPIDEMIA

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OBJECTIVES: Previous research has demonstrated that prevalence of dyslipidemia in Russian adults is high. However, there is limited data on patients’ treatment rate and cardiovascular disease (CVD) risk. This study used data from a cross-sectional, population-based survey of Russians to estimate dyslipidemia treatment rate and cardiovascular disease (CVD) risk levels. METHODS: This study used data from two administrations (2011 and 2013) of the Russia National Health and Wellness Survey, an Internet-based survey administered to a demographically representative adults (18 and older; n=20,039). Those who were at least 40 years and self-reported a diagnosis of dyslipidemia by a medical provider (n=1,633) were included in the study. Data analysis consisted of using mean and standard deviations for continuous data and counts and percentages of categorical data to report socio-demographic characteristics, medication use, and CVD risk (moderate, high, and very high), which was derived using a modified Systematic Coronary Risk Evaluation algorithm (SCORE: 2016 version) that included self-reported low-density lipoprotein cholesterol (LDL-C) and blood pressure (BP). RESULTS: Those who reported a diagnosis of dyslipidemia were more likely to be middle-aged (mean age=52.9, SD=13.6), women (58.5%), and from the middle/upper socioeconomic class (27.1%). Only 28.2% of patients reported using prescription medications for high cholesterol; 96% were statins. Only 448 respondents (27.4%) knew their LDL-C and BP. Application of the modified SCORE algorithm found that 67.0%, 22.8% and 10.3% had moderate, high, and very high risk for CVD, respectively. CONCLUSIONS: A small percentage of adult Russians reported treating dyslipidemia with lipid-lowering prescriptions or knew their LDL-C level and blood pressure. Taken together, these findings indicate most patients were unaware of their health status and treatment options, which puts them at risk for a range of potential health problems including premature death. It underscores the need for dyslipidemia assessment, education and treatment in Russia.

PCV30: THE PREVALENCE OF PATIENTS AT VERY HIGH RISK FOR CARDIOVASCULAR EVENTS IN THE UNITED KINGDOM

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OBJECTIVES: The primary objective was to estimate the prevalence of patients at very high risk of cardiovascular events in the United Kingdom. METHODS: This was a cross-sectional study using the Clinical Practice Research Datalink (CPRD). We included patients age ≥18 in 2013 with treated hypercholesterolemia (≥2 prescriptions for lipid modifying therapy [LMT]). We defined two very high risk populations based on 2016 European Society of Cardiology guidelines: documented cardiovascular disease (CVD) and type 2 diabetes without documented CVD (DM2w/oCVD). CVD included acute coronary syndrome ([ACS]: myocardial infarction, unstable angina, revascularization, stable angina, or cardiac ischemia), ischemic stroke ([IS] also included transient ischemic attack or carotid stenosis), and peripheral arterial disease ([PAD] also included abdominal aortic aneurysm). RESULTS: In 2013, 9.4% of all CPRD patients (504,907) received LMT (>95% received statins) and 4.8% were at very high risk for CVD (2.8% CVD and 2% DM2w/oCVD). In the CVD population, 73% had ACS, 18% had IS, and 9% had PAD. The ACS subgroup included 35% with myocardial infarction and 65% with stable or unstable angina, revascularization, or cardiac ischemia; in the IS subgroup 31% of patients had ischemic stroke and 69% had carotid stenosis; and the PAD subgroup included 93% with PAD and 7% with abdominal aortic aneurysm. In the overall CVD population, 26% had type 2 diabetes, 25% had recurrent CVD, and 7% had both. In the CVD and DM2w/oCVD populations, 24% and 14% respectively received a high-intensity statin or statin with ezetimibe. A substantial proportion of the CVD population had LDL-cholesterol levels above commonly suggested thresholds: 24% above 2.6 mmol/L (100 mg/dL) and 62% above 1.8 mmol/L (70 mg/dL). In the DM2w/oCVD population the respective proportions were 23% and 59%. CONCLUSIONS: Our analysis shows the need for additional intensive LDL lowering in well-defined populations at very high risk for cardiovascular events.

PCV31: CHARACTERISTICS AND RISK FACTOR BURDEN OF PATIENTS RECEIVING LIPID MODIFYING THERAPY IN THE UNITED KINGDOM

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OBJECTIVES: To describe the characteristics and risk factor burden of patients at very high risk of cardiovascular events initiated on statin and/or ezetimibe therapy. METHODS: This is a retrospective cohort study involving the

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OBJECTIVES: In the last 10 years, different treatments for stroke prevention in atrial fibrillation (SPAF) have been launched in Spain. However, little is known about clinical outcomes and cost associated to patient events in real world practice. The aim of this model is to assist in the decision making of treatment selection based on the risk of a patient having an event. METHODS: The health outcomes model is based in five Real World Evidence (RWE) studies published in 2016. Safety outcomes data has been standardized for the population older than 40 years old. It allows data extrapolation for Spanish SPAF regional citizenry. The model compares real world clinical results and associated cost of various Direct Oral Anticoagulants (DOAcs), adjusted to selected population (national, regional, provinces and healthcare areas). Population data was obtained from Statistics National Institute and two published Spanish studies, market share was provided for IMS and cost per event was according to DRG (Diagnostic Related
OBJECTIVES: Current evidence suggests that adding proprotein convertase subtilisin–kexin type 9 (PCSK9) inhibitors to current lipid lowering therapies (LLTs) may favor achievement of unprecedented reductions in LDL-Cholesterol (LDL-C). This study assessed potential budgetary impact of PCSK9 inhibitor alirocumab in the context of the Italian National Health Service (INHS). METHODS: The addition of alirocumab to LLT was assessed in a population strictly defined as per AIFA prescribing criteria. Data from the national electronic medical report Cegedim was used to estimate the size of the potentially eligible Italian population (i.e. patients not reaching predefined LDL-C levels despite treatment with high-potency statins and ezetimibe or who are statin-intolerant). Alirocumab annual uptake of 15%, 19% and 20% was assumed for year 1, 2 and 3, respectively, considering a treatment drop-out rate of 20%. Calculations were made on full year treated (FYT) patients. Drug unit costs were applied in line with dosing schedule and published prices. Sensitivity analyses were conducted, altering annual therapy uptake (+10%), treatment drop-out rate (+10%) and drug price (-5%, -10%). RESULTS: This analysis suggests that 1,887 FYT patients could be treated with alirocumab in the first year, with a respective yearly impact of €9.66mil on the INHS. Estimated annual cost of treatment per patient is €5,118. Alirocumab treated population is estimated to increase to 4,863 and 6,287 FYT patients in Year 2 and Year 3, respectively with a consequent budgetary impact of €24.72mil and €31.96mil. Sensitivity analysis suggested that treatment uptake variation has the highest financial impact with potential variation in range of €7.73mill to €11.59mill in the first year after treatment.
OBJECTIVES: Palmas de Gran Canaria, Spain, Universitario Nuestra Señora de Candelaria, Santa Cruz de Tenerife, Spain, JM Crespo C

PCV38: BUDGET IMPACT OF POST-STROKE DYSPHAGIA: DATABASE ANALYSES OF HOSPITAL DISCHARGES IN FRANCE AND SWITZERLAND

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OBJECTIVES: Oropharyngeal dysphagia is prevalent in hospitalized post-stroke patients and is associated with increased mortality and comorbidities. The aim of our analysis was to evaluate the impact of dysphagia on Length of Hospital Stay (LOS) and costs. The hospital perspective was used to assess costs. METHODS: Hospital discharge databases comparing hospital stays for stroke associated with dysphagia vs stroke without dysphagia in France and Switzerland were analyzed. The French Medical Information System Program (PMSI) database analysis focused on 62,297 stays for stroke in the public sector. 6,037 hospital stays for stroke were analyzed from Swiss OFS (Office fédéral de la statistique: Statistique des coûts par cas 2012) database. Diagnosis codes and listing of procedures were used to identify dysphagia in stroke patients. RESULTS: Patients with post-stroke dysphagia accounted for 8.4% of stroke hospital stays in Switzerland, which is consistent with recently reported prevalence of dysphagia at hospital discharge (Arnold et al, 2016). The French database analysis identified 4.2% stays with post-stroke dysphagia. We hypothesize that the difference between the Swiss and French datasets may be explained by the limitations of the analysis based on diagnosis and procedure coding. Post-stroke dysphagic patients stayed longer at hospitals (LOS of 23.7 vs. 11.8 days in France and LOS of 14.9 vs. 8.9 days in Switzerland) as compared to post-stroke patients without dysphagia. Post-stroke dysphagia was associated with €30,000 and CHF14,000 cost increase in France and Switzerland respectively. CONCLUSIONS: Post-stroke dysphagia is associated with increase of length of hospital stay and higher hospital costs.

PCV37: BUDGET IMPACT OF ALTEPLASE IN TREATMENT OF ACUTE ISCHEMIC STROKE IN TURKEY

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Objectives: Cerebrovascular diseases are the sixth cause of total DALYs in Turkey and the Turkish Social Security Institution (SSI) faces a challenge on reimbursement decisions for treatment. Alteplase is a recombinant human tissue plasminogen activator indicated for treatment of acute ischemic stroke (AIS). Clinical trials have proved efficacy in reducing 90-day disability measured by the Modified Rankin Score (mRS) if administered within 4.5 hours of onset of symptoms. The agent is used as an addition to Standard of Care (SoC). This study aimed at assessing the budget impact of Alteplase from national perspective in Turkey. Methods: A budget impact model assessing the impact with and without use of Alteplase was developed. First, the number of individuals with acute ischemic stroke that are hospitalized and eligible for Alteplase was determined from published data and expert views. Calculations were made for 0 to 1.5 hours after onset, 1.5 to 3.0 hours after onset and 3 to 4.5 hours after onset for both scenarios. Acute ischemic stroke hospitalization costs and the average annual costs after hospitalization were included. Cost estimations were calculated according to mRS score. Literature review and expert opinions were used in calculating the Turkish costs. Results: Number of patients eligible for Alteplase was estimated as 12,950. The budget impact of Alteplase was estimated as 1,490,712 TRY, 1,510,634 TRY, 1,530,555 TRY, 1,550,477 TRY, 1,570,398 TRY for the first, second, third, fourth and fifth years respectively. Conclusions: The burden of AIS on the Turkish healthcare system and unmet need is expected to increase with current ageing trends. The budget impact model revealed that the efficacy of Alteplase, its budget impact is affordable for the Turkish SSI. In addition to this, reduced disability with the use of Alteplase will reduce resources needed for disabilities and will have an additional budget decreasing impact.

PCV38: BUDGET IMPACT ANALYSIS OF PRASUGREL FOR PATIENTS WITH ACUTE CORONARY SYNDROME UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN SPAIN

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OBJECTIVES: To evaluate the budget impact (Bl) of increase Prasugrel prescription versus Ticagrelor and
Clopidogrel in the treatment of patients with acute coronary syndrome undergoing Percutaneous Coronary Intervention from a Spain healthcare payer perspective. METHODS: A BI model was developed to capture drug and clinical events (acute myocardial infarction, stroke, Urgent Target Vessel Revascularization (UTVR) and major/minor bleeding) costs (€ 2017) over a 3-year period. The scenarios evaluated were I) current scenario based on Spanish market research data from 2016, II) increase prasugrel prescription only or III) increase prasugrel and ticagrelor. Using available data with clinical cost data for hospital and outpatient procedures and pharmaceutical costs, the model reported on the economic differences associated with the three scenarios. The resulting cost per patient, cost differences and results of a 1-way sensitivity analysis are reported. RESULTS: The total impact after 3 years is € 229M for scenario I, € 241M for scenario II and € 257M for scenario III, which is equivalent to increases of 5.5% and 12.5%, respectively. The greater incorporation of prasugrel and ticagrelor leads to reduced events and the cost of myocardial infarctions (€ -5.2M, -6.12% scenario II vs I, € -10.5M, -12.34% Scenario III vs I), stroke (€ -0.74M, -6.42% scenario II vs I, € -0.71M, -6.15% scenario III vs I) and the UTVR (€ -4.3M, -8.19% scenario II vs I, € -2.4M, -4.55% scenario III vs I). The higher incorporation of ticagrelor increase the cost related to bleedings. On the other hand, the cost per patient of prasugrel is lower than ticagrelor (€ 1,212.76 vs € 1,518.75) cost due to lower pharmacological cost and fewer events such as UTVR, stroke and bleeding. CONCLUSIONS: This study provides additional health economic rationale for boost prasugrel prescription, due to the reduction of clinical events rate with marginal BI.

PCV39: BUDGET IMPACT ANALYSIS OF SACUBITRIL/VALSARTAN INTRODUCTION FOR HEART FAILURE TREATMENT FROM THE FRENCH HOSPITAL PERSPECTIVE

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OBJECTIVES: The study objective was to estimate the budget impact related to sacubitril/valsartan introduction in treatment strategy for patients with symptomatic chronic heart failure (HF) and reduced ejection fraction. The ESC 2012 HF guidelines recommend treatment with an ACE inhibitor or angiotensin II receptor blocker. Sacubitril/valsartan demonstrated a significant risk reduction of cardiovascular deaths by 20% and hospitalizations for HF by 21% versus enalapril, an ACE inhibitor. METHODS: A budget impact model was developed to estimate the impact of sacubitril/valsartan introduction in HF treatment strategy. HF patients eligible for sacubitril/valsartan were estimated from a local prevalence rate calculated by matching characteristics of HF patients in terms of age and gender distribution (Échantillon généraliste de bénéficiaires, 2012) with local INSEE data. Number of hospitalized patients for HF was estimated from PMSI database (2012). The following ICD10 codes were extracted as principal diagnosis, related diagnosis or associated diagnoses: I500, I501, I509, I110, I130 and I132. For each hospitalization, a weighted disease related group (DRG) cost (€, 2012) was calculated. No discount rate was applied. RESULTS: If 100,000 patients are treated with sacubitril/valsartan, about 4,500 deaths and 39,000 hospitalizations may be avoided over 5 years. From a DRG perspective those avoided hospitalizations may lead to cost savings of about 130m€. From a hospital budget perspective this may lead to a 10m€ avoided budget deficit. Indeed, there was a difference between weighted DRG cost (3,329€) and costs incurred in the national cost study (Etude Nationale de Coûts à l'Échelle Nationale, 2016) increase prasugrel and ticagrelor. The higher incorporation of ticagrelor increase the cost related to bleedings. On the other hand, the cost per patient of prasugrel is lower than ticagrelor (€ 1,212.76 vs € 1,518.75) cost due to lower pharmacological cost and fewer events such as UTVR, stroke and bleeding. CONCLUSIONS: This study provides additional health economic rationale for boost prasugrel prescription, due to the reduction of clinical events rate with marginal BI.

PCV40: BUDGET IMPACT OF IV IRON THERAPY WITH FERRIC CARBOXYMALTOSE IN PATIENTS WITH CHRONIC HEART FAILURE AND IRON DEFICIENCY IN FRANCE

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OBJECTIVES: Iron deficiency (ID) is highly prevalent in chronic heart failure (CHF) patients and imposes a significant disease burden. CHF with ID is a major reason for hospitalization and represents important costs for national health care budgets. In France, Intravenous iron therapy with ferric carboxymaltose (FCM) is the only treatment recommended for those patients. This analyze aims to evolute the budget impact of FCM versus placebo for patients with chronic heart failure and iron deficiency in the French health care setting. METHODS: An event-based budget impact model was adapted to forecast the budget impact from the French health insurance perspective over a 5-year horizon. The main objective of the model is to assess the costs associated with changes of disease progression in patients treated with FCM versus placebo. In the model, cost saving may occur through NYHA class improvement and rate of hospitalization. Epidemiological parameters for France are derived from a literature review. Clinical evidence is based on a pooled analysis of four clinical trials (FER-CARS-01, FAIR-HF, EFFICACY-HF and CONFIRM-HF). Cost parameters use the French Diagnostic-Related Groups and hospital activity from the French national hospitalizations database (PMSI). Market shares of FCM versus placebo are provided by Vifor Pharma.
Scenario analysis assess the influence of various factors, including FCM dose, cost of other medication, cost of hospitalization, cost of outpatient visits by NHYA levels. **RESULTS:** Compared to placebo, the use of FCM in France for patients with CHF and ID results in a decrease in costs associated with hospitalizations due to CHF, outpatient visits, and other medications than FCM. **CONCLUSIONS:** In this study, costs of the use of FCM in iron deficient CHF from the national health insurance perspective are expected to be in favor of an increase use in France. A final round of validation with expert is carried out to ensure robustness.

**PCV41: BUDGET IMPACT ANALYSIS OF TREPROSTINIL TO TREATMENT OF PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION NYHA CLASS IV WITHOUT RESPONSE TO PHARMACOLOGICAL THERAPIES IN MEXICO**

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**OBJECTIVES:** To estimate the financial implications of introducing Treprostinil to treatment of patients with pulmonary arterial hypertension NYHA class IV without response to pharmacological therapies in the budget of public health institutions in Mexico. **METHODS:** A budget impact analysis was performed where two scenarios were considered: the current scenario in which the target population is treated with the standard therapy (diuretics, digitalis and vaso dilators); on the other hand, the future scenario where these patients are treated with Treprostinil based in a market penetration rate of 2% in the first year and increases of 2% per annum over a 5-year horizon (2017-2021). Direct medical costs were considered, which are the drugs for each of the therapies included in the analysis. The target population was estimated based on the prevalence of pulmonary arterial hypertension NYHA class IV without response to pharmacological therapies in patients aged 16 to 65 years and affiliated with a public health institution. The costs and results are presented in pound sterling (£, 2017) and the epidemiology data used was obtained from institutional sources in the country and from a panel of experts (Delphi method). **RESULTS:** The average annual cost per patient was £ 68,167.70 for treatment with Treprostinil. In the penetration rate, the time horizon and the population eligible for treatment (280 in 2017, 284 in 2018, 287 in 2019, 291 in 2020 and 294 in 2021), the estimated additional average consumption is £ 1,183,990.00. Represents 0.0187% of the total budget allocated to medicines, all within the 5 years’ time horizon. **CONCLUSIONS:** The introduction of Treprostinil into the public health sector in Mexico does not represent a significant financial impact of mexican’s budget.

**PCV42: ANALYSIS OF CLINICAL AND ECONOMIC EFFECTIVENESS OF STATINS FOR SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN KAZAKHSTAN**

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**OBJECTIVES:** Secondary prevention of cardiovascular disease (CVD) means 1) prevention of premature death, 2) reduction in the progression of coronary artery atherosclerosis or achievement of its partial regression and 3) prevention of clinically significant complications. It is generally accepted, that the most effective lipid-lowering medicines are statins; but at the present time there is no clear answer which of the statins are clinically and economically more effective in clinical practice. This research aim was to evaluate clinical effectiveness, safety and economic effectiveness of statins for secondary prevention of CVD in Kazakhstani clinical practice. **METHODS:** For opportunity to evaluate clinical effectiveness and safety of statins for secondary prevention of CVD the systematic literature search was conducted in databases named MEDLINE, EMBASE, NICE, The Cochrane Library. Types of articles: systematic review, meta-analysis. Publication date: no later than 10 years (since 2007). **RESULTS:** As a result of systematic search we found 3 meta-analysis, which had the strong evidences confirmed clinical effectiveness and safety of statins for secondary prevention of major coronary events (OR 0.69, 95% CI 0.62–0.77) and all-cause mortality (OR 0.82, 95% CI 0.75–0.90). In the group of statins, using Atorvastatin in clinical practice is more preferred and should be as the first-line therapy. For economic analysis we took Atorvastatin, Simvastatin, Rosuvastatin, because these statins are reimbursed free of charge by the government. The costs of 1 year of treatment for 1 patient in a standard dose are 1 652 USD for Atorvastatin (20 mg/day); 2 343 USD for Simvastatin (20 mg/day); and 6 699 USD for Rosuvastatin (20 mg/day). **CONCLUSIONS:** We found the strong evidences confirmed clinical effectiveness and safety of statins for secondary prevention of major coronary events and all-cause mortality. In the group of statins, Atorvastatin has advantages in clinical and economic effectiveness and can be recommended as the first-line therapy.

**PCV43: BUDGET IMPACT ANALYSIS OF EMPAGLIFLOZIN (JARDIANCE®) IN TYPE-2 DIABETES PATIENTS WITH HIGH CARDIOVASCULAR RISK IN THE SOUTH AFRICAN SETTING: A RETROSPECTIVE CLAIMS**
DATABASE ANALYSIS


**OBJECTIVES:** Type-2 diabetes mellitus (T2DM) patients at increased risk of cardiovascular (CV) complications contribute around 50% of mortality. Empagliflozin significantly reduces CV risk and mortality when administered on top of standard of care (SoC) (EMPA-REG OUTCOME trial). This study assessed the financial implications of providing empagliflozin for T2DM patients at increased CV risk in South Africa from the perspective of a private health insurance company. **METHODS:** A budget impact model compared treatment with and without empagliflozin on top of SoC. Clinical inputs were sourced from the EMPA-REG OUTCOME study. Local epidemiology, costs and treatment patterns were collected from the claims database of a private health insurance provider. Drug costs were calculated from the single exit price of treatments weighted by the share of each drug class. Clinical events were identified with ICD-10 codes except for revascularisation where CPT4 codes were used. Deterministic sensitivity analysis was performed on all model inputs. **RESULTS:** Across 21,583 privately-insured T2DM patients at increased CV risk and eligible to use empagliflozin, rising to 43,166 patients in year 3, the estimated budget impact was a net saving of R6.2 million in year 1 (Y1), R46.6 million (Y2) and R140.8 million (Y3). A rise in drug acquisition costs was offset by savings in CV event costs including renal failure, transient ischaemic attack, development of macroalbuminuria, and revascularization. Drug cost savings were achieved from Year 3 due to a reduction in insulin use. Insulin usage, mean dose, and acquisition cost had the greatest budget impact. **CONCLUSIONS:** Managing the risk of CV events is essential among T2DM patients. Empagliflozin is budget saving from Year 1 due to savings on CV management costs.

**PCV44:** HEALTH CARE COST IN PATIENTS UNDERGOING ELECTRICAL CARDIOVERSION: AN ANALYSIS FROM THE EDOXABAN VERSUS WARFARIN IN SUBJECTS UNDERGOING CARDIOVERSION OF ATRIAL FIBRILLATION (ENSURE-AF) STUDY

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**OBJECTIVES:** Electrical cardioversion (EC) restores and maintains sinus rhythm in atrial fibrillation (AF) patients. Edoxaban, a direct oral anticoagulant indicated for prevention of stroke or systemic embolic event (SEE) in patients with non-valvular atrial fibrillation (NVAF) was compared with enoxaparin–warfarin in patients undergoing EC in ENSURE-AF (NCT 02072434) study, a phase 3b open-label, multi-national open-label trial comparing edoxaban with enoxaparin/warfarin followed by warfarin alone in 2,199 NVAF patients. ENSURE-AF showed edoxaban had comparable rates of bleeding and thromboembolisms, and greater treatment satisfaction when compared to enoxaparin/warfarin. In this analysis, we aimed to describe differences in health care cost in ENSURE-AF patients from a German health care perspective. **METHODS:** Health care resources utilization during the 28 days of active treatment including all-cause and CV-related hospital admissions, length of stay, emergency department visits for CV reasons not resulting in hospitalizations, and patient visits to investigational site were assessed. Analyses were based on all randomized patients receiving ≥1 dose of study medication (N=2,149). German costs were used to populate the analysis, (Lauer-Taxe cost for drug-related costs, previously published data for outpatient and hospitalization costs, and AMNOG data for INR-related costs) **RESULTS:** Proportion of patients with hospital admission and emergency room visits were similar in both groups, but patients in the edoxaban group had significantly fewer hospitalized days (mean=3.43 vs. 5.41 days per patient, p=0.026), and fewer study site visits (mean=4.75 vs. 7.60, P<0.0001), leading to lower cost in the edoxaban group (€391.17 per patient) compared to enoxaparin-warfarin group (€498.90 per patient). Therefore, on average edoxaban patients showed cost-savings of €107.73 per patient from a German health care system perspective. **CONCLUSIONS:** Patients undergoing electrical cardioversion and receiving edoxaban in ENSURE-AF trial had lower health care cost compared with enoxaparin–warfarin group, due to reduced time spent in hospital and lower number of clinic visits

**PCV45:** BENEFIT-RISK AND MEDICAL COSTS OF RIVAROXABAN 15MG VERSUS VITAMIN K ANTAGONISTS FROM A FRENCH NATIONWIDE COHORT OF 220,000 PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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**OBJECTIVES:** Rivaroxaban, a direct oral anticoagulant indicated for prevention of stroke or systemic embolic event (SEE) in patients with non-valvular atrial fibrillation (NVAF)– was compared with vitamin K antagonists (VKAs) in the Rivaroxaban in the Management of Atrial Fibrillation (Rivaroxaban-AF trial). This study assessed the financial implications of providing rivaroxaban for AF patients at increased CV risk in France from the perspective of a private health insurance company. **METHODS:** A budget impact model compared treatment with and without rivaroxaban on top of SoC. Clinical inputs were sourced from the Rivaroxaban-AF trial. Local epidemiology, costs and treatment patterns were collected from the claims database of a private health insurance provider. Drug costs were calculated from the single exit price of treatments weighted by the share of each drug class. Clinical events were identified with ICD-10 codes except for revascularisation where CPT4 codes were used. Deterministic sensitivity analysis was performed on all model inputs. **RESULTS:** Across 23,079 privately-insured AF patients at increased CV risk and eligible to use rivaroxaban, rising to 55,424 patients in year 3, the estimated budget impact was a net saving of €107.73 per patient from a German health care perspective. Clinical admission and emergency room visits were similar in both groups, but patients in the rivaroxaban group had hospitalization costs, and AMNOG data for INR-related costs. Drug cost savings were achieved from Year 3 due to a reduction in insulin use. Insulin usage, mean dose, and acquisition cost had the greatest budget impact. **CONCLUSIONS:** Managing the risk of CV events is essential among T2DM patients. Empagliflozin is budget saving from Year 1 due to savings on CV management costs.
OBJECTIVES: To compare the benefit-risk and medical costs of rivaroxaban low dosage (15mg) versus vitamin-K antagonists (VKA) for non-valvular (NV) atrial fibrillation (AF) in real-life setting. METHODS: All new users of anticoagulant for NVAF in 2013 or 2014 were identified and followed for 1 year in the French SNIIRAM nationwide claims database. NVAF patients were those with long-term disease registration, hospitalisation, or procedure for AF, without rheumatic valve disease or valve replacement. Patients with rivaroxaban 15mg were 1:1 matched with those with VKA, on gender, age, date of the first drug dispensing, and high-dimensional propensity score, including arterial thrombosis and bleeding risk factors. Relative risk (RR) of the composite criterion (hospitalisation with primary diagnosis for stroke and systemic embolism, major bleeding, and death) during drug exposure was estimated using Cox proportional hazard risk model. Medical costs were calculated according to the collective perspective for the same period. RESULTS: Of 220,011 incident anticoagulant users treated for NVAF in 2013 or 2014, 23,356 patients with rivaroxaban 15mg were matched with the same number of VKA patients. The risk of the composite was significantly lower with rivaroxaban 15mg than VKA (RR: 0.89 [CI95%: 0.84 to 0.94]). The mean cost per patient was higher for anticoagulants and drugs for AF (€688 vs €97), but lower for lab tests (€196 vs €464), transports (€216 vs €289), nursing acts (€677 vs 962€), medical visits (€848 vs €952), specific AF hospitalisations (€892 vs €1,066), and total medical cost (€8,337 vs €10,010). CONCLUSIONS: The study shows that rivaroxaban 15mg for NVAF is cost-saving compared to VKA with a better benefit-risk in real-life setting and a 17% lower medical cost for the French collective perspective.

PCV46: BENEFIT-RISK AND MEDICAL COSTS OF RIVAROXABAN 20MG VERSUS VITAMIN K ANTAGONISTS FROM A FRENCH NATIONWIDE COHORT OF 220,000 PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: To compare the benefit-risk and medical costs of rivaroxaban 20mg (recommended dosage) versus vitamin-K antagonists (VKA) for non-valvular (NV) atrial fibrillation (AF) in real-life setting. METHODS: All new users of anticoagulant for NVAF in 2013 or 2014 were identified and followed for 1 year in the French SNIIRAM nationwide claims database. NVAF patients were those with long-term disease registration, hospitalisation, or procedure for AF, without rheumatic valve disease or valve replacement. Patients with rivaroxaban 20mg were 1:1 matched with those with VKA, on gender, age, date of the first drug dispensing, and high-dimensional propensity score, including arterial thrombosis and bleeding risk factors. Relative risk (RR) of the composite criterion (hospitalisation with primary diagnosis for stroke and systemic embolism, major bleeding, and death) during drug exposure was estimated using Cox proportional hazard risk model. Medical costs were calculated according to the collective perspective for the same period. RESULTS: Of 220,011 incident anticoagulant users treated for NVAF in 2013 or 2014, 31,563 patients with rivaroxaban 20mg were matched with the same number of VKA patients. The risk of the composite was significantly lower with rivaroxaban 20mg than VKA (RR: 0.69 [CI95%: 0.64 to 0.73]). The mean cost per patient was higher for anticoagulants and drugs for AF (€726 vs €102), but lower for lab tests (€177 vs €439), transports (€216 vs €279), nursing acts (€338 vs 583€), medical visits (€897 vs €941), specific AF hospitalisations (€1,100 vs €1,244), and total medical cost (€7,411 vs €8,916). CONCLUSIONS: The study shows that rivaroxaban 20mg for NVAF is cost-saving compared to VKA with a better benefit-risk in real-life setting and a 17% lower medical cost for the French collective perspective.

PCV47: COMPARATIVE EFFECTIVENESS AND MEDICAL COST OF DABIGATRAN VERSUS VITAMIN K ANTAGONISTS FROM ENGEL 2: A FRENCH NATIONWIDE COHORT OF 100,000 PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: The aim of the ENGEL 2 study was to compare effectiveness, risk and medical costs of dabigatran versus vitamin-K antagonists (VKA) for non-valvular (NV) atrial fibrillation (AF) in real-life setting. METHODS: All new users of anticoagulant for NVAF in 2013 were identified and followed for 1 year in the SNIIRAM, the French nationwide claims database. NVAF patients were those with long-term disease registration or diagnosis of
hospitalisation for AF, without valvular disease history. Patients treated with dabigatran were 1:1 matched with those treated with VKA, on gender, age, date of the first anticoagulant dispensing, and high-dimensional propensity score, including major arterial thrombosis and bleeding risk factors. The 4 main outcomes were hospitalisation with primary diagnosis for i) clinically relevant bleeding, ii) arterial thrombotic event, iii) acute coronary syndrome, and iv) death. Relative risk (RR) was estimated using Cox proportional hazard risk model during drug exposure. Medical costs were calculated from the collective perspective for the same period. **RESULTS:** Among the 103,101 new anticoagulant users treated for NVAF in 2013, 20,489 patients with dabigatran were matched to the same number of patients with VKA. The risk of each main outcome was significantly lower for dabigatran compared to VKA, with 29% less events for the composite of the 4 outcomes (RR = 0.71, CI95%: 0.66 to 0.76). The mean cost per patient was higher for anticoagulants and AF drugs (€637 vs €934), but lower for lab tests (€162 vs €384), nursing procedures (€450 vs €702), medical visits (€722 vs €768), transportation (€177 vs €247), cardiovascular hospitalisations (€1,649 vs €2,058), and at the end for total medical cost (€6,747 vs €8,009). **CONCLUSIONS:** The study shows that dabigatran for NVAF is cost-saving compared to VKA due to its better benefit-risk in real-life setting with a 16% lower medical cost for the collective perspective.

**PCV48: MEDICAL COST EVALUATION OF APIXABAN VERSUS WARFARIN IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION: JAPANESE CLAIMS DATABASE ANALYSIS**

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**OBJECTIVES:** The aim of the study was to compare economic costs associated with apixaban vs warfarin in patients with nonvalvular atrial fibrillation (NVAF) using Japanese claims database provided by Medical Data Vision Co., Ltd. **METHODS:** A retrospective cohort study was conducted using de-identified claims data from 275 institutions provided by Medical Data Vision. Adult NVAF patients newly initiated on oral anticoagulants (OAC) from 1 March 2011 to 31 March 2016 were eligible. Based on the first(index) OAC prescription, patients were assigned to apixaban or warfarin groups, and cohorts were matched using propensity score. Per patient cumulative 12 months medical cost and healthcare resource use were compared for the patients who has the follow up period of at least 12 months after the index date. **RESULTS:** After propensity score matching, there were 1,752 warfarin-apixaban matched patients. Compared to warfarin, apixaban were associated with a significantly lower total cost(warfarin: 1,619,418 yen, apixaban: 1,337,258 yen, difference: -282,160 yen per year, p<0.001) in spite of higher OAC cost (warfarin: 15,843 yen, apixaban: 100,113 yen, difference: 84,270 yen per year, p<0.001). Of the total cost, the cost of hospitalization was significantly lower for apixaban versus warfarin(warfarin: 1,228,532 yen, apixaban: 926,183 yen, difference: -302,350 yen per year, p<0.001) with lower total length of stay (warfarin:24.3 day, apixaban:15.5 day, difference: -8.8 day per year, p<0.001). **CONCLUSIONS:** NVAF patients newly treated with apixaban had lower total medical costs and healthcare resource use compared with those treated with warfarin.

**PCV49: EFFECTS OF ADHERENCE TO PHARMACOLOGICAL SECONDARY PREVENTION AFTER MYOCARDIAL INFARCTION ON HEALTHCARE EXPENDITURES**

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**OBJECTIVES:** Following acute myocardial infarction (AMI) patients are at increased risk of mortality, morbidity, and excess costs. Current guidelines recommend using anti-platelet agents, statins, β-blockers, and angiotensin-converting enzyme inhibitors for secondary prevention after AMI. Non-adherence to medication is considered a major health policy issue, accounting for a considerable worsening of the disease, poor prognosis, death, and increased healthcare costs. We compare healthcare expenditures according to the level of adherence to guideline-recommended medications over a period of 3 years after AMI. Furthermore, we identify the most important factors driving costs, rehospitalization, death, and adherence. **METHODS:** We analyze statutory health insurance data from patients enrolled in the Disease Management Program (DMP) coronary artery disease (CAD) with main hospital discharge diagnosis of AMI. They are assumed to be adherent to a medication if the proportion of days covered (PDC) exceeded a threshold of 80%. A generalized linear model (GLM) with gamma distribution and log-link was used to analyze the influence of adherence on healthcare expenditures. Additional GLMs were used to analyze factors influencing costs, rehospitalization, death, and adherence. **RESULTS:** Healthcare expenditure per day was higher in groups adherent to more guideline-based drugs, ranging from €39.38 (no drugs) to €244.58 (three drugs). Healthcare expenditures converged over the 3-year follow-up period. Excess costs were mainly driven by hospitalization costs. The greatest influence on costs was death. Adherence to all drugs decreased the number of rehospitalizations but had no influence on death. The likelihood of being adherent was higher with worse health conditions. **CONCLUSIONS:** PDC for all guideline-based medications was low and declined over time. As PDC was higher in patients with poor health condition and in deceased patients it is of public health interest to establish when physicians start prescribing guideline-recommended medications.
PCV50: COST EFFECTIVENESS ANALYSIS OF HEMOSTATIC MATRIX PADS VS STANDARD OF CARE IN CARDIAC SURGERY (ITALIAN HOSPITAL PERSPECTIVE)

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OBJECTIVES: To compare costs and effectiveness of using two different hemostatic matrices (Hemopatch vs. dry wet gauze compression or similar standard of care (SOC)) in cardiac surgery from the Italian hospital perspective. METHODS: Using clinical outcomes from a published randomized control trial (Weltert 2016), a costing framework was utilized to model the economic impact of using Hemopatch in 170 cardiac surgeries. In this trial, patients treated with Hemopatch had a 97.6% hemostasis success rate (defined as reaching hemostasis in three minutes) which was statistically significantly better than 65.8% with SOC (p<0.001). Additionally clinically significant endpoints studied in the trial (blood transfusions and surgical revisions) were also analyzed. It was assumed that each surgery utilized 2 units of Hemopatch (dimensions of 4.5 x 9 cm) and 2 units of SOC. The Italian product acquisition costs for Hemopatch and SOC were included along with outcome-related costs derived from the literature and adjusted to 2017 EUR using standard inflation estimates. One-way sensitivity analysis (OWSA) and probabilistic sensitivity analyses (PSA) were performed by varying all variables within the 95% confidence interval (CI) of the point estimate or ±20% when CI was not available. RESULTS: Considering only product acquisition cost, Hemopatch had an incremental cost effectiveness ratio (ICER) of €619.81 per hemostasis success when compared to SOC. However, when considering the cost and potential difference in the frequency of transfusions and revisions compared to SOC, the ICER reduced to €474.27 and Hemopatch was associated with a reduction of 1.87 revisions and 17.85 transfusions, saving €3,901.74 and €3,966.27, respectively. Sensitivity analysis demonstrated model robustness. CONCLUSIONS: This analysis supports the use of Hemopatch over standard of care in cardiac surgery in Italian hospitals, as it offers a statistically significant higher hemostasis success rate and may lead to sizable cost savings from reduced transfusions and surgical revisions.

PCV51: THE ECONOMIC IMPACT OF DIETARY SODIUM REDUCTION IN CANADA

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OBJECTIVES: The average Canadian sodium intake is double the amount recommended. Excess dietary sodium consumption is a risk factor for the development of high blood pressure (BP), estimated to cause about 30% of hypertension and 17% of cardiovascular disease (CVD). The cost attributable to high dietary sodium intake in Canada is unknown. Mathematical modeling can be used to explore the potential health and economic impacts of a population-wide reduction in dietary sodium. METHODS: The Canadian Cardiovascular Disease Policy model (C-CVDPDM) is a computer simulation state transition model, which simulates CVD events, costs and health consequences from a public payer perspective for the Canadian population. It can be used to evaluate the economic impact of population health interventions. Using the CVDPDM and a 50-year time horizon, we examined the health and economic impact of a population-wide reduction in dietary sodium of 1800 mg/day. Sensitivity analyses were conducted using modest dietary sodium reductions of 500 mg/day and 1500 mg/day. RESULTS: Reducing dietary sodium by 1800 mg/day is projected to reduce the annual number of new cases of coronary heart disease by 199,808, stroke by 120,381, and myocardial infarction by 115,528, and to reduce the annual number of deaths from any cause, including CVD by 89,734. Overall, the model projected a gain of 24,285 quality-adjusted life years (QALYs), and a savings of $414 million, annually. Modest reductions in dietary sodium intake were also cost saving. CONCLUSIONS: A population-wide reduction in dietary sodium could substantially decrease healthcare costs and improve health outcomes. The results of this work may be useful to policy makers in revising Canadian sodium regulation and policy.

PCV52: COMPARISON OF INCREMENTAL COST-UTILITY RATIOS AND SALES OF DIRECT ORAL ANTICOAGULANTS ACROSS EU-5 COUNTRIES

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OBJECTIVES: To establish within-study and between-study variations in incremental cost-utility ratios (ICUR) of direct oral anticoagulants (DOAC) versus vitamin K antagonists (VKA) for atrial fibrillation (AF) patients across EU-5 countries. Additionally, we aimed to perform a descriptive comparison between total sales per country and ICURs identified. METHODS: OVID-Medline and Embase were systematically searched for original publications of cost-utility analyses reporting ICURs for any DOAC versus VKA in AF in France, Germany, Italy, Spain or United Kingdom (UK) published between 2010 and 2017. Minimum and maximum ICURs and one-way sensitivity analyses (OWSA)
results were collected. ICURs reported for UK were transformed into Euros (€). DOACs sales from April 2016 to March 2017 were extracted for each country from QuintilesIMS MIDAS database. Sold units per AF patient were calculated based on reported prevalence per country and overall population in 2016. RESULTS: A total of 624 unique references were identified, 16 publications reporting 26 cost-utility analyses for France (2), Germany (7), Italy (5), Spain (5) and the UK (7) were included. Minimum and maximum ICUR per country were 12.227€ and 15.638€ for France, 15.207€ and 294.349€ for Germany, 5.600€ and 16.162€ for Italy, 6.397€ and 29.957€ for Spain and 5.637€ and 25.886€ for UK. The variable with the highest impact on ICURs in OWSA was risk of ictus associated to DOAC, followed by drug acquisition cost and time horizon. Italy was the country with the highest DOAC units sold per AF patient followed by Germany, UK, France and Spain. CONCLUSIONS: Differences between DOAC’s ICURs and sales per AF patient arose across countries. Italy was the country for which a lowest DOAC vs VKA ICUR was reported and it was also associated with the highest DOAC units sold per AF patient. However, there seems to be additional criteria other than ICUR driving DOAC’s use.

PCV53: ECONOMIC BURDEN OF HOSPITALIZATIONS RELATED TO PULMONARY ARTERIAL HYPERTENSION (PAH) IN FRANCE

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OBJECTIVES: To assess the current economic burden of hospitalizations related to pulmonary arterial hypertension (PAH) in France. METHODS: A retrospective database analysis (HO-15-16391 study, funded by GSK) was performed using the French national hospital discharge database (PMSI-MCO, 2013). All hospital stays in 2013 with PAH ICD-10 codes (I27.0, I27.2) as principal or associated diagnosis were extracted. Only incident adult patients were analyzed (not hospitalized with PAH in 2011-2012). A medically pre-defined selection algorithm was completed with the input of medical experts in order to exclude any patient identified as presenting with another pulmonary hypertension group. Patients were followed for a year following their index stay. A separate algorithm and a medical review excluded hospitalizations not related to PAH, and classified selected admissions as inclusion (diagnosis, treatment initiation), monitoring and worsening, based on the delay of admission occurrence, length of stay, reason for hospitalization, presence of certain comorbidities and death. Hospital costs associated with PAH management were estimated using published official tariffs in France for 2013 and 2014 expressed in 2015 Euro. RESULTS: A cohort of 384 patients newly diagnosed with PAH was identified. Mean age of patients was 59.6 years old (±16.7), 63% were female. The 1,271 hospital stays were classified as: 415 inclusion stays (32.7%), 604 PAH worsening stays (47.5%) and 252 PAH worsening stays (19.8%). The annual economic burden of hospitalizations for PAH was estimated to €3.6 million with inclusion stays accounting for 28%; monitoring stays for 21%; worsening stays for 51%. The median cost per stay was estimated to be €1,535 [336-108,668], varying from €1,269 [362-6,825] for monitoring stays to €4,121 [518-108,668] for worsening stays. Four patients (1%) had a lung transplantation, which accounted for 10% of total costs (€357,277). CONCLUSIONS: PAH worsening is a major driver of hospital-related costs supporting the relevance of clinically validated therapeutic strategies preventing disease progression.

PCV54: THE IMPACT OF AGEING ON THE FUTURE COSTS AND BURDEN OF HEART FAILURE IN PORTUGAL

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OBJECTIVES: To estimate, the impact of population ageing on the costs and burden of Heart Failure (HF) in Portugal over a twenty-year horizon, between 2014 and 2034. METHODS: HF costs were estimated using a prevalence-based approach. Costs and disability were assumed zero for patients in class I of the New York Heart Association (NYHA) Functional Classification. The prevalence rate was estimated using microdata from a previous epidemiological survey. Average direct costs per patient were estimated using: 1) a primary care national database with records of 25,337 patients registered with HF; 2) National DRG microdata; 3) expert panel; 4) national literature, reports and legislation. Indirect costs associated to patients’ absenteeism and early exit from the labour force were considered. The burden was measured in Disability Adjusted Life Years (DALY) resulting from the sum of Years Lost due to Disability (YLD) and Years of Life Lost (YLL) due to premature death. For YLL, mortality rates reported in the European Detailed Mortality Database were considered. For YLD, disease duration and the overall incidence were
estimated using the software DisMod II. Disability weights were retrieved from published literature. Population ageing was carried out by a shift-share analysis using the official demographic projections. RESULTS: Considering only population ageing on a 20-year horizon, HF prevalence (class II-IV) is expected to increase by 25%, reaching over 312,000 patients in 2034. Total costs in 2014 and 2034 are estimated, respectively, at €289M and €364M (at today's prices), with an increase in the costs per inhabitant of 34%. In 2034, total DALY are expected to be 25% higher than in 2014, from 21,162 to 26,521. The contribution of YLL will increase from 54% to 61%. CONCLUSIONS: Population ageing will substantially increase the burden of HF in Portugal. Health policy makers should consider new strategies to deal with this problem.

**PCV55:** CHRONIC HEART FAILURE (CHF) IN THE CZECH REPUBLIC: COST-OF-ILLNESS ANALYSIS & DISEASE BURDEN BASED ON AHEAD REGISTRY DATA MINING

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OBJECTIVES: In the absence of local real life mortality & morbidity and costs data associated with CHF in the Czech Republic, we aimed to describe CHF socio-economic disease burden (DB) from health care system perspective. This is necessary to be clarified in order to better understand added value of novel therapies. METHODS: We mined data from existing Acute Heart Failure Database (AHEAD). Subgroup of 1274 patients hospitalized in 2 centers in Moravia for acute heart failure (AHF) and afterwards developing CHF that are included in the AHEAD (local registry including patients after AHF hospitalization = index hospitalization), were followed up for 2 years and frequency of hospitalization and their mortality rate were assessed. Six endpoints were determined – AHF re-hospitalization, acute coronary syndrome hospitalization, cardiovascular (CV) hospitalization, non-CV hospitalization, hospitalization for any cause and overall mortality. Patients were classified into 4 groups based on outcome they reached – no death and no hospitalization; death without hospitalization; hospitalization but no death; hospitalization and death. Each hospitalization event was assigned with particular costs based on DRG tariff, just in-patient costs were described. RESULTS: Czech patients were generally older than patients in RCTs (median age 75.9 years). After 24 months of follow-up, 36 % of patients died and 68.2 % of patients had at least one hospitalization/ died. Average number of hospitalizations was 1.2 (SD 1.6). The average annual CHF in-patient costs are 2.8k USD (77% of costs attributed to CV hospitalization). Based on 1.6% CHF prevalence, there is 5.3% of all direct health care spending in the Czech represented by hospitalization of CHF patients. CONCLUSIONS: Patients in real life are in significantly higher risk of hospitalization and all-cause mortality (by approx. 80 %), compared to RCT population. Overall HF DB in the Czech is notable and compared to published evidence it is greatly underestimated.

**PCV56:** BURDEN OF CARDIOVASCULAR DISEASE (CVD) FOR PATIENTS WITH FAMILIAL HYPERCHOLESTEROLEMIA (FH) OR ATHEROSCLEROTIC CVD (ASCVD) AND THE IMPACT OF LOW DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C) LOWERING IN TWO MIDDLE EAST COUNTRIES

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OBJECTIVES: To estimate the burden of CVD and the impact of LDL-C lowering in patients with FH or ASCVD with uncontrolled LDL-C levels in Saudi Arabia (SA) and United Arab Emirates (UAE). METHODS: The number of statin-treated national patients with FH or ASCVD with uncontrolled LDL-C≥100mg/dL (≥2.6 mmol/L) in SA and UAE was estimated based on country population and disease prevalence. The clinical benefits of evolocumab as an add-on therapy to statins were derived from a long-term cardiovascular outcomes study (FOURIER) and the Cholesterol Treatment Trialists’ Collaboration, a large meta-analysis of statin outcomes trials, modeled over a lifetime to determine the impact on CV events, hospitalization costs, and quality adjusted life years (QALY). RESULTS: The number of statin-treated national patients with FH or ASCVD with uncontrolled LDL-C was estimated at 28,692 FH and 293,697 ASCVD in SA; 2,419 FH and 27,606 ASCVD in UAE. Over the lifetime of an individual with FH, the additional LDL-C lowering with evolocumab is projected to result in a 0.52 (28%) CVD event reduction, a decrease in hospitalization costs of $5,225 USD in SA and $5,008 USD in UAE, and an average increase of 3.26 QALY. Similarly, over the lifetime of an individual with ASCVD, the additional LDL-C lowering with evolocumab was projected to result in a 0.44 (23%) CVD event reduction, a decrease in hospitalization costs of $4,403 USD in SA and $4,219 USD in UAE, and an average increase of 1.84 QALY. CONCLUSIONS: CVD burden is significant in SA and UAE for FH and ASCVD patients. There is a great potential for clinical and economic benefits with further LDL-C reduction using evolocumab on top of statin therapy.

**PCV57:** THE COST OF ILLNESS OF HEART FAILURE IN PORTUGAL
OBJECTIVES: To estimate direct and indirect costs associated to adult Portuguese patients with heart failure (HF) in 2014. METHODS: A prevalence-based approach was adopted to estimate costs associated to HF. Prevalence in 2014 by the New York Heart Association (NYHA) Functional Classification was estimated using microdata from a previously conducted national community-based epidemiological survey. Only patients at NYHA classes II-IV were considered to have costs and it was conservatively assumed that patients were either followed in hospital ambulatory care or in primary care. Primary care costs were estimated using a database covering a large population, with records of medications, medical visits and medical tests or diagnostic procedures for 25,337 patients with a HF diagnosis in 2014. Hospital resource consumption was estimated using national DRG microdata. Resource utilization in hospital ambulatory care and in emergency department (ED) episodes was estimated according to experts’ opinion and the national literature, respectively. Unit costs were based on the official NHS tariffs. The indirect costs associated to patients’ absenteeism and early exit from the labour force were based on national sources and conservative assumptions. RESULTS: The class II-IV prevalence rate in the population aged 25+ was estimated at 3.4%, corresponding to 249,592 patients in 2014. HF patients have about 1.1 million medical visits, over 36,000 hospitalizations and approximately 53,000 ED episodes. In 2014, the overall direct and indirect costs were estimated at €289.4M with an average annual cost per patient of €1,159. Medication, medical visits, exams/diagnostic procedures, hospitalization and ED episodes accounted for 29%, 20%, 21%, 26% and 2% of the €244.9M direct costs, respectively. The indirect costs associated to absenteeism and premature exit from the labour market were estimated at €16.4M and €28.1M, respectively. CONCLUSIONS: Heart failure is a costly condition and should receive adequate attention from the Portuguese health policy makers.

PCV58: ECONOMIC BURDEN OF HEART FAILURE IN ASIAN COUNTRIES

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OBJECTIVES: We conducted this study to estimate economic burden and find unmet needs in 4 Asian countries including Korea (KR), Taiwan (TW), Thailand (TH), and Malaysia (MY). METHODS: It was a retrospective, cohort, medical chart review, and non-interventional study in 4 countries of 6 tertiary hospitals. With different Gross Domestic Product (GDP) per capita (KR $27,811, TW $22,639, TH $5,921, MY $11,009), it aimed not to compare the results among countries, but to estimate and describe it respectively. Patients who met those criteria were included: 1) over 19 years old, 2) diagnosed with HF (ICD 9 or 10) codes and 3) ≥1 hospitalization or ≥2 outpatient visit. Index period was one year (Jan. 1 to Dec. 31 in 2014). We collected variables including demographics, healthcare cost and resumption including drugs. RESULTS: A total of 568 patients were included (KR 200, TW 200, TH 100, MY 68). We particularly focused on patients with hospitalization experience and there were KR 40, TW 187, TH 49, and MY 48 patients, respectively. In Korea, the hospitalization cost per event was $7,419 and $10,714 in annual cost per patient. In Taiwan, cost for hospitalization was $3,019 and $4,790 of annual cost per patient. In Thailand, cost for hospitalization was $5,285 and annual cost per patient was $7,181. In Malaysia, cost for hospitalization was $744 with $1,776 of annual cost. The length of stay per hospitalization was KR 12.2 days, TW 15.7 days, TH 14.2 days, and MY 5.5 days, respectively. Drug consumption varied in countries. Other than diuretics, the most frequently prescribed agent in 4 countries was nitrate in KR, anticoagulant in TW, and beta-blockers in both TH and MY. CONCLUSIONS: The burden of HF is considerable and especially hospitalization is significant factor contributing to cost of disease. Consequently, effort to raise awareness of HF is required to reduce it.

PCV59: BURDEN OF CARDIOVASCULAR DISEASE (CVD) FOR PATIENTS WITH FAMILIAL HYPERCHOLESTEROLEMIA (FH) OR ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD) AND THE IMPACT OF REDUCING LOW DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C) LOWERING IN LATIN AMERICAN COUNTRIES

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OBJECTIVES: To estimate the burden of CVD and impact of LDL-C lowering in patients with FH or ASCVD with uncontrolled LDL-C levels in Mexico, Colombia, and Brazil. METHODS: The number of statin-treated patients with FH or ASCVD with uncontrolled LDL-C≥100mg/dL (≥2.6 mmol/L) in Mexico, Colombia, and Brazil was estimated based on country population and estimated disease prevalence. The clinical benefits of evolocumab as an add-on therapy to statins were derived from a long-term cardiovascular outcomes study (FOURIER) and the Cholesterol Treatment Trialists’ Collaboration, a large meta-analysis of statins outcomes trials, modeled over a lifetime to determine the impact on CV events, hospitalization costs, and quality adjusted life years (QALY). RESULTS: The number of statin-treated patients with FH or ASCVD with uncontrolled LDL-C was estimated at 0.15-0.37 million FH and 2.85 million ASCVD patients with uncontrolled LDL-C in Mexico; approximately 0.29-0.73 million FH and 2.5 million ASCVD patients in Colombia. Over the lifetime of an individual with FH, the additional LDL-C lowering with evolocumab is projected to result in a 0.52 (28%) CVD event reduction, and an increase in 3.26 QALY. The cost of hospitalization may decrease by $5,377USD in Mexico, $3,468USD in Colombia, and $612 in Brazil. Similarly, over the lifetime of an individual with ASCVD, evolocumab was projected to result in a 0.44 (23%) CVD event reduction, and an increase in 1.84 QALY. For ASCVD patients, the cost of hospitalization may decrease by $4,603USD in Mexico, $2,883USD in Colombia, and $512USD in Brazil. CONCLUSIONS: CVD burden is significant in Latin America for FH and ASCVD patients. There are potentially long-term clinical, humanistic and economic benefits when LDL-C is reduced below target LDL-C goals.

PCV60: BURDEN OF ILLNESS OF DEEP VEIN THROMBOSIS IN EUROPE – MORTALITY AND HEALTH RELATED QUALITY OF LIFE

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OBJECTIVES: Deep-vein thrombosis (DVT) and pulmonary embolism (PE; collectively termed venous thromboembolism [VTE]) are a major healthcare burden in Europe, but exact estimates of this burden are lacking. This study reports results from the PREFER study concerning mortality and quality of life of DVT patients. METHODS: The PREFER in VTE registry was a prospective, observational, multicenter study, carried out in seven European countries, designed to provide data concerning treatment patterns, resource utilization, mortality and quality of life. Data was available for 2,056 patients with a first-time and/or recurrent DVT with follow-up documentation at 1, 3, 6 and 12 months. Survival was analyzed using logistic regression, assessing the impact of baseline characteristics with a breakdown in cancer and non-cancer patients. Quality of life - as measured by EQ-5D-5L – was analyzed using the similar variables applying a repeated measures tobit regression. RESULTS: In DVT patients with a mean age of 60 years, 42.9% with active cancer and 4.7% of those without active cancer died within a year. Higher age, the presence of liver disease and lower BMI were significant predictors in both groups. Additionally, smoking history, previous AF, major surgery, varicose veins or bed rest >5 days were significant predictors in the non-cancer group. Average quality of life improved from baseline to 12 months in both the cancer (from 0.72 to 0.87) and non-cancer group (0.70 to 0.79). When scoring non-survivors at zero, average quality of life decreased in the cancer group to 0.55 at 12 months. Higher age, BMI and the presence of selected co-morbidities significantly added to the quality of life burden. CONCLUSIONS: Mortality rates and quality of life estimates in DVT patients are below age-adjusted UK estimates. The effect of co-morbidities is significant and limits the potential to draw firm conclusions about the real “net” burden of DVT.

PCV61: BURDEN OF ILLNESS OF PULMONARY EMBOLISM IN EUROPE – MORTALITY AND HEALTH RELATED QUALITY OF LIFE

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OBJECTIVES: The incidence rate of pulmonary embolism (PE) is estimated at 0.95 per 1000 in Europe. The evidence of PE associated burden of illness in Europe is scarce. The aim of this study was to assess the burden of PE, in terms of mortality and health-related quality of life (HRQoL), as a function of patient characteristics, across Europe. METHODS: The PREFER in VTE registry was a prospective, observational, multicenter study conducted in seven European countries (France, Italy, Spain, UK, and DACH (Germany, Switzerland and Austria)). Venous thromboembolism (VTE) patients, following an acute event (index event), were recruited and followed at 1, 3, 6 and 12 months. The study sample was 1399 patients with PE. Subgroup analysis by country and with active cancer were conducted. The association between patient characteristics and mortality/HRQoL (EQ-5D-5L) were examined using a regression approach with the total sample. RESULTS: Average mortality rate at 12 months was 8.1%, varying between observed regions (1.4% in DACH to 16.8% in Italy), and substantially differed between patients with active cancer and those without (42.7% vs. 4.7%). Cancer was one of the most significant predictors for mortality, other predictors include age, BMI, more than 5 days bed rest, vascular disease, previous AF, smoking history and symptoms of palpitations. EQ-5D-5L index score at baseline (right after the index event) was 0.712 (SD: 0.265), and gradually improved to 0.835 (0.212) at 12 months. When scoring non-survivors at zero, average quality of life decreased to 0.743 at 12 months. Similarly, the index scores varied between observed countries and cancer subgroups. Active cancer, previous stroke and provoked VTE are amongst other significant factors for predicting index scores. CONCLUSIONS: PE is associated with a substantial burden of illness – increasing mortality rate and decreasing HRQoL. Country variation exist and active cancer has a significantly large impact on PE burden.

PCV62: BURDEN OF ILLNESS OF PULMONARY EMBOLISM IN EUROPE – HEALTHCARE RESOURCE UTILIZATION AND PRODUCTIVITY LOSS

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OBJECTIVES: Pulmonary embolism (PE) is likely associated with a substantial economic burden to society, however, respective evidence in Europe is scarce. The aim of this study was to report healthcare resource utilization (HCRU) and absence from work of PE patients using the PREFER in VTE registry. METHODS: The PREFER in VTE registry was a prospective, observational, multicenter study in seven European countries, providing data concerning treatment patterns, HCRU, mortality and quality of life. Data was available for 1,399 patients with a first-time and/or recurrent PE with follow up documentation at 1, 3, 6 and 12 months. Descriptive statistics were presented by cancer and country subgroups. Logit and Cox regression was implemented to investigate the relationship between baseline characteristics and hospitalization and return to work, respectively. RESULTS: Average age was 62.3 years old. Cancer patients were mostly treated with heparin (84.9%), while non-cancer patients were treated with combinations of heparin, VKA and NOACs. NOACs were used less in Italy and Spain (4.5% and 6.1 %). VTE-related re-hospitalization rate and average length of stay at 12 months varied substantially between countries, from 26.2% in UK to 12.3% in France, and from 12.9 days in Italy to 3.9 days in France, respectively. PE patients were often co-managed by general practitioners in France and DACH (Germany, Austria and Switzerland) (>84%), whereas the number was lower in other countries (<47%). The regression results confirmed the country variation of HCRU. Of working subjects, 60% returned to work at 1 month but more than 30% had not returned after one year. Cancer was a significant predictor for not returning to work. CONCLUSIONS: Medical treatment of PE differs between cancer and non-cancer patients. VTE related resource utilization differs markedly between countries. Work-loss seems high in patients with PE, but may at least in part reflect the presence of co-morbidities.

PCV63: MODELLING THE BURDEN OF CARDIOVASCULAR DISEASE IN MEXICO AND THE IMPACT OF REDUCING MODIFIABLE RISK FACTORS

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OBJECTIVES: This study aims to estimate the current and future burden of cardiovascular diseases (CVD) in Mexico, and quantify the impact of reducing modifiable risk factors. METHODS: A burden of disease model was used to forecast the burden of CVD in Mexico, and estimate the impact of reducing modifiable risk factors (tobacco use, hypertension, type 2 diabetes, obesity and physical inactivity) in the general Mexican population, in accordance with World Health Organization (WHO) targets. Another model estimated the impact of reducing LDL-cholesterol through
increased access to effective treatment for two high risk populations: heterozygous familial hypercholesterolemia (HeFH) and secondary prevention (SP), with a focus on patients with LDL-cholesterol >100 mg/dL. Inputs for the models included disease and risk factor prevalence, population forecast, CVD event rates, and treatment effectiveness, primarily derived from the published literature. Direct costs to the public health care system and indirect costs from lost production due to premature mortality, hospitalizations, and absenteeism were included, although the cost of programs and pharmacological interventions to reduce risk factors was not considered. **RESULTS:** The prevalence of CVD is projected to increase to 2.7 million adults by 2035, while the economic burden, including both direct and indirect costs, would increase to US$24.9 billion. The value of reducing modifiable risk factors (except LDL-cholesterol) is estimated at US$28 billion over the forecast period. Similarly, the value of reducing LDL-cholesterol through increased access to effective treatment would be up to US$4.2 billion for HeFH patients and up to US$58.3 billion for SP patients over the forecast period. **CONCLUSIONS:** The burden of CVD is significant and growing. Efforts to achieve WHO risk factor targets and further lower LDL-cholesterol through increased access to effective treatment for high-risk patients are projected to greatly reduce the clinical, economic, and humanistic burden of cardiovascular disease in Mexico.

**PCV64: BURDEN OF ILLNESS OF DEEP-VEIN THROMBOSIS IN EUROPE – HEALTHCARE RESOURCE UTILIZATION AND PRODUCTIVITY LOSS**

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**OBJECTIVES:** Deep-vein thrombosis (DVT) forms a major healthcare burden in Europe, but exact estimates concerning the economic burden on society are lacking. This study reports results from the PREFER study concerning resource utilization and absence from work in DVT patients. **METHODS:** The PREFER in VTE registry was a prospective, observational, multicenter study carried out in Europe (France, Italy, Spain, the UK, and DACH [Germany, Switzerland and Austria]), designed to provide data concerning treatment patterns, resource utilization, mortality and quality of life. Data was available for 2,056 patients with a first-time and/or recurrent DVT, followed for 12 months. Data about resource utilization concerns only resource utilization directly related to DVT. Descriptive statistics were presented per country and by cancer subgroup. The probability of being hospitalized and length of stay were analyzed as a function of demographics, previous events and co-morbidities. Using similar variables, time until return to work was analyzed using Cox regression. **RESULTS:** Patients were on average 60 years old. Cancer patients were mostly treated with heparin (83.9%), non-cancer patients with heparin (63.1%), followed by VKA (45.0%). NOAC’s were less often used in Spain and Italy (<7.0%). 20.5% of the patients with and 12.2% of patients without active cancer (n=88; n= 1462) were hospitalized for on average 8.2 and 10.1 days, respectively. The hospitalization-rate was highest in Italy (16.7%) and lowest in France (7.7%). Furthermore, the average length of stay was highest in Italy (16.6 days) and lowest in DACH (5.2 days). Physician visits were highest in DACH (9.3), lowest in the UK (2.6). Of those working, 50% returned to work at 1 month; more than 30% never returned to work within 500 days. **CONCLUSIONS:** Medical treatment of DVT differs between cancer and non-cancer patients. VTE-related resource utilization differs remarkably between countries. Work-loss seems high, but questions may be raised concerning the causality due to the presence of co-morbidities.

**PCV65: SHORT-TERM DIRECT AND INDIRECT COST BURDEN OF CARDIOVASCULAR EVENTS IN PATIENTS WITH A HISTORY OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE IN THE US**

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**OBJECTIVES:** To estimate short-term direct and indirect costs of cardiovascular events (CVE) among patients with atherosclerotic cardiovascular disease (ASCVD) **METHODS:** The Truven Health MarketScan Commercial Database was used to identify adults (age ≥18–<64) with ASCVD and a CVE (index event) from 1/1/2014 to 9/30/2015. CVE was defined as an inpatient stay with admitting diagnosis of myocardial infarction (MI), ischemic stroke (IS), transient ischemic attack (TIA), unstable angina (UA), or inpatient or outpatient revascularization (coronary artery bypass graft or percutaneous coronary intervention) without an associated CVE. A 24-month pre-index period was used to assess ASCVD and patients were followed until death or 90 days, whichever occurred first. Short-term (90 day) direct healthcare costs were calculated for all patients. A subset analysis was conducted of patients in the MarketScan Health and Productivity Management (HPM) database to capture indirect costs due to productivity loss due to workplace absence (WA) and short- and long-term disability (STD and LTD). Direct and indirect costs were estimated
across type of CVE. RESULTS: 8,870 patients met inclusion criteria (mean age 55.9, SD=6.5; 32.7% female). The majority (42.0%) had revascularization as their index CVE, followed by MI (31.5%), IS (19.1%), TIA (5.8%), and UA (1.5%). Short-term direct costs following CVE were highest for revascularization patients ($74,179), followed by MI ($59,187), IS ($51,436) UA ($35,793) and TIA ($25,548). In the 90 days following CVE, patients accrued 19 WA, 16 STD and 5 LTD days with associated costs highest for IS ($7,857), followed by revascularization ($6,542), MI ($5,754) and TIA ($5,106); no eligible HPM patients had an index UA event. CONCLUSIONS: The direct and indirect costs among ASCVD patients in the 90-days following a CVE are substantial ranging from $40,899 to $80,721. Reducing risk of CVE can potentially lower the direct costs and help employers decrease absenteeism and disability days for their employees.

PCV66: MODELLING THE BURDEN OF CARDIOVASCULAR DISEASE IN TURKEY AND THE IMPACT OF REDUCING MODIFIABLE RISK FACTORS

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OBJECTIVES: This study aims to estimate the current and future burden of cardiovascular diseases (CVD) in Turkey, and quantify the impact of reducing modifiable risk factors. METHODS: A burden of disease model was used to forecast the burden of CVD in Turkey, and estimate the impact of reducing modifiable risk factors (tobacco use, hypertension, type 2 diabetes, obesity and physical inactivity) in the general Turkish population, in accordance with World Health Organization (WHO) targets. Another model estimated the impact of reducing LDL-cholesterol through increased access to effective treatment for two high risk populations: heterozygous familial hypercholesterolemia (HeFH) and secondary prevention (SP), with a focus on patients with LDL-cholesterol >100 mg/dL. Inputs for the models included disease and risk factor prevalence, population forecast, CVD event rates, and treatment effectiveness, primarily derived from published literature. Direct costs to the public health care system and indirect costs from lost productivity due to premature mortality, hospitalizations, and early retirement were included, although the cost of programs and pharmacological interventions to reduce risk factors was not considered. RESULTS: The prevalence of CVD is projected to increase to 5.4 million adults by 2035, while the economic burden, including both direct and indirect costs, would increase to US$5.7 billion. The value of reducing LDL-cholesterol through increased access to evolocumab could lead to savings of up to US$691.3 million for HeFH patients and up to US$8.1 billion for high-risk SP patients over the forecast period. CONCLUSIONS: The burden of CVD is significant and growing. Efforts to achieve WHO risk factor targets and further lower LDL-cholesterol through increased access to effective treatment for high-risk patients are projected to greatly reduce the clinical, economic, and humanistic burden of cardiovascular disease in Turkey.

PCV67: MODELLING THE BURDEN OF CARDIOVASCULAR DISEASE IN BRAZIL AND THE IMPACT OF REDUCING MODIFIABLE RISK FACTORS

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OBJECTIVES: This study aims to estimate the current and future burden of cardiovascular diseases (CVD) in Brazil, and quantify the impact of reducing modifiable risk factors. METHODS: A burden of disease model was used to forecast the burden of CVD in Brazil, and estimate the impact of reducing modifiable risk factors (tobacco use, hypertension, type 2 diabetes, obesity and physical inactivity) in the general Brazilian population, in accordance with World Health Organization targets. Another model estimated the impact of reducing LDL-cholesterol through increased access to effective treatment for two high risk populations: heterozygous familial hypercholesterolemia (HeFH) and secondary prevention (SP), with a focus on patients with LDL-cholesterol >100 mg/dL. Inputs for the models included disease and risk factor prevalence, population forecast, CVD event rates, and treatment effectiveness, primarily derived from the published literature. Direct costs to the public health care system and indirect costs from lost production due to premature mortality, hospitalizations, disability, and absenteeism were included, although the cost of programs and pharmacological interventions to reduce risk factors was not considered. RESULTS: The prevalence of CVD is projected to increase to 13.6 million adults by 2035, while the economic burden, including both direct and indirect costs, would increase to US$40 billion. The value of reducing modifiable risk factors (except LDL-cholesterol) is estimated at US$28 billion over the forecast period. Similarly, the value of reducing LDL-cholesterol through increased access to effective treatment would be up to US$4.6 billion for HeFH patients and up to US$39.2 billion for SP patients over the forecast period. CONCLUSIONS: The burden of
CVD is significant and growing. Efforts to achieve WHO risk factor targets and further lower LDL-cholesterol through increased access to treatment for high-risk patients are projected to greatly reduce the clinical, economic, and humanistic burden of cardiovascular disease in Brazil.

**PCV68: MYOCARDIAL REvascularization: Comparative Cost Study in South America Health Care System.**

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**OBJECTIVES:** To compare the procedure’s costs for myocardial revascularization performed in 2004 and 2015, and their variations among different cities hospitals accredited by Brazilian Government Health Care System (BGHS), by the coronary bypass surgery (CBS) and percutaneous transluminal coronary angioplasty (PTA) among hospitals over a one-year follow-up. **METHODS:** Data from 368 procedures and 86 patients were submitted to 87 CBS and 240 patients to 267 PTA, between January 2015 and December 2015, and October 2003 and April 2004 respectively, were collected. Each group was subdivided in Subgroup A (A1 to A5), B and C, in respect to the manner of payment. **RESULTS:** The mean cost for A subgroup were R$12,985.18 (USD $4,400), subgroup B (CBS) was R$7,759.78 (USD $2,900) per procedure; in the PTA group the cost/angioplasty was R$6,307.79 (USD $2,100). At the end of a year, the end values were R$7,875.73 (USD $2,600) for the CBS and R$8,234.96 (USD $2,900) for the PTA group (USD RATE 3:1). **CONCLUSIONS:** The authors concludes that: There is a difference between subgroup A and B, regarding the median cost (33%), considering 10 years gap. The cost/angioplasty in the PTA group was minor than CBS group, and 50% minor than CBS group ten years later.

**PCV69: A BUSINESS CASE FOR STROKE REDUCTION INITIATIVES IN ATRIAL FIBRILLATION: 3-YEAR FINANCIAL PROJECTIONS FOR THREE UK REGIONS**

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**OBJECTIVES:** Atrial Fibrillation (AF) is a common and treatable risk factor for ischaemic stroke and vascular dementia with rising incidence. Oral anticoagulation (OAC) therapy is a well-evidenced way to prevent AF-related strokes, as supported by NICE Clinical Guidelines (CG180, 2014). **METHODS:** In March 2017 the Academic Health Science Network (AHSN) launched the AF Business Case Model using publicly-reported practice-level data to help Clinical Commissioning Group (CCGs) across England identify specific areas for improving four key gaps in the diagnosis and management of AF. The cost-impact analysis identified the most cost efficient way to increase OAC therapy in order to reduce the risk of stroke, and generates a ‘business case report’ to facilitate local decision-making. **RESULTS:** The business case analysis for three regions in England reveals the net cost impact of a 12-month programme to close gaps in AF management. The 3-year net savings, based on combined health and social care costs, were as follows: Yorkshire and the Humber AHSN (101,788 patients on AF register): Identifying undiagnosed AF: £21,469.04; Assessing AF stroke risk: £8,191.23; Initiating OAC in eligible patients: £25,008.65; and Perfecting OAC: £27,134.56. Imperial College Health Partners, North West London (patients on AF register: 23,551): Identifying undiagnosed AF: £9,326,444; Assessing AF stroke risk: £8,212.38; Initiating OAC in eligible patients: £10,997.21; and Perfecting OAC: £12,813,309. **CONCLUSIONS:** The AF Care Pathway Business Case Model helps define local healthcare investment priorities along the AF management pathway to achieve long-term cost savings and improvements in clinical outcomes. Initiating and perfecting inadequate OAC in currently diagnosed, eligible patients would achieve the greatest combined cost saving in all three regions reviewed in this cost-impact analysis.

**PCV70: MODELLING THE SOCIETAL IMPACT OF ALIROCUMAB IN PATIENTS WITH SEVERE HYPERCHOLESTEROLEMIA TREATED WITH APHERESIS IN GERMANY**

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**OBJECTIVES:** Patients with severe hypercholesterolemia are at high risk of cardiovascular events. Many of them do not achieve recommended LDL-C target levels by maximal lipid lowering therapy and therefore have to undergo
PCV71: ONE YEAR COST OF ISCHEMIC STROKE AND INTRACRANIAL HEMORRHAGE ACCORDING TO DISABILITY FOR ATRIAL FIBRILLATION PATIENTS IN FRANCE

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OBJECTIVES: Patients with atrial fibrillation (AF) are at high risk of cerebral thromboembolic and hemorrhagic events, with potential residual disability. The aim of this research was to estimate the one-year costs of these events in the French context. METHODS: A retrospective analysis of the French National Hospital Discharge Abstract database was performed for years 2013-2015. AF patients hospitalized for either an ischemic stroke, a hemorrhagic stroke or an intracranial hemorrhage with an identified diagnosis of FA or a previous hospitalization for AF were followed during one year. Readmissions to acute care, admissions and stays in rehabilitation centers were identified per patient. Data were matched with Dijon registry data to identify patients according to their Modified Rankin Score at discharge, reclassified in “no disability” = Rankin 0-1, “slight to moderate disability” = Rankin 2 to 4, “severe disability” = Rankin 5. Costs were documented using the French National Cost Survey. RESULTS: 20,625 stays for ischemic strokes, and 4,647 intracranial hemorrhages were identified. In-hospital mortality was respectively 14.3% and 34.2 %. Respectively 50.2% and 56.5% of surviving patients had no disability, 35.2% and 30.3% had a slight to moderate disability, and 14.6% and 13.2% a severe disability. Costs of initial stays were € 8,353 for patients who died, € 6,108, € 7,708, € 9,908 according to disability for ischemic strokes. Costs for intracranial hemorrhages were respectively €7,307 for patients who died, € 7,627, € 9,654 and € 8,863 according to disability. One year costs for survivors according to disability levels were € 7,277, € 30,293 and € 19,508 for ischemic strokes, out of which rehabilitation accounted for 2.2%, 61.7% and 48.0%. One year costs for intracranial hemorrhages were € 9,628, € 33,810 and € 21,986, amongst which rehabilitation weighted 2.1%, 54.9% and 42.6%. CONCLUSIONS: Disability and rehabilitation drive one-year costs for AF patients who experience intra-cerebral events.

PCV72: COST-EFFECTIVENESS OF SACUBITRIL/VALSARTAN IN THE TREATMENT OF HEART FAILURE IN COLOMBIA

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OBJECTIVES: To analyze the cost-effectiveness of sacubitril/valsartan versus usual care in heart failure with reduced ejection fraction (HFrEF) for patients classified as New York Heart Association (NYHA) Class II-IV, in Colombia. METHODS: Previously developed UK cost-effectiveness model based on PARADIGM-HF (McMurray, 2014) trial was adapted to Colombia using the Latin-American trial subgroup (N=1,433) and Colombia-specific epidemiologic and economic data to assess the impact of sacubitril/valsartan versus usual care (ACEI). A (Markov) cost-utility model structured as a regression-based cohort model with one-month cycling was utilized to examine a hypothetical cohort of HFrEF patients receiving therapy. Clinical outcomes included mortality, hospitalization, and adverse events. Quality-adjusted-life years (QALY) were derived from the trial. Costs (2015 COP$) include drug, hospitalization and resource use. Primary outcome was cost-utility (cost/QALY gained) over a 30-year time horizon. Sensitivity analyses were performed. RESULTS: Base-case results suggest that compared with an ACEI, sacubitril/valsartan is associated with incremental costs of COP$16.6 million and 0.50 QALYs gained, resulting in an
incremental cost-effectiveness ratio of COP$32.4 million per QALY gained. Increased costs of pharmacological therapy were offset by reductions in hospitalization costs. All-cause and CV-related mortality are projected to be reduced at all time points. Expected survival is estimated to increase from 7.20 years for those receiving an ACEi to 8.11 years for a cohort of patients receiving sacubitril/valsartan. Overall, results were not sensitive to changes in model parameters; results were most sensitive to parameters used to estimate CV mortality and duration of treatment effect. CONCLUSIONS: The Colombia-adapted model estimates suggest that sacubitril/valsartan represents a cost-effective intervention in the treatment of HFrEF (NYHA Class II-IV) versus an ACEi, assuming a willingness-to-pay threshold of 3 times the 2015 per capita GDP in Colombia (COP$52.4 million). Consequently, sacubitril/valsartan represents reasonable value compared with other commonly accepted health care interventions.

**PCV73: COST-EFFECTIVENESS OF RADIOFREQUENCY CATHETER ABLATION OF ATRIAL FIBRILLATION BASED ON REAL-WORLD DATA: MANUAL OR ROBOTIC?**

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**OBJECTIVES:** Atrial fibrillation (AF) is the most common cardiac arrhythmia, associated with significant mortality and morbidity and thus a relevant socioeconomic impact. The purpose is to outline the general overview of manual and robotic navigation techniques for radiofrequency catheter ablation (RFA) of AF from a cost-effectiveness point of view with hospital perspective. **METHODS:** The analysis of the different techniques has been conducted through a cost-effectiveness study facing two manual and one robotic technique to obtain the RFA as the definitive treatment of AF. The study has used a decision-tree model for patients with AF based on a real world data database consisting of 688 registries with records from 2005 to 2015, all of them with a 1-year follow-up. The cost of each RFA technique was calculated from daily costs procedures of HM Hospitals. **RESULTS:** After the 1-year follow-up from the first RFA treatment, the use of steerable sheath is always cost-effective. The associated ICER of the robotic navigation system is 21,461.35 € per additional percentage point of success in RFA procedure versus the use of non-steerable sheath. **CONCLUSIONS:** The results of the cost-effectiveness analysis shows the advantages of the steerable sheath versus other RFA techniques in order to treat atrial fibrillation. The robotic navigation system is not cost-effective versus steerable sheath although it achieves similar success rates.

**PCV74: COST-EFFECTIVENESS OF IVABRADINE IN THE TREATMENT OF CHRONIC HEART FAILURE FROM THE MEXICAN PERSPECTIVE**

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**OBJECTIVES:** To assess the cost-effectiveness of ivabradine for the treatment of chronic heart failure as an adjuvant to the standard therapy in patients with systolic dysfunction, NYHA class II to IV, with sinus rhythm, heart rate ≥ 75 bpm. The study was conducted in comparison with standard therapy alone, from the perspective of public health institutions in Mexico. **METHODS:** A Markov model was developed with 8 health states. The model cycles were 3 months and the time horizon was 2 years, and extrapolated to 5 years. The costs of hospitalization and standard therapy were obtained from government sources. The transition probabilities to the 1st hospitalization state and death state were obtained from the sub-analysis of SHIFT study (Böhm, y otros, 2013), second and third hospitalization states were taken from another sub-analysis (Borer, y otros, 2012) The main effectiveness outcome were life-years gained (LYG). incremental cost effectiveness ratio (ICER) per LYG was calculated to compare the treatments. **RESULTS:** Over a 2-year time horizon, treatment with ivabradine plus standard therapy produced 1.78 LYG at a cost of $84,236.07, versus 1.69 LYG with standard therapy at a cost of $86,100.07. Thus, ivabradine plus standard therapy represents a saving of $1,864.00, therefore it is a dominant alternative. Moreover, in a 5-year horizon, treatment with ivabradine plus standard therapy represents 3.23 LYG at a cost of $144,681.27, versus 2.78 LYG with standard therapy at a cost of $128,401.29. The ICER was $35,937 which means that ivabradine plus standard therapy is a cost-effective option. **CONCLUSIONS:** This study demonstrated that ivabradine plus standard therapy is a cost-effective option over a 2-year horizon. Over a 5-year horizon, ivabradine plus standard therapy is a cost-effective option for public health institutions in Mexico.

**PCV75: PRECISION COST-EFFECTIVENESS ANALYSIS OF RADIOFREQUENCY CATHETER ABLATION IN A REAL-WORLD ATRIAL FIBRILLATION POPULATION**

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OBJECTIVES: Cost-effectiveness of treating atrial fibrillation (A-fib) with radiofrequency catheter ablation (RFA) has been analyzed in several studies based on decision-analytic Markov models. The aim of this study was to re-evaluate this topic using a novel framework based on real world evidence (RWE), and identify precision cohorts in which RFA was more cost-effective. METHODS: A 3-year registry data of 8302 Chinese A-fib patients were used for the economic evaluation of RFA using clinical metrics (e.g., mortality rate, occurrence of adverse events) and economic metrics (incremental cost-effectiveness ratio (ICER), and net monetary benefit (NMB)). Patient population was further segmented into sub-cohorts based on patients’ features including demographic information, chronic conditions, current drug treatments, and clinical test results to differentiate the effect of the RFA treatment. RESULTS: Positive clinical effectiveness of RFA was observed in the overall population, with a lower mortality rate of 0.985% in treated patients compared with 4.744% in non-treated patients, a gain of 0.098 quality-adjusted life years (QALYs) associated with an incremental cost of ¥10,075 within the 3-year timeframe, resulting in an ICER of ¥102,413 per QALY gained, and an NMB of ¥4,682 assuming the willingness to pay equaled to ¥165,000 following the WHO-recommended effective-cost threshold of three times the national annual GDP per capita. Several sizable cohorts were identified in which RFA was associated with higher NMB and lower ICER. For example, patients with renal disease (e.g., blood creatinine higher than 120µmol/L) benefited significantly more from RFA. The advantages and limitations of using ICER and NMB to evaluate short-term cost-effectiveness through RWE were also discussed. CONCLUSIONS: RFA was shown to be a cost-effective treatment in a real-world A-fib population, in which sub-cohorts of patients gaining more NMB from RFA were identified. This approach may have implications for future explorations in precision health economics and outcomes research.

PCV76: COST-EFFECTIVENESS OF EDOXABAN IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION IN HONG KONG

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OBJECTIVES: Atrial fibrillation (AF) is a common arrhythmia associated with debilitating consequences such as stroke, heart failure and venous thromboembolism. In HK, 20-25% of stroke cases are related to AF leading to a significant burden. Warfarin has been the frontline oral anticoagulant for AF but with high bleeding risk and hence monitoring and dose adjustment are required. The non-vitamin-K antagonist oral anticoagulants (NOACs) are alternatives to warfarin for preventing stroke and systemic embolism in non-valvular AF (NVAF) patients. This study aims to evaluate the cost-effectiveness of edoxaban in HK as an alternative to rivaroxaban or warfarin. METHODS: A Markov model with monthly life cycle was populated with epidemiological and economic parameters to project cost-effectiveness of edoxaban over life-time horizon. Probabilities of clinical events for edoxaban and rivaroxaban compared to warfarin were derived from a network meta-analysis. Data on resource utilization and treatment cost of clinical events were derived from primary data from hospitals in HK or published literature. Health state utilities and treatment discontinuation rates were extrapolated from literatures. All costs were 2017 figures and cost and effectiveness were both discounted at 3% per annum. Sensitivity analyses were performed to test model robustness. RESULTS: Total per-patient healthcare cost over remaining lifetime horizon for high-dose edoxaban was lower than rivaroxaban by US$2,437 with mean QALYs gained of 0.054 per patient, suggesting edoxaban being dominant over rivaroxaban. Similar findings were obtained from low-dose edoxaban. Compared with warfarin, high-dose (low-dose) edoxaban led to an ICER of US$4,917 (US$2,294). Multivariate probabilistic sensitivity analysis showed that both high- and low-dose edoxaban has 100% probability of being cost-effective compared to warfarin using 50,000 USD per QALY gained. CONCLUSIONS: This study showed that once-daily edoxaban (60 mg/30 mg dose-reduced) regimen appears to be a dominant or highly cost-effective treatment relative to rivaroxaban (20mg/15mg dose-reduced) for stroke prevention in AF in Hong Kong.

PCV77: COST-EFFECTIVENESS OF STATIN PRIORITISATION BASED ON ABSOLUTE RISK REDUCTION FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

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OBJECTIVES: Statins are prescribed for primary cardiovascular disease (CVD) prevention based on absolute risk of CVD over 10 years (ARR10). Individuals with lower ARR10 but high LDL cholesterol may experience the same 10-year absolute CVD risk reduction (ARR10) from statin therapy as those with higher ARR10 but moderate LDL. This study aimed to estimate the cost-effectiveness of ARR10-based statin treatment incremental to ARR10-based treatment. METHODS: A microsimulation version of the CVD Policy Model, a decision-analytic state-transition model, was employed. The model estimated health and cost outcomes for a cohort of CVD-free individuals, accounting for outcomes and costs associated with statin treatment and CVD events. Individual demographic and risk factor profiles
were randomly drawn from U.S. National Health and Nutrition Examination Surveys 1999-2010, producing a cohort of 50,000 CVD-free individuals (50% women) who were simulated from ages 40-80 years. Moderate-intensity statin therapy was simulated first for those with AR10≥7.5% (standard of care) and was then extended to those with AR10≥2.3% (the minimum ARR10 at the 7.5% AR10 threshold). ARR10 was assigned using a formula that accounted for LDL and AR10. AR10 was assigned using the 2013 U.S. Pooled Cohorts CVD Risk Score. Effectiveness was quantified in quality-adjusted life years (QALYs), costs were quantified in 2017 $U.S., and both were discounted at an annual rate of 3%. The primary outcome was the incremental cost-effectiveness ratio (ICER). RESULTS: Incremental to treating all AR10≥7.5%, adding treatment of remaining AR10≥2.3% yielded an ICER of $15,783/QALY.Treating remaining AR10≥2.3% would prevent 1,223 lifetime CVD events in the cohort. Women benefited most (68% of 1,245 QALYs gained). In scenario analyses, results were sensitive to treatment adherence (ICER: Dominant-$52,598/QALY) and efficacy (ICER: $4,984-70,628/QALY) inputs. CONCLUSIONS: Statin treatment based on ARR10 is cost-effective and would yield significant lifetime health gains in U.S. adults. Women would gain most from ARR10-based statin treatment when AR10<7.5%.

PCV78: COST-EFFECTIVENESS OF EICOSAPENTAENOIC ACID (EPA) ON PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE
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OBJECTIVES: Eicosapentaenoic acid (EPA) was shown to reduce cardiovascular events when added to statin therapy. The aim of this study is to analyze cost-effectiveness of EPA plus statin compared with statin monotherapy for primary prevention of cardiovascular disease in Japan. METHODS: Markov model was applied to assess the costs and benefits associated with EPA over a 30-year time horizon from Japanese health-care payer perspective. Incremental cost-effectiveness ratio (ICER) with benefits expressed as quality adjusted life year (QALY) was estimated. The impact on survival, number of events was based on the Japan EPA Lipid Intervention Study (JELIS). Sensitivity analyses were conducted to explore the influence of various input parameters on costs and outcomes. RESULTS: EPA-plus-statin therapy compared with statin monotherapy resulted in greater cost (total 30-year costs €31,899 vs €20,137 per person, respectively) and improved utilities (average 18.8 vs 18.7 QALYs, respectively). ICER was €236,538 per QALY gained. At a cost-effectiveness threshold of €40,000 per QALY gained, the probability that EPA-plus-statin was cost-effective compared statin monotherapy was 39%. Sensitivity analyses showed much lower EPA drug cost might improve ICER within cost-effectiveness threshold. CONCLUSIONS: EPA plus statin was not cost-effective for primary prevention of cardiovascular disease in Japan.

PCV79: A SYSTEMATIC REVIEW OF COMPARATIVE EFFECTIVENESS OF EZETIMIBE AND PCSK9 INHIBITORS
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OBJECTIVES: Recently published clinical guidelines recommend the use of ezetimibe and Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9) inhibitors for patients with persistent high LDL-C despite treatment with maximal tolerated statin dose. The objective of this study was to systematically review the cost-effectiveness of ezetimibe and PCSK9 inhibitors for these patients. METHODS: We searched PubMed, Embase, and Cochrane Database of Systematic Reviews to identify studies published from May 2007 to April 2017. Full-text, original articles evaluating the economic value of ezetimibe and PCSK9 inhibitors were selected. From the selected articles, two reviewers independently extracted data on the study population, comparators, economic model, perspective, time horizon, discount rate, type of costs, clinical data source, economic and clinical outcomes, sensitivity analyses, funding source, and country. RESULTS: A total of 13 articles meeting all inclusion criteria were reviewed. Cost-effectiveness analyses were conducted in six different countries including the US (n=5) and UK (n=4). All studies selected a lifetime horizon except one study with a 5-year time horizon. Only two studies adopted a societal perspective. Of the 13 studies, seven studies included ezetimibe in their economic evaluations. Ezetimibe monotherapy was considered to be cost-effective compared with no treatment. The ezetimibe/simvastatin combination therapy was also cost-effective compared with statin therapy. However, ezetimibe combined with other statins was not always considered to be cost-effective compared with statin therapy. Five studies included PCSK9 inhibitors, and one study included both ezetimibe and PCSK9 inhibitor in their cost-effectiveness analyses. The PCSK9 inhibitor monotherapy was not cost-effective compared with statins or ezetimibe. The cost-effectiveness of the PCSK9 inhibitor/statin combination therapy was not consistent across studies. CONCLUSIONS: Given the current cost of ezetimibe and PCSK9 inhibitors, their cost-effectiveness results depended largely on the types of statins being used together and comparator treatments. Cost reductions of ezetimibe and PCSK9 inhibitors may potentially impact their cost-effectiveness in future.
PCV80: USE OF DISEASE RISK SCORE IN THE EVALUATION OF EFFECTIVENESS FOR PURPOSES OF HTA

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OBJECTIVES: Clinical effectiveness of non-randomized studies can be influenced by confounding factors. Disease risk score (DRS) is a statistic method for eliminating confounding factors in studies, where it is not possible to separate subjects into sets using randomization. The aim of the study was to use the disease risk score method in creating balanced patient data sets and their use in the cost effectiveness analysis. METHODS: In the study we retrospectively reviewed the records of 615 patients with atrial fibrillation (228 patients were treated with conventional pharmacology therapy and 387 patients were treated with catheterization ablation). In the study we used two models of DRS: unexpoused-only DRS and full-cohort DRS. Balanced data sets were further used to evaluate treatment efficacy (percentage of patients with sinus rhythm at the end of follow-up). Costs were assessed from the perspective of health care payer and then used to calculate cost-effectiveness. RESULTS: In the original data set of 615 patients, the sinus rhythm in the conventional treatment group was at 10.1% patients and in the ablation treatment group at 86.3% patients. The CEA was for the conventional group 4250 and for the ablation group 3001. Using unexpoused-only disease risk score method, we created data set of 191 patients in both treatment groups. The CEA was for the conventional group 5460 and for the ablation group 2998. Using full-cohort disease score method, we created data set of 150 patients in both treatment groups. The CEA was for the conventional group 3783 and for the ablation group 3011. CONCLUSIONS: The results of the two balanced data sets were not significantly different from the results of the original data set but using DRS helped to get a more precise estimate of the clinical effect on the basis of proved removal of bias from the original data.

PCV81: COST-EFFECTIVENESS OF APIXABAN FOR STROKE PREVENTION IN ATRIAL FIBRILLATION: AN KAZAKHSTAN PERSPECTIVE

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OBJECTIVES: Apixaban, dabigatran, and rivaroxaban are 3 novel oral anticoagulants (NOACs) currently approved for stroke prevention in patients with atrial fibrillation (AF). Although warfarin remains the standard of care in Kazakhstan. The objective of this study was to evaluate the cost-effectiveness of apixaban against other NOACs and warfarin from the considering costs and savings for public payers perspective in Kazakhstan. METHODS: A Markov model was developed to evaluate the pharmacoeconomic impact of apixaban versus other NOACs over a lifetime. Direct comparisons from the Aristotle trial versus warfarin and pair-wise indirect treatment comparisons against other NOACs were used to assess relative effect size for following end points: ischemic stroke, hemorrhagic stroke, intracranial hemorrhage, other major bleeds, clinically relevant non major bleeds, myocardial infarction, and treatment discontinuations. Main outcomes are given in terms of costs per quality-adjusted life years gained. Resource use and costs were estimated from published data. Discount rate of 3% was used to discount both cost and QALYs. RESULTS: The model predicted that apixaban would lead to 0.22 YOLs (discounted) and 0.27 QALYs gained (discounted), at an incremental cost of $1564 (discounted). This resulted in ICERs of $5428 per YOLs and $6529 per QALY gained. Being the option with lower cost of all the comparators apixaban resulted in a dominant alternative. Sensitive analysis indicated that warfarin option costs were very sensitive to international normalized ratio (INR) monitoring frequency and cost but in general results were robust over a wide range of inputs. CONCLUSIONS: Although this analysis vs NOACs was limited by the absence of head-to-head trials, based on the indirect comparison data available, our model projects that apixaban may be a cost-effective alternative to dabigatran, rivaroxaban and warfarin for stroke prevention in AF patients from the savings for public payers perspective in Kazakhstan.


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OBJECTIVES: Emergent percutaneous coronary artery intervention (PCI) is an effective therapy to restore blocked heart blood flow in patients with ST segment elevation myocardial infarction (STEMI). This technique is classically performed through femoral artery access (FAA), or recently radial access (RA). Previous evidence in selected low
risk patients suggest better clinical outcomes for radial access by reducing access site complications with promising data on cost reduction. There is no study in real life high risk patients with clinical outcomes and economical evaluation, so we developed an economic evaluation to compare FAA and RA procedures. **METHODS:** A single-center retrospective observational study was carried out with 387 consecutive STEMI patients who underwent e-PCI from 2006 to 2014 with no clinical exclusion criteria. Clinical endpoints were procedural success, access site crossover, mortality, length of in-hospital stay and complication rate. Economical endpoints were total cost and costs by category at hospital setting. Hospital’s perspective was adopted with micro costing bottom-up method. Average costs were obtained from the hospital’s accounting system and other Health Care data bases. A discount rate of 3% per year was applied. Depending on the different type of variables Student’s t test, chi-square, Fischer’s exact tests and linear regression were used. To determine independent predictor factors logistic regression was carried out. Bootstrapping was performed with 1000 iterations for robustness and sensitivity analysis. **RESULTS:** A significant reduction >20% (OR=0.29, 95% CI 0.16 to 0.48 p=0.00) in complication rates favoring RA group (cardiac, vascular, bleeding and in-hospital infection) was found with an average saving of 3875€ [95% bootstrapped CI 1590.46 to 6098.17 p=0.001] per procedure with radial access. **CONCLUSIONS:** In e-PCI setting of STEMI there is a clinical outcome improvement (reduced procedure related mortality and complications) and cost reduction if radial access is used, being a dominant (more effective and less costly) strategy compared to FAA in our hospital real life cost-effectiveness study.

**PCV83: THE IMPACT OF MISSED TREATMENT OPPORTUNITIES ON OUTCOMES IN HOSPITALISED HEART FAILURE PATIENTS: MODELLING ANALYSIS BASED ON THE NATIONAL HEART FAILURE AUDIT**

**Objective:** Many patients with hospitalised heart failure (HF) do not receive treatments as recommended by clinical guidelines, resulting in suboptimal outcomes. We aimed to investigate the potential impact of implementing recommended HF therapies on health outcomes, and to estimate the costs and effectiveness of methods for improving provider adherence. **METHODS:** The health benefits of ACE inhibitor, beta blockers and optimal therapy (ACE inhibitors and beta-blockers if not contraindicated) following hospitalisation for HF were combined with evidence on uptake. The aim was to examine how much health was lost as a result of failure to follow guidelines, and how much could be gained using different strategies to promote uptake. The net health benefits of the different treatments (measured in quality-adjusted life-years (QALYs)) were estimated using a previously developed decision analytic model and relative effects of treatment from the literature. Data on the number of patients who would have benefitted from the addition of an ACE inhibitor, beta-blockers or optimal therapy (ACE inhibitors and beta-blockers if not contraindicated) was estimated from 2010 to 2013 using the National Heart Failure Audit (NHFA). **RESULTS:** Each treatment recommended in the guidelines was associated with positive net health benefit. In 2010, 4019 (38.3% of) patients would have benefitted from some additional treatments (optimal therapy) rising to 4,886 patients in 2013 (although falling to only 25.2% of HF patients). Failure to follow guidelines is predicted to result in large losses in health. For example, in 2010, if all patients had received the optimal therapies they were eligible to receive, 1,569 QALYs would have been gained, implying a maximum justifiable investment in interventions to promote uptake of £31.4 million. **CONCLUSIONS:** Current gaps in translation of evidence to practice in hospitals are associated with significant health losses. Strategies to encourage the full uptake of guidelines could be effective and cost effective.

**PCV84: COST-EFFECTIVENESS OF LANDIOLOL, AN ULTRA-SHORT-ACTING BETA-BLOCKER, FOR PREVENTION OF POSTOPERATIVE ATRIAL FIBRILLATION IN GERMANY**

**Objective:** Postoperative atrial-fibrillation (POAF) is common among surgical patients and associated with a worse outcome. Arterial-fibrillation (AF) is the most frequent complication arising after coronary-artery-bypass-grafting (CABG) surgery, occurring in 30% of cases. The incidence of this complication is even higher after valve-replacement surgery (30–40%) and after compound operative procedures (40–60%). Beta-blockers reduce POAF and supraventricular tachycardia and have direct arrhythmogenic activity. Landiolol hydrochloride, is an ultra-short-acting beta-blocker half-life of approximately 4 min. The selectivity ratio of landiolol is higher than other beta-blockers. **METHODS:** A decision-model was developed to reflect the cost-effectiveness of landiolol vs. no-prevention, standard-of-care (SoC) and esmolol for the patient group with different cardiac surgeries and a subgroup of CABG. The model benefit is expressed in a reduction in POAF episodes and reduced complications. Clinical data were derived mainly from the meta-analysis of Li et al. (2015) involving 807 patients (9 RCTs). The model calculates total inpatient costs (incl. surgery, ICU, complication and re-hospitalisation) over the hospital-length-of-stay (LOS). Costs from published sources were used (2016 Euro) from the German hospital perspective. A one-way deterministic sensitivity-analysis accounts for uncertainty. **RESULTS:** Patients with POAF had a higher incidence of mortality, morbidity and LOS including ICU and more frequent readmissions and finally higher costs. Per patient costs with
landiolol are estimated between 24,234.21€-25,910.02€ and AF occurred in 12.4%-19.1% of cases. Against no-prevention landiolol is able to reduce hospital cost by 1,638.10€ and decreases POAF by 24.9%. Compared with SoC landiolol lower hospital costs by 1,840.63€ and reduce POAF events by 20.1%. Analysing the CABG subgroup, per patient costs with landiolol are estimated between 23,960.86€-24,216.84€. AF cases occurred in 8.8%-12.1% of patients. Compared to comparators landiolol is able to reduce costs between 1,536.92€ (no-prevention) and 1,448.23€ (esmolol). **CONCLUSIONS:** The economic-analysis shows that the use of landiolol is highly cost-effective and associated with cost-savings.

**PCV85:** THE USE OF THE PROPENSITY SCORE IN THE COST-EFFECTIVENESS ANALYSIS OF THE ATRIAL FIBRILLATION TREATMENT.

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**OBJECTIVES:** Clinical effectiveness of non-randomized studies can be influenced by confounding factors. One of the methods that can be used to get a precise estimate of a clinical effect from non-randomized clinical trials is a propensity score. The aim of the study was to evaluate the possibilities of using propensity score for assessing the efficiency of health technologies and its practical use in the cost effectiveness analysis. **METHODS:** In the study we retrospectively reviewed the records of 615 patients with atrial fibrillation (228 patients were treated with conventional pharmacology therapy and 387 patients were treated with catheterization ablation). Two methods of propensity score matching were used: nearest neighbour and caliper matching. Balanced data sets were further used to evaluate treatment efficacy (percentage of patients with sinus rhythm at the end of follow-up). Costs were assessed from the perspective of health care payer and then used to calculate cost-effectiveness. **RESULTS:** In the original data set of 615 patients, the sinus rhythm in the conventional treatment group was at 9.20% patients and in the ablation treatment group at 86.3% patients. The CEA was for the conventional group 4660 and for the ablation group 3001. Using nearest neighbour matching method, we created data set of 196 patients in both treatment groups. The CEA was for the conventional group 4660 and for the ablation group 3022. Using caliper matching method, we created data set of 124 patients in both treatment groups. The CEA was for the conventional group 4420 and for the ablation group 2973. **CONCLUSIONS:** The results of the two balanced data sets were not significantly different from the results of the original data set but using propensity score helped to get a more precise estimate of the clinical effect on the basis of proved removal of bias from the original data.

**PCV86:** IS IT COST-EFFECTIVE TO VACCINATE PATIENTS WITH ACUTE CORONARY SYNDROME AGAINST INFLUENZA VIRUS?

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**OBJECTIVES:** Influenza vaccination can reduce the risk of hospitalization and mortality concerned with cardiovascular events, particularly, the probability of major adverse cardiovascular events (MACEs) in Acute Coronary Syndrome (ACS) patients. Numerous studies have studied the influence of influenza vaccination, however, no studies have examined its influence in ACS patients regarding cost-effectiveness. Therefore, we aimed to estimate MACEs and its related costs in the cost-effectiveness. **METHODS:** Using data derived from the Health Insurance Review and Assessment - National Patient Sample, the direct and indirect costs of MACEs in ACS patients were estimated with a probabilistic model. Sensitivity analyses for vaccine effectiveness were conducted to verify whether the parameters of the model are uncertain by testing the effect of a 60% to 80% vaccine efficacy against influenza. **RESULTS:** The cost of influenza vaccination in ACS patients in Korea was estimated to be $22.6 million. Additionally, influenza vaccination can potentially reduce the MACEs-related hospitalization cost, transportation cost, and caregiver cost of ACS patients by $59.1 million, $186,224, and $28 million, respectively. Also, indirect costs would decrease by $21.5 million. Thus, the overall reduction in costs would be $86.2 million annually. The sensitivity analysis showed that influenza vaccination would be cost-effective in ACS patients with a probability of 99.8%. **CONCLUSIONS:** Influenza vaccination in ACS patients reduces the cost of hospitalization and untimely death due to MACE and appears to be highly cost-effective. Therefore, nationwide supports for influenza vaccination to ACS patients are highly recommended to relieve socioeconomic burdens concerned with ACS.

**PCV87:** THE COST-EFFECTIVENESS OF SACUBITRIL/VALSARTAN IN THE TREATMENT OF CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION IN TURKEY
OBJECTIVES: To evaluate the cost-effectiveness of sacubitril/valsartan relative to angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB), in the treatment of chronic heart failure with reduced ejection fraction (HFrEF). METHODS: A regression-based cohort model demonstrating the progression of HFrEF from clinically stable state to death was adapted to the Turkish setting. Individual patient data generated in PARADIGM-HF clinical trial were used as the source of clinical parameters. These data were extrapolated to future by using multivariate regression and survival analysis techniques. The time horizon was 30 years, which might be considered as life-time, given the age of patients. An expert panel, with the participation of experts in cardiology, was established for the adaptation of clinical data to Turkish practice. The analysis was undertaken from payer’s perspective. Only direct costs were taken into account. Local costs of medications, hospitalization, monitoring and adverse events were converted based on TL/EUR currency rate of 3.7166 at end of 2016. Incremental cost effectiveness ratio (ICER) per life year (LY) gained were calculated. Willingness-to-pay (WTP) threshold was set as the local gross domestic product (GDP) per capita (11,014USD = 9,987EUR as of 2015). RESULTS: The patient population was assumed to consist of 73% male, with a mean age and EF of 62.3 years and 29.4% respectively. Although the cost of sacubitril/valsartan was higher compared with ACEI or ARB; it was associated with 1.40 LYs longer survival compared with ACEI/ARB (survival durations were 11.08 LYs with sacubitril/valsartan and 9.68 LYs with ACEI or ARB). The ICER values corresponding to sacubitril/valsartan use instead of ACEI/ARB were 7,086EUR/7,021EUR per LY gained, respectively. CONCLUSIONS: Sacubitril/valsartan, in view of its significant improvement in survival and an ICER value below WTP threshold, is suggested to be a cost-effective alternative for the treatment of patients with HFrEF in Turkey.

PCV88: STATIN COST EFFECTIVENESS: A SYSTEMATIC REVIEW INCLUDING THE RECENT LITERATURE

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OBJECTIVES: To conduct a systematic review of the literature on statin cost-effectiveness published up to April 2017. METHODS: PubMed, Embase, and Cochrane Database of Systematic Reviews were searched to identify studies published in English between May 2007 and April 2017. Studies were selected if they conducted economic evaluation of statins as first- or second-line treatment for patients with hypercholesterolemia and/or at risk for cardiovascular disease. The outcome of interest was the cost-effectiveness results of statins reported in the studies. In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, two reviewers independently screened the title, abstract, and full-text articles. From the selected studies, data were extracted independently by two reviewers, and discrepancies were discussed with a third reviewer to reach consensus. RESULTS: After removing duplicates and irrelevant articles, we identified a total of 283 articles; of these, 16 articles met our inclusion criteria. Nine studies compared statins with placebo or no treatment in their economic evaluations while seven studies evaluated cost-effectiveness between different statins. Statins (simvastatin, atorvastatin, and rosvuastatin) were considered to be cost-effective compared with placebo or no treatment in some countries. However, one study found pravastatin to be cost-ineffective compared with no treatment for primary prevention of coronary artery disease. Atorvastatin has consistently been reported as cost-effective compared with simvastatin. Mixed results were reported regarding the cost-effectiveness of rosvuastatin compared with atorvastatin: two studies found rosvuastatin could be economically more favorable than atorvastatin while one study reported the opposite findings. CONCLUSIONS: Most statins were found to be cost-effective compared with placebo or no treatment. In addition, some statins were found economically favorable over other statins. Notably, these cost-effectiveness results should be interpreted with the consideration of the specific healthcare settings where statins were placed for their economic evaluations.

PCV89: HEALTH ECONOMIC EVALUATION OF ELECTIVE CARDIOVERSION OF ATRIAL FIBRILLATION WITH RIVAROXABAN VERSUS VITAMIN K ORAL ANTAGONISTS

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OBJECTIVES: Electrical cardioversion (ECV) is a procedure in which a direct-current electric shock is used to, quickly and effectively restore the normal sinus rhythm. Appropriate anticoagulation reduces the risk of embolic events during and after the ECV procedure. The aim of this study is to estimate the cost-effectiveness of rivaroxaban compared to a vitamin K oral antagonist (VKA) in patients with atrial fibrillation (AF) undergoing elective ECV in the Netherlands. METHODS: A static transmission model over a one year time-horizon was developed to compare rivaroxaban to VKAs in terms of clinical outcomes, health effects and costs. The clinical outcomes were AF-related
events, such as stroke and hemorrhages. Costs were assessed from a societal perspective, also accounting for indirect costs due to productivity losses and informal care. The final outcomes were incremental costs and quality-adjusted life years (QALYs). Cost-effectiveness was assessed at a willingness-to-pay (WTP) of €20,000/QALY gained. RESULTS: The use of rivaroxaban as an anticoagulant in patients with AF scheduled for ECV would lead to a health gain of 0.23 QALY per patient and would cost €1.83 per patient from the societal perspective resulting in an incremental cost-effectiveness ratio (ICER) of €7.92/QALY gained. The probability of rivaroxaban being cost saving was 49.6% compared to VKAs from this perspective. From the health care payer perspective, total costs would be €509 per patient with a health gain of 0.23 QALY per patient resulting in an ICER of €2,198/QALY gained. CONCLUSIONS: The use of rivaroxaban in elective electrical cardioversion is a cost-effective alternative for VKAs. Rivaroxaban has almost a 50% probability to be cost-saving and would increase a patients’ quality of life when taking into account non-healthcare costs such as productivity loss and informal care costs.

PCV90: COST-EFFECTIVENESS ANALYSIS OF STANDARD THERAPY WITH PHOSPHOCREATINE VS STANDARD THERAPY IN PERIOPERATIVE MANAGEMENT OF CARDIAC SURGERY PATIENTS WITH EXTRACORPOREAL CIRCULATION, WITH ISCHEMIC HEART DISEASE OR WITH CHRONIC HEART INSUFFICIENCY

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OBJECTIVES: To determine the preferential scheme of medical therapy in perioperative management of cardiac surgery patients with extracorporeal circulation, with ischemic heart disease or with chronic heart insufficiency from the point of view of pharmacoeconomic analysis with the use of standard therapy in comparison with standard therapy + phosphocreatine. METHODS: The developed pharmacoeconomic model was based on the results of meta-analysis of Landoni G. and co-authors, and an open-label non-interventional comparative study by FSBI A.N. Bakoulev Scientific Center of the MOH of Russia. Final result of the cost analysis included the direct expenses associated with complications due to the surgery. The time horizon was 1 year. RESULTS: Use of phosphocreatine in perioperative management of cardiac surgery patients has led to the higher values of LYG in comparison with the use of standard therapy and is more efficient as a result of improvement of such parameters as: frequency of myocardial infarction cases, frequency of arrhythmia cases, the need in inotropic therapy, the need to stay in emergency department and the number of inpatient days. In case of the standard therapy + phosphocreatine, the values of LYG constituted 0.96 years, and in case of the standard therapy – 0.88 years. The cost of a 12-months treatment with standard therapy and with standard therapy + phosphocreatine constituted 83,566 rubles and 75,337 rubles respectively. Cost-effectiveness analysis reveals that the cost-effectiveness ratio in the group of standard therapy + phosphocreatine constitutes 78,444 rubles, whereas in the group of standard therapy – 95,176 rubles. CONCLUSIONS: Insignificant increase of the standard therapy cost by adding phosphocreatine makes it possible to prevent perioperative complications and mortality of cardiac surgery patients, is cost saving and make expenses efficient. Standard therapy + phosphocreatine is a dominant treatment method in comparison with the standard therapy.

PCV91: COST-EFFECTIVENESS ANALYSIS OF ACEI AND ARBS II DRUGS IN PATIENTS WITH ARTERIAL HYPERTENSION

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OBJECTIVES: Compare cost-effectiveness of use of 8 drugs of antihypertensive group ACEI (fosinopril, lisinopril, ramipril and perindopril) and ARBS II (losartan, valsartan, candesartan and telmisartan) in patients with arterial hypertension in Russia for one-year period. METHODS: The criterion of effectiveness in the pharmacoconomic study is the achievement of target blood pressure levels. Apart from efficiency criterion determination for cost-effectiveness analysis as well as cost analysis unwanted cardiovascular event are identified including myocardial infarction, stroke and heart failure, as well as side effects of drug therapy such as hypotension, cough and angioedema. Efficacy data and the incidence of cardiovascular events and side effects of the investigated drugs are taken from randomized clinical studies. Direct costs analysis is carried out based on existing standards for the provision of emergency and specialized medical care in arterial hypertension, myocardial infarction, stroke, heart failure and angioneurotic edema, as well as costs of relief of hypotension and cough and one of pharmacotherapy. For reference, we used the Euro: 1 Euro = 67 RUB. RESULTS: The effectiveness analysis shows that the highest blood pressure levels among the investigated drugs, is of ramipril – 85% and valsartan – 82.7% and the lowest perindopril – 46% and telmisartan – 58%. The highest total costs per year per patient are for ramipril - 1038 and losartan - 1022 €, the lowest total cost had fosinopril – 340 € and lisinopril – 415 €. In the result cost-effectiveness analysis, the highest cost-effectiveness ratio is for losartan – 15 € and telmisartan – 12 €, and the lowest ratio have the fosinopril – 4 and lisinopril – 7 €. CONCLUSIONS: The treatment regimen with the use of the medicinal product fosinopril is dominant from the point
of view of cost-effectiveness analysis because this therapy is less costly for a single case of achievement of target blood pressure levels.

**PCV92: A REVIEW OF ECONOMIC EVALUATIONS CONSIDERING SCREENING INTERVENTIONS FOR THE RISK ASSESSMENT OF VENOUS THROMBOEMBOLISM IN WOMEN CONSIDERING COMBINED ORAL CONTRACEPTIVES**

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**OBJECTIVES:** Use of combined oral contraceptives (COCs) in women increases the risk of venous thromboembolism (VTE), which can have a major impact on quality of life. VTE is also associated with an increase in healthcare costs. Our aim was to systematically review cost-effectiveness analyses (CEAs) considering any screening for risk of VTE in women using COCs, to assess the quality of these studies, and to summarize the results. **METHODS:** A search strategy was performed in MEDLINE, Embase, the Centre for Review and Dissemination (CRD) database including the Economic Evaluation Database from the UK National Health Service, and Cochrane reviews. Two reviewers independently screened and determined the final articles, and a third reviewer resolved any discrepancies. Consolidated Health Economic Evaluation Reporting Standards were used to assess the quality of reporting in terms of perspective, effectiveness measures, model structure, cost, time-horizon and discounting. **RESULTS:** Four publications (three from Europe, one from the United States) were deemed suitable to be included in the review and to undergo full assessment. According to current criteria, none of the studies were of sufficient quality of reporting. Incremental cost-effectiveness ratio was above accepted thresholds of €40,000 to €50,000. The studies varied in terms of type of costs assessed, country settings, model assumptions and uncertainty around input parameters. Key drivers of CEAs were sensitivity and specificity of the test, incidence rate of VTE, relative risk of prophylaxis, and costs of the test. **CONCLUSIONS:** Universal screening strategies for risk of VTE in regards to COCs may not be cost-effective according to accepted cost-effectiveness thresholds within Europe. However, modifications to the targeted population and cost could potentially make screening for VTE economically viable. Further cost-effectiveness studies that explore individual screening based on standardized economic methods are required to improve decision making for this pertinent issue within personalized medicine.

**PCV93: COST-EFFECTIVENESS ANALYSIS OF SACUBITRIL/VALSARTAN COMPARED WITH STANDARD ACEI THERAPIES FOR HEART FAILURE PATIENTS WITH REDUCED EJECTION FRACTION IN TAIWAN**

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**OBJECTIVES:** Heart failure (HF) is highly prevalent in the elderly people and has been considered as an intractable disease due to poor survival and life quality. Recently, a novel oral therapy, sacubitril/valsartan, has proven its efficacy in reducing cardiovascular (CV) mortality (by 20%) and all-cause mortality (by 16%) compared with enalapril, an angiotensin-converting enzyme inhibitor (ACEi) in HF patients with reduced ejection fraction (HFrEF). Taiwan has a universal health insurance program govern by a single payer, National Health Insurance Administration (NHIA). Due to stringent cost containment, the economic evaluation for a new drug is crucial for decision-making. The aim of this study is to perform a cost-effectiveness analysis for sacubitril /valsartan compared with 4 types of ACEi for HFrEF patients from a single payer’s perspective. **METHODS:** We adopted a 2-state Markov model developed by McMurray et al. The effectiveness was derived from the PARADIGM-HF trial. Medical utilization and cost data were derived from the NHIA claimed data. Both incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) were estimated. The ceiling ratio was set at Gross Domestic Product (GDP) per capita in Taiwan, around $23,000, per life year gained (LYG). A 3.5% discount rate was used for cost and effectiveness with a lifetime follow-up. **RESULTS:** The LYG of 0.6838 results in an ICER of $18,449 for sacubitril /valsartan vs. enalapril. The corresponding ICERs are $17,750, $17,638, $17,774 for ramipril, prindopril, and lisinopril, respectively. The quality-adjusted life year (QALY) gained of 0.5646 results in an ICUR of $22,345 for sacubitril /valsartan vs. enalapril. The most influential parameter in univariate sensitivity analysis is the constant term in the statistical model of CV mortality. **CONCLUSIONS:** Sacubitril/valsartan compared with ACEi for HFrEF patients is cost-effective given on a ceiling ratio of $23,000 per LYG in Taiwan.

**PCV94: COST-EFFECTIVENESS ANALYSIS OF IVABRADINE IN THE TREATMENT OF PATIENTS WITH CHRONIC HEART FAILURE IN IRAN**

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OBJECTIVES: Ivabradine is a heart rate-lowering agent approved to reduce the risk of hospitalization in chronic heart failure (CHF) patients with sinus rhythm and a baseline heart rate $\geq 75$ bpm. The aim of this study was to assess the cost-effectiveness of Ivabradine plus standard care (SoC) in comparison with current SoC alone from the perspective of Iranian healthcare system. METHODS: A cost-effectiveness, cohort-based Markov model was developed using the Microsoft Excel to assess the incremental cost-effectiveness ratio (ICER) over a 10-year time horizon in a cohort of 1000 patients. All clinical inputs of the model (i.e. mortality rates, hospitalization rates, NYHA class distribution, adverse events) were estimated from SHIFT randomized clinical trial data. The effectiveness was measured as Quality-adjusted life years (QALYs) using the utility values derived from Iranian HF-QoL study. Direct medical costs were obtained from hospital records and national tariffs. Deterministic and probabilistic sensitivity analysis were conducted to show the robustness of the model over the uncertainty of key parameters. RESULTS: Ivabradine therapy would be associated with an incremental cost per QALY of $6,060 (incremental cost of $2175 and QALYs gained 0.36) versus SoC over a 10-year time horizon. The probabilistic sensitivity analysis showed that Ivabradine is expected to have a 58% chance of being cost-effective accepting a threshold of $6,500 per QALY. Furthermore, deterministic sensitivity analysis indicated that the model is most sensitive to the Ivabradin drug acquisition cost. CONCLUSIONS: The cost-effectiveness model suggests that, the addition of Ivabradine to SoC therapy was associated with improved clinical outcomes and also increased costs. From an Iranian healthcare system, the analysis indicates that the clinical benefit of Ivabradine can be achieved at a reasonable cost in eligible CHF patients with sinus rhythm and a baseline heart rate $\geq 75$ bpm.

PCV96: COST-EFFECTIVENESS OF APIXABAN IN PREVENTION OF STROKE AND SYSTEMIC EMBOLISM IN THE CZECH REPUBLIC

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OBJECTIVES: Apixaban is an oral anticoagulant, direct factor Xa inhibitor. The aim of the analysis was to compare costs and effectiveness of apixaban in the first line prevention of stroke and systemic embolism in vitamin K antagonist (VKA) suitable patients with atrial fibrillation. The analysis was conducted from the perspective of the public healthcare payer in the Czech Republic. METHODS: To assess on cost-utility of apixaban, a Markov model was developed. The analysis was focused on the first line prevention of stroke and systemic embolism in VKA suitable patients suffering from atrial fibrillation with at least one risk factor present (age of 75 years or higher, diabetes mellitus, hypertension, symptomatic heart failure of class II or higher according to NYHA classification). Hazard ratios used in the comparison were obtained from the ARISTOTLE double-blind head-to-head clinical trial. Apixaban was compared to warfarin in terms of lifetime costs per quality-adjusted life year. Drug costs, acute care costs, and management costs were assumed. RESULTS: In the base case scenario, the incremental cost-effectiveness ratio (ICER) of apixaban compared to warfarin reached 18 074 EUR/QALY. QALYs and LYs gained on apixaban treatment were 6.035 and 8,465 whereas patients on warfarin treatment gained only 5.851 and 8,288. Moreover, apixaban prevented the occurrence of most serious events as it reduced the number of strokes by 19 and bleeds by 65 (measured per 1000 patients). CONCLUSIONS: Our analysis demonstrated apixaban prolongs total survival and improves quality of life of VKA suitable patients with atrial fibrillation. Use of apixaban brought lower risk of serious events. Results indicate apixaban treatment is also very cost-effective as the ICER stays well below willingness to pay threshold.

PCV96: THE COST EFFECTIVENESS OF SACUBITRIL/VALSARTAN FOR THE TREATMENT OF CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION IN KOREA

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OBJECTIVES: This study aims to estimate the cost-effectiveness of sacubitril/Valsartan compared with Enalapril for the treatment of chronic heart failure patients with reduced ejection fraction (HFrEF) in Korea. METHODS: A regression-based cohort-model was used comparing sacubitril/Valsartan with ACEI (Enalapril) in chronic heart failure patients with HFrEF New York Heart Association Functional Classification II-IV symptoms. Health statues in Markov model to evaluate all-cause mortality, hospitalizations, adverse events and quality-of-life for each treatment groups over life time horizon (30 years). The primary source of clinical evidence was the PARADIGM-HF study. Costs and Health outcomes were evaluated over lifetime (30 years), discounted at 5% from the perspective of the health-care perspective. Alternative analyses were implemented that cardiovascular mortality based on PARADIGM-HF trial and non-cardiovascular mortality obtained from Korea life-tables. Cost data was mainly from National insurance statistical data in Korea, and Utility values were derived from survey results with general population to capture the Korean-specific health status values. The outcome of interest was incremental cost-effectiveness ratio (ICER), expressed as cost per quality adjusted life year (QALY) gained. RESULTS: The expected costs and QALYs of treating HFrEF with sacubitril/Valsartan are higher than ACEI (Enalapril) with 5% discounted rate for 30 years. The sacubitril/Valsartan
strategy compared to Enalapril showed a decrease in the number of hospitalizations (8% reduction annually) and hospitalization costs (around $396 USD for lifetime). The base case scenario shows that ICER of sacubitril/Valsartan versus ACEI (Enalapril) would be around $15,160 USD per QALYs gained. With 3% discount rate, ICER value would be $14,189 USD per QALYs gained. The results were robust in one-way sensitivity analyses. Exchange rate used was 1,123 KRW per USD (2017 June). CONCLUSIONS: At a suggested threshold around 1GDP, treating of HFrEF patients with sacubitril/Valsartan versus Enalapril is cost-effective from health-care perspective in Korea.

**PCV97: THE COST EFFECTIVENESS OF ABOBOTULINUMTOXIN A FOR HEMIPARESIS IN ADULTS WITH UPPER LIMB SPASTICITY AFTER STROKE OR TRAUMATIC BRAIN INJURY IN THE UNITED KINGDOM – A BAYESIAN ANALYSIS**

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**OBJECTIVES:** Approximately one-third of patients who experience stroke and 75% with physical disability after severe traumatic brain injury will develop spasticity. Spasticity is a condition in which certain muscles are continuously contracted. AbobotulinumtoxinA (aboBoNT-A; Dysport®) is used in the management of spasticity, aiming to improve function, quality-of-life and to prevent or delay future musculoskeletal complications or bone deformities. The objective of this research was to evaluate the cost-effectiveness of two dosages of aboBoNT-A (500U and 1000U) compared to best supportive care (BSC) in the management of upper limb spasticity in adults (AULS) from the perspective of the UK NHS. METHODS: A lifetime Bayesian state-transition model was developed to assess efficacy and cost-effectiveness of treatments across all health states, clinical input parameters and utility values were derived from aboBoNT-A pivotal studies. Resource use estimates were obtained from the previously published literature on spasticity patients. All other parameters and analyses met the criteria of NICE’s reference case. One-way and probabilistic sensitivity analyses along with scenario analyses were conducted to test robustness. RESULTS: The base-case analysis demonstrated that, under the assumptions described above, both doses of aboBoNT-A dominate BSC, i.e. are less costly and more effective. Incremental lifetime QALYs (vs BSC), aboBoNT-A 500U: 0.18; aboBoNT-A 1000U: 0.21. Incremental lifetime Costs (vs BSC), AboBoNT-A 500U: £47,338; aboBoNT-A 1000U: £42,969. Sensitivity and scenario analyses found that cost-savings were driven by the choice of resource use estimates and QALY gains by the health state transition probabilities. CONCLUSIONS: The management of AULS with aboBoNT-A is likely a cost-effective (and potentially cost-saving) option from the UK NHS perspective. This research highlights the potential benefits of aboBoNT-A to AULS patients, payers and, ultimately, to society.

**PCV98: COST-EFFECTIVENESS ANALYSIS OF APIXABAN AND RIVAROXABAN FOR TREATMENT OF ACUTE VENOUS THROMBOEMBOLISM IN CHINA**

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**OBJECTIVES:** Venous thromboembolism (VTE), comprising deep-vein thrombosis (DVT) and pulmonary embolism (PE), is a major healthcare concern that results in substantial morbidity and mortality with great economic burden for healthcare systems. Hence, the need for effective and efficient treatment of patients with VTE is important for both clinical and economic reasons. The objective of this study was to project the cost-effectiveness of apixaban compared with rivaroxaban in the treatment of acute VTE and prevention of recurrent VTE in China health care setting. METHODS: A Markov decision model, which included both the acute VTE (represented as a decision tree) and the long-term complications (represented as a Markov model), was developed to assess economic outcomes in Chinese VTE patients receiving either apixaban or rivaroxaban. Transition probabilities and utilities were obtained from the literatures. Direct medical costs, obtained from local resources. Both costs and outcomes were discounted at 5%. The incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained was calculated. Probabilistic sensitivity analysis (PSA) was carried out to deal with uncertainty. RESULTS: The base-case analysis showed that apixaban saved $2,876.14 and 0.009 quality-adjusted life years (QALYs) and 0.010 LYs were gained compared with rivaroxaban. apixaban was associated with a reduced total cost in DVT (-$21.46) and PE (-$1.93) compared to rivaroxaban. Therefore, apixaban was a dominant (less costly, more effective) alternative over rivaroxaban for the management of DVT and PE. PSA revealed that the probability of apixaban being cost effective at a threshold of $53,980.00 per QALY gained was 100%. CONCLUSIONS: In acute anticoagulation use apixaban was found to be cost-saving in comparison with rivaroxaban. Lower drug costs of Apixaban indicated a more favorable ICER. The cost-effectiveness of long-term or life-long use should be tested in future research.
PCV99: LIFELONG APIXABAN TREATMENT IS COST-EFFECTIVE FOR THE PREVENTION OF VENOUS THROMBOEMBOLISM IN THE NETHERLANDS

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OBJECTIVES: Dutch guidelines advise lifelong anticoagulant treatment with direct oral anticoagulants (DOACs) or vitamin K antagonists (VKAs) for patients with idiopathic venous thromboembolism (VTE) who do not have high bleeding risk. The aim of this study was to analyze the economic effects of lifelong treatment of apixaban in the Netherlands, based on updated and adapted previous modelling exercises for use of apixaban in acute VTE patients. METHODS: We performed a cost-effectiveness analysis (CEA) simulating a population of 1,000 VTE patients. Two different CEA were explored: lifelong apixaban treatment vs. no treatment after the first 6 months (base case analysis). In scenario analysis, the initial treatment period of 6 months with apixaban versus LMWH/VKA was also included. The primary outcome of the model is the incremental cost-effectiveness ratio (ICER) in costs ($ per quality adjusted life-year (QALY), with one QALY defined as one year in perfect health. To account for any influence of the uncertainties in the model a probabilistic sensitivity analysis (PSA) was conducted, in which the ICER was recalculated 2,000 times while varying all input parameters over their range. These results were summarized in a cost-effectiveness acceptability curve (CEAC). The treatment was considered cost-effective with an ICER less than €20,000/QALY, which is the most commonly used willingness-to-pay (WTP) threshold for preventive drugs in the Netherlands and potentially indicative for other European countries as well. RESULTS: The model showed a reduction in recurrent-VTE and no increase in major bleeding events for lifelong treatment. Deterministic results showed ICERs of €9,830/QALY and €8,231/QALY in the base case and scenario analysis, respectively. The probabilities of being cost-effective at WTP threshold of €20,000/QALY were 70.4% and 79.5%, respectively. CONCLUSIONS: Lifelong treatment with apixaban is cost-effective for the prevention of recurrent VTE in Dutch VTE patients.

PCV100: COST-UTILITY ANALYSIS OF RHNTK-TPA COMPARED WITH RT-PA IN THE TREATMENT OF ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) IN CHINA

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OBJECTIVES: ST-segment elevation myocardial infarction (STEMI) is associated with significant increase in morbidity and mortality. Recombinant Human TNK Tissue-type Plasminogen Activator for Injection (rhTNK-TPA) is the latest generation proven effective thrombolysis strategy in STEMI treatment. Clinical study (Phase II trial) had demonstrated its thrombolysis efficacy. However, no studies have evaluated the economic impact of rhTNK-TPA in China in acute STEMI patients. The current study utilizes Chinese efficacy and cost data to evaluate cost utility of rhTNK-TPA versus rt-PA in STEMI patients to provide evidence for relevant medical decision making. METHODS: A decision-tree model, constructed to predict acute stage (30 days) and long-term (10 years)’s total cost and QALYs gained for rhTNK-TPA and rt-PA groups, respectively. Clinical efficacy, safety data and utility values were abstracted from the Phase II trial, published meta-analysis and literatures. Chinese local cost data is extracted from literature review and through a micro-costing study of 41 attending physicians at 7 tertiary hospitals located in representative cities of Beijing, Shanghai, Guangzhou, Foshan, Zhanjiang, Chengdu and Xi’an in China. RESULTS: The total cost for the rhTNK-TPA group in acute stage (30 days) and long-term (10 years) was ¥30,846 and ¥103,028.49, respectively, while the total cost for the rt-PA group was ¥31,314 and ¥103,030.36, respectively. The QALYs gained for the rhTNK-TPA group in acute stage (30 days) and long-term (10 years) was 0.0345 and 4.470, respectively, while the total QALYs gained for the rt-PA group was 0.0343 and 4.441, respectively. Compared with rt-PA, rhTNK-TPA is dominant in the treatment of acute STEMI with more QALY gained and lower overall cost. CONCLUSIONS: Compared with rt-PA, rhTNK-TPA is a cost-effective alternative in the treatment of acute STEMI both in acute stage and long-term in China.

PCV101: COST SAVING DUE TO SELF-CARE BEHAVIOR OF CARDIOVASCULAR PATIENTS

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OBJECTIVES: Cardiovascular diseases is the most important cause of morbidity and mortality and make economic burden for health system. The purpose of this study was evaluation of the influence of self-care behavior for
**PCV102: HEART FAILURE (HF) IN APULIA REGION - ITALY (LOCAL HEALTH UNIT BARLETTA – ANDRIA – TRANI): ANALYSIS OF THE THERAPEUTIC PATHWAYS AND RELATED HEALTHCARE CONSUMPTION.**

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**OBJECTIVES:** To analyze therapeutic pathways of patients with HF, and to estimate healthcare resource consumption. **METHODS:** An observational retrospective cohort analysis based on administrative databases of 1 Local Health Unit in Italy was performed. Patients ≥18 with a hospitalization discharge diagnosis of HF (ICD-9-CM 428.xx; 402.xx) from January 1st, 2010 to December 31st, 2014 (inclusion period) were included. The index-date (ID) was the first hospitalization for HF during inclusion period. All patients were characterized 12 months prior the ID and followed up after the ID for 12 months. Patients were excluded if not treated with specific drugs as: ACE-inhibitors, ARBs, diuretics, digitalics, beta-blockers. Two cohorts were built: patients with HF as primary and patients with HF as secondary diagnosis. **RESULTS:** A total of 2,669 patients with HF were enrolled in the study, 1,960 as primary and 709 as secondary diagnosis. About 49% and 55% males, mean age of 77.0±10.4/76.5±11.1 years in both cohorts. Mortality during 12 months of follow-up was 46% and 43% respectively. Charlson Index score was >0 for more than 90% of patients. In follow-up period, half of the patients present a switch from the original therapy, 10% of the patients requires an add-on. Healthcare resource consumption for patients discharged alive is 11,900€ for patients with primary diagnosis and 12,500€ for patients with secondary diagnosis. Cost for a hospitalization is around 3,600€ for HF patients in primary diagnosis and 4,200€ in secondary diagnosis. **CONCLUSIONS:** Our findings highlight that, in real-world setting, HF has a strong impact on National Health Service. During follow-up period, a high percentage of patients were under-treated, more of half of the patients changed their therapy or added drugs. A big effort, by cardiologist should be done to give the right therapies to the right patients, in order to improve therapeutic pathways and quality life.

**PCV103: DIRECT COSTS AND HEALTHCARE RESOURCE USE ASSOCIATED WITH PATIENTS WITH HYPERCHOLESTEROLAEMIA AND ESTABLISHED CARDIOVASCULAR DISEASE IN SPAIN**

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**OBJECTIVES:** Cardiovascular disease (CVD) is a major cause of premature death worldwide. Elevated levels of blood lipids represent a major risk factor for CVD events. This study aims to estimate healthcare resource use (RU) associated with CVD events among patients receiving lipid-modifying therapy and to calculate the resulting direct healthcare costs to the Spanish Healthcare system. **METHODS:** An expert panel with 4 cardiologists and internists was created to estimate RU and cost associated with the management of patients with established CVD receiving lipid-modifying therapy. A three-stage technique was adopted. During a 1st round experts achieved consensus on the clinical situations related to hypercholesterolemia. At a 2nd round experts answered to a questionnaire concerning resource consumption associated with patient journey. Finally, at a 3rd round experts validated the weighted mean results obtained from the questionnaires. Phases of patient journey considered were: index situation (ie. patients...
entering in secondary prevention), follow up and recurrent CVD acute events. Medical visits, clinical procedures/examinations, surgeries, inpatient/outpatient/intensive care hospitalizations and cardiac rehabilitation were resources considered. Only low, moderate and high intensity lipid-modifying drug costs were included. Costs for each phase were obtained by multiplying mean estimates of RU by unit costs from official sources. **RESULTS:** Direct costs per patient during 18 months of aortic aneurysm, acute coronary syndrome (ACS), ischaemic heart disease (IHD), peripheral artery disease (PAD) and ischaemic stroke were estimated as 40,882,96€, 37,971,22€, 37,226,13€, 28,306,82€ and 7,866,82€, respectively. Medical procedure/examination costs assumed major role during index situation and recurrent CVD events in ACS, IHD and PAD; whereas hospitalizations accounted for the highest cost for aortic aneurysm and ischaemic stroke. Lipid-modifying drug costs were very low. **CONCLUSIONS:** The economic burden of established CVD is substantial for the Spanish Healthcare system, therefore a more efficient strategy is required to prevent CVD.

**PCV104: THE ECONOMIC IMPACT OF CAREGIVER FOR PATIENTS WITH ATRIAL FIBRILLATION: AN ITALIAN SURVEY**

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**OBJECTIVES:** Atrial fibrillation (also called AF) is an irregular heartbeat (arrhythmia) caused by anatomical and electrophysiological features of left atrium. It can increase the risk of blood clots which can lead to stroke, heart failure and other heart-related complications. An average of 2.04% of the population is living with AF and the role of caregiver is very relevant for them. Generally, caregiver is a family member (informal) or an expert (formal), who takes care of a patient suffering from a chronic disease. Most of AF patients follow an anticoagulant therapy and need a specific support to reach periodically hospital centers, as well as many others services. **METHODS:** FederAipa (Federation of Italian Anticoagulant Patient Associations) had conducted a survey among AF patients, aiming to analyze the direct non-health needs of patients with atrial fibrillation, focusing on welfare concerns and the economic impact of formal and informal caregiver. FederAipa provided surveys between May and July 2016, and received 364 responses. The responders were represented for 52.2% by men and 47.8% by women and the average age was 71.3 years. **RESULTS:** It has been observed that 19.2% of those interviewed need to pay for home care due to their limited autonomy condition, leading to a cost between 159 euro and 468 euro per week. Furthermore, the analysis showed that the average annual cost of caregiver can vary from 11,384.00 euro per patients without stroke to 15,897.00 euro per patients with stroke, considering the assumption of 18.14 euro per hour. Therefore, having a stroke increases the direct cost for caregiver assistance by + 39.6% than to those who did not have a stroke. **CONCLUSIONS:** The difference of the economic impact of formal and informal caregivers between patients with stroke and patients who did not have stroke among responders at the FederAipa questionnaire, resulted very high and significant.

**PCV105: REPRESENTATIVENESS OF ROUTINELY COLLECTED PATIENT-REPORTED OUTCOME DATA IN CORONARY REVASCULARIZATION PATIENTS?**

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**OBJECTIVES:** Patient-reported outcomes (PROs), such as health-related quality of life (HRQoL), are currently considered as important tools for assessment of healthcare quality and effectiveness. However, although a representative sample is essential, it is rarely possible to convince all patients to respond to HRQoL surveys and, therefore, possible over- or underrepresentation of some patient groups can lead to biased estimates. Our aim was to find out how well the patient views obtained by routine collection of PROs in a cardiology unit represent the actual case mix. **METHODS:** The representativeness of the responses obtained to routine HRQoL data collection was studied in the Kuopio University Hospital Center which has since 2012, as part of the routine admission process of elective patients, collected HRQoL data using the 15D questionnaire. Elective coronary artery bypass grafting and percutaneous coronary intervention patients treated between June 2012 and August 2014 were included and the characteristics of the patients with a baseline (n=260 and 290 for CABG and PCI, respectively), or both baseline and follow-up HRQoL measurements (n=203 and 189 for CABG and PCI, respectively) were compared with those who did not respond (n=144 and 448 for CABG and PCI). Furthermore, the associations between patient characteristics and the likelihood of obtaining HRQoL data were investigated with logistic regression **RESULTS:** Baseline questionnaires were less likely obtained from older CABG patients (OR, 95% CI 0.25, 0.28-0.91) and those with more severe disease (0.20, 0.05-0.79). Among PCI patients, women (0.69, 0.46-1.02), smokers (0.70, 0.49-1.02), and
those with more severe disease (0.21, 0.08-0.52) or more hospital days were underrepresented. **Conclusions:** Routinely collected PROs in cardiac patients appeared to be biased towards younger and healthier patients. This needs to be recognized when evaluating the representativeness of such data and every effort should be made to guarantee a response rate as high as possible.

**PCV106: Low Density Lipoprotein Cholesterol (LDL-C) Target Goal Achievement Rate According to Physicians’ Compliance to Established Clinical Guidelines from National Cholesterol Education Program-Adult Treatment Panel (NCEP-ATP) and American College of Cardiology/American Heart Association (ACC/AHA): Results from Korea CRISTAR Study**

**OBJECTIVES:** This aimed to compare low density lipoprotein cholesterol(LDL-C) target goal achievement rates of patients with cardiovascular disease risks by physicians’ compliance levels to guidelines while lipid lowering management. **METHODS:** Korea-CRISTAR study, a cross sectional, observational study using a total of 2,409 outpatients treated with statin ≥6months, but ≤2years, was performed in nationwide-26tertiary hospitals from December 2014 to October 2015. In this analysis, we excluded 435patients from total patient pool because group classification by guidelines couldn’t be determined(2 from NCEP-ATP and 433 from ACC/AHA). Physicians’ compliance to NCEP-ATP and ACC/AHA was defined by LDL-C target goal setting and prescription of statin dose, respectively. Patients were further classified into 4 groups by physicians’ compliance levels; total compliance(compliant to both guidelines), partial complianceII(compliant to either NCEP-ATP or ACC/AHA) and total non-compliance(compliant to neither NCEP-ATP nor ACC/AHA). LDL-C target goal achievement which was defined in NCEP-ATP was compared by compliance levels. **RESULTS:** Among a total of 1974patients, 33.8%(668patients) received total compliant treatment while 12.6%(248patients) was treated with total non-compliant lipid lowering management. 48.4%(956 patients) had statin therapy only compliant to NCEP-ATP(partial compliance I) and 5.2%(102patients) was found to be treated only compliant to ACC/AHA(partial compliance II). LDL-C target goal achievement rates differed by physicians’ compliance levels. Patients on total compliant treatment showed the higher LDL-C target goal achievement rate(68.7%) while the lower rate (40.7%) was found in patients on total non-compliant treatment. For those on partial compliant statin therapy, better achievement rate was found to be present in patients whose statin therapy was only compliant to NCEP-ATP(63.6%) than the other partial compliant group of patients(49.0%) (p<0.0001). **CONCLUSIONS:** This highlights guideline-based treatment should be taken into account while lipid lowering management to decrease CVD risks. However, result interpretation and application should be carefully done given outcome parameter was derived from NCEP-ATP while exposure parameters were extracted from both guidelines.

**PCV107: Cost-Effectiveness of a Polypill for Patients with or at High Risk of Cardiovascular Disease in an NHS Setting**

**OBJECTIVES:** There are approximately 7 million people living with CVD in the UK, with an estimated impact on healthcare costs of £11 billion per year. The National Institute for Health and Care Excellence (NICE) recommends that patients with CVD are prescribed medications including statins, blood pressure lowering therapies and anticoagulants. However, most do not take recommended medications on a long-term basis. Reasons for this can include the complexity of the medication regimen. One way to simplify the medication regimen would be to introduce
a CVD polypill. The ‘Use of a Multi-drug Pill in Reducing Cardiovascular Events’ (UMPIRE) clinical trial compared a polypill to usual care in patients with or at high risk of CVD. We used the outcomes from this trial to investigate the long-term impact of introducing the polypill in an NHS setting. METHODS: We developed a discrete event simulation model to model the cost-effectiveness of a polypill (comprising of an aspirin, statin and 2 antihypertensive medications) compared to usual care (single medications). The 2011 Health Survey for England dataset was used to derive our model population and an estimate of adherence to medication in usual care. We used data from the UMPIRE trial to model the long-term effect of a polypill on medication adherence compared to usual care. We allowed for medication adherence to vary over time as people aged and had CVD events such as stroke or heart attack. We simulated a lifetime in both scenarios for each individual and estimated lifetime costs and quality adjusted life years (QALYs). RESULTS: Introducing a CVD polypill into an NHS setting results in cost savings of £1,555,000 and a gain of 27 QALYs per 10,000 persons. CONCLUSIONS: The introduction of a polypill would provide patients with a simpler medication regime and increase treatment effectiveness with a subsequent downstream effect on healthcare costs.

PCV108: MEDICATION ADHERENCE AND RISK OF HOSPITALIZATION IN PULMONARY ARTERIAL HYPERTENSION (PAH) PATIENTS TREATED WITH ENDOTHelin RECEPTOR ANTAGONISTS (ERAS) OR PHOSPHODIESTERASE TYPE 5 INHIBITORS (PDE5iS)

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OBJECTIVES: Pulmonary arterial hypertension (PAH) is a rare, progressive disease characterized by increasing pulmonary vascular resistance and right heart failure. We evaluated the relationship between adherence in PAH patients treated with ERAs or PDE5is and hospitalization risk. METHODS: Using the PharMetrics Plus claims database, the patient’s most recent PAH therapy was identified between 1/1/2009-6/30/2015. Therapies included ERAs: ambrisentan, bosentan, and macitentan, and PDE5is: sildenafil and tadalafil. Patients had continuous healthplan enrollment ≥3 months pre- and ≥6 months post-index. Relationships between medication adherence measured by proportion of days covered (PDC) and percent hospitalized, re-hospitalized within 30 days post-discharge, and mean hospitalizations were analyzed with descriptive statistics and modified Cox regression using a time-varying measure of PDC. RESULTS: Among 755 ERA and 1,578 PDE5i patients, hospitalizations declined as PDC increased from >20% to ≥80%. As PDC increased from 40-59% to ≥80%, hospitalizations decreased from 45% to 23% for ERA and from 49% to 28% for PDE5i; and mean hospital admissions per 1,000 patients declined from 714 to 352 for ERA and from 1,115 to 459 for PDE5i. For patients with PDC ≥ 80%, ERA had a lower percent hospitalized (p=0.02) and fewer hospital admissions (p=0.02) versus PDE5i. The rate of rehospitalization was lower for patients with PDC ≥ 80% PDC < 20% (21% vs. 67% for ERA and 23% vs. 57% for PDE5i). Higher PDC reduced the risk of hospitalization for ERA patients and PDE5i patients (as estimated by the modified Cox model) (HR=0.549 for PDC, p=0.018 and HR=0.321 for interaction of PDC with ERA therapy, p=0.013). An increase in PDC from 0.50 to 1.00 reduced risk by 58% for ERA and 26% for PDE5i patients. CONCLUSIONS: Higher adherence to PAH medications was associated with lower risk and fewer hospitalizations. Reduction in risk was greater for ERA compared to PDE5i.

PCV109: PERSISTENCE IN HYPERTENSION THERAPY IN PATIENTS WITH AND WITHOUT DEPRESSION IN GERMANY

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OBJECTIVES: The goal of the present retrospective work was to study the impact of depression on persistence with antihypertensive drugs in general practices in Germany. METHODS: This study included adults with hypertension and depression who received antihypertensive drugs from physicians in 1,262 general practices in Germany between January 2013 and December 2015. Hypertension controls without depression were matched (1:1) to the hypertension cases with depression based on age, gender, physician, and initial antihypertensive therapy, using a propensity score method. The main outcome of the study was the rate of persistence with antihypertensive drugs in individuals with hypertension with and without depression in the 12 months following the index date. Persistence was estimated as therapy duration without treatment disruption, which was defined as at least three months without oral antihyperglycemic drugs. The effect of depression on persistence with antihypertensive treatment was analyzed in the entire population and in various subgroups using Cox regression models. RESULTS: The study included 24,627 hypertension patients with depression and 24,627 hypertension patients without depression. The mean age was 59.7 years (SD=12.1 years), and 37.3% were men. After 12 months of follow-up, the rate of persistence with antihypertensive therapy was 64.5% in individuals with depression and 66.9% in individuals without depression (p-value=0.232). Depression was found to have no significant impact on discontinuation in the overall population (HR=1.01, 95% CI: 0.99-1.03) or in the different subgroups (HRs ranging from 0.93 to
1.03. CONCLUSIONS: Depression was not significantly associated with persistence with antihypertensive drugs in Germany

PCV110: A QUALITATIVE EXPLORATION OF REASONS FOR (NON-) ADHERENCE TO ORAL ANTICOAGULANT THERAPY IN PATIENTS WITH ATRIAL FIBRILLATION.

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OBJECTIVES: In chronic conditions like atrial fibrillation (AF) up to half of the patients do not take their drugs as prescribed. The aim of this study was to examine patients' reasons for (non-) adherence to oral anticoagulant therapy (OAT). METHODS: Factors impacting OAT adherence were first examined through literature review. The results were validated in an expert-panel consisting of eight key informants with expertise in the field of OAT. This was followed by five focus groups with patients with AF from the United Kingdom, Germany, France, Italy and Spain (n=48). A trained moderator led each 60-minute audio-recorded group using a structured interview guide discussing factors that might impact OAT adherence: socio-economic factors, health system-related factors, therapy-related factors, patient-related factors and condition-related factors. RESULTS: Initially, all patients reported to take their medication as prescribed, mentioning fear for AF-related stroke as their greatest motivator. When prompted by specific questions, patients admitted they occasionally skip or miss a dose. A total of 178 positive and 185 negative statements with regard to factors impacting OAT were made. Lack of knowledge (n=11); poor patient-doctor relationship (n=14), distraction due to employment or social environment (n=12), prior bleeding event(s) or the fear of bleeding (n=11); and changes in routine (n=16) were most often named as barriers to adherence, while patient-related factors such as medication-taking habits and routines (n=30); patients' personality, motivation and attitudes (n=40) and good quality services (n=37) promote adherence. CONCLUSIONS: Modifiable factors that could impact OAT adherence include patient knowledge; satisfaction with quality of care; and patient-related factors like attitude and habit/skills. Physicians should take more time to listen to patients, explain the treatment rationale and educate them on risk and benefits of OAT. Furthermore, it is important to convince patients of the importance to evolve habits and routines in taking their oral anticoagulation drugs

PCV111: COMPARISON OF METHODS TO MEASURE PATIENT ADHERENCE AND PERSISTENCE WITH PHARMACOLOGICAL THERAPY: A SYSTEMATIC REVIEW


OBJECTIVES: Adherence and persistence are key factors influencing the effectiveness of pharmacological therapies, particularly in chronic conditions. In absence of a 'gold standard' method to estimate adherence and persistence, a systematic review comparing different approaches was conducted. METHODS: This review adhered to published guidance for performing systematic reviews. Eleven electronic databases and 8 grey literature sources were used to identify studies and guidelines, reporting on different methods to estimate adherence and persistence to long-term oral and subcutaneous therapies for chronic diseases. The primary disease area of interest was hypercholesterolemia; other therapeutic areas included type 2 diabetes, hypertension, osteoporosis and rheumatoid arthritis. Outcomes of interest were measures of accuracy, correlation, strength and weaknesses, patient acceptability, guideline recommendations, and advantages/disadvantages of the different medication adherence/persistence measures. RESULTS: 4,158 records were retrieved until end of March 2017. Title/abstract screening excluded 4,007 records. Full papers were examined for the remaining 151 records and 28 relevant studies were finally identified. These studies were in patients with or at risk of CV disease (n=27), including those with hypertension (n=5), hypercholesterolemia (n=8) and diabetes (n=5). One study was in patients with rheumatoid arthritis and none were found in patients with osteoporosis. Study designs included validation studies of adherence/persistence scales (n=7), observational studies (n=17), systematic reviews (n=6), and randomized trials (n=5). Methods used to measure adherence/persistence fell into three broad categories: Medication counts, medication adherence/persistence scales, and reviews of medical/pharmacy records. The majority of studies (n=16) reported on the correlation between measurement methods, usually comparing the method to actual medication counts or prescription records. Further studies described barriers to use (n=2), advantages/disadvantages (n=12), and practicality (n=2) of different measurement methods. CONCLUSIONS: The adherence/persistence methods are further evaluated, aiming to recommend the approach with the highest accuracy, most strengths and acceptability to patients.
PCV112: A COMPARATIVE STUDY BETWEEN HYPERTENSIVE PATIENTS WITH AND WITHOUT CO-MORBIDITIES; KNOWLEDGE, ACCEPTANCE OF ILLNESS AND QUALITY OF LIFE AS QUANTIFIABLE VARIABLES IN KPK, PAKISTAN.

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OBJECTIVES: This study determines patient knowledge about hypertension, patient Quality of life and Acceptance of illness. This is a comparison study between two groups of hypertensive patients i.e. with and without co-morbidities. METHODS: A cross-sectional study design was used and data was collected with a validated questionnaire. The questionnaire based study involved 240 adult hypertensive patients with mean age 44.44 ±10.92 years.

RESULTS: Knowledge of disease, Quality of life and Acceptance of illness were found to be better in patients who were without a concurrent disease. Assessing quality of life, 75% of patients without co-morbidities had no problem in mobility, 66.3% had moderate problem in self-care with concurrent disease in comparison to group without co-morbidities where 92.5% patients had no problem in self-care. Out of them, 16 patients with concurrent disease had EQ-5D index values with negative sign in contrast to other group where no patient was found with a negative sign. No patient with concurrent disease group had score 1 while 26 patients in other group were found having scored 1. QoL score, 26 patients had 5 score in patients without concurrent disease, while no patient was found to have 5 score in the other group. With concurrent disease 92.7% patients had poor AOL while 3.1% patients had complete AOL. No patient score of full 40 in this group. In the other group 81.6% patients had poor AOL score while 7.6% had complete AOL. Three patients out of total respondents in this group had score 40.

CONCLUSIONS: Patient’s inability, dependence and feeling of being a burden increases with increased number of years of disease and leads to non compliance and non adherence and puts a high economic cost on overall disease burden on the health economy of the country.

PCV113: MEDICATION ADHERENCE AND QUALITY OF LIFE OF UNCONTROLLED HYPERTENSION PATIENTS IN KOREA.

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OBJECTIVES: According to Korean’s National Nutrition Examination Surveys, hypertension patients’ awareness, treatment, and control rate are low despite high prevalence. This study aims to investigate medication adherence and quality of life (QoL) of uncontrolled hypertension patients in Korea. METHODS: Inclusion criteria are as follows; over 20 yrs old, patients whose systolic blood pressure (SBP) > 140mmHg or diastolic blood pressure (DBP) > 90mmHg, despite taking antihypertensive drugs, Demographic characteristics, treatment status (controlled/uncontrolled) and patient reported outcome (EQ-5D, Morisky 4-Items Self-Report Measure of Medication questionnaire (MMAS-4)) were assessed at baseline, 3 months (FU1), and 6 months (FU2) after enrolment. RESULTS: We enrolled 1,001 patients from 13 university hospitals and collected data prospectively in the period from February, 2014 to June, 2016. Mean age of patients was 64.6±12.5 years old and male was 52.3%. The mean SBP decreased from 150.8mmHg at baseline to 134.3 at FU2, and the mean DBP from 85.7 to 79.2mmHg; 59% of patients had controlled hypertension during follow up. The patients’ QoL was analyzed by the EQ-5D and the mean score was 0.87±0.11, 0.88±0.11 and 0.87±0.11 at baseline, FU1 and FU2 respectively. Medication adherence was analyzed by MMAS-4, the mean score was 0.52±0.82 and 0.45±0.75 (lower score means better adherence) at FU1 and FU2 respectively. For items of MMAS-4 at FU2, patients who responded question that ask ever forgetting or feeling tired to take drugs was 22.8%, 18.8% respectively; only 67.9% patients are fully adherent. Patient with better medication adherence show higher rate of controlled hypertension and higher QoL analyzed by EQ-5D. The patient group whose BP was well controlled showed higher EQ-5D-VAS score. CONCLUSIONS: Our data demonstrates there are still rooms for improvement of medication adherence. Since medication adherence, blood pressure control and quality of life are closely inter-related, strategy to enhance medication adherence would be clinically important.
**PCV114: THE EFFECT OF PERCEIVED FINANCIAL BURDEN OF PRESCRIPTION CO-PAYMENTS ON MEDICATION ADHERENCE**

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**OBJECTIVES:** In the Republic of Ireland, co-payments were recently introduced on medications dispensed under the General Medical Services scheme (GMS). GMS eligibility is determined by means-testing and older age, and provides free healthcare at the point of use. The co-payment, currently €2.50 per item, was considered suitably low to reduce medication wastage without impacting adherence to essential medication. Research to date has shown the co-payment to have minimal impact on antihypertensive medication adherence. However, the dual eligibility criteria have led to variability in the socioeconomic status of patients within the GMS which may have obscured the impact of the co-payment on adherence to essential medicines to those in the lowest socioeconomic classes. **METHODS:** Our objective was to assess the effect of perceived financial burden of the co-payment on antihypertensive adherence in patients within the GMS. We recruited community dwelling older adults (N=1592) from 106 community pharmacies in the Republic of Ireland between March and May 2014, administering a structured telephone interview and following up at 12 months. Dispensing records from the pharmacy were linked to each patient interview. Perceived financial burden was assessed at baseline using a single questionnaire item. Adherence was assessed at 12 months using an 8-item self-report questionnaire and by calculating the proportion of days covered (PDC) from linked dispensing records. **RESULTS:** At baseline 75.1% (n=1152) of participants were GMS eligible and 30.1% of GMS participants reported feeling financially burdened by medication costs. In linear regression models adjusted for socio-demographics, medical history, and medication use, financially burdened GMS participants had significantly lower self-reported adherence (β= -0.32, 95% CI -0.51 to -0.14), although this was not evident with refill adherence (β= -0.03, 95% CI -0.08 to 0.02). **CONCLUSIONS:** Further work on the financial barrier to antihypertensive adherence within the GMS is warranted and its potential impact on long-term patient outcomes.

**PCV115: THE EFFECT OF CHANGING UTILITY ELICITATION METHODS IN CARDIOVASCULAR DISEASE: A SYSTEMATIC LITERATURE REVIEW**

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**OBJECTIVES:** To explore changes in utility elicitation methods and estimates for cardiovascular disease (CVD) in recent years. **METHODS:** A systematic literature review was conducted in Embase and PubMed to identify studies published between September 1992 and February 2017 reporting utilities for stroke (S), myocardial infarction (MI), and angina (stable and undefined/unstable). Grey literature was also searched. Median utility values were calculated from reported average utilities. Changes in the past 5 years (2013-2017 vs. 1992-2012) in utility methods and estimates were assessed. **RESULTS:** 235 studies reported CVD utilities (stroke: 93 pre-2013 vs. 83 post-2013; MI: 40 vs 32; stable angina: 11 vs 15; undefined/unstable angina: 21 vs 7). Median average utilities for stroke and MI have increased over time (stroke: 0.62 pre-2013 vs. 0.65 post-2013; MI: 0.71 vs. 0.79); however, median values for angina decreased (stable angina: 0.83 vs. 0.72; undefined/unstable angina: 0.81 vs. 0.74). The proportion of utility estimates generated from EQ-5D has nearly doubled (from 49% to 82%), likely due to the increase in trials using this instrument (22 [18%] pre-2013 were trial-based vs. 43 [39%] post-2013). The use of other utility methods has declined: standard gamble (SG): 17 (12%) pre-2013 vs. 2 (2%) post-2013; time trade-off (TTO): 19 (13%) vs. 4 (3%); Health Utilities Index (HUI): 15 (10%) vs. 2 (2%); SF-6D: 9 (6%) vs 8 (7%). When comparing common elicitation methods (across CVDs), direct methods yielded higher median values (TTO: 0.75; SG: 0.72) than indirect methods (EQ-5D: 0.68; HUI: 0.63; SF-6D: 0.69). **CONCLUSIONS:** CVD utility methods have changed substantially since 2012. Populations evaluated might have changed over time due to improvements in treatments, or differences in evaluated populations. A larger number of trials report EQ-5D, whereas direct methods are in decline. As direct methods can yield higher values, source and methods are important to consider.

**PCV116: PATIENTS’ PRIORITIES FOR ORAL ANTICOAGULATION THERAPY IN NON-VALVULAR ATRIAL FIBRILLATION**

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**OBJECTIVES:** The effectiveness of oral anticoagulants (OACs) is critically dependent on patients’ adherence. One determinant that is thought to influence adherence are drug characteristics and more specifically drug convenience. We studied the relative impact of attributes related to convenience, safety and costs of available OACs on therapy...
value from the patient’s perspective. **METHODS:** Literature review and expert validation were used to select four main attributes: effectiveness (risk of ischemic stroke), safety (risk at major bleed, minor bleed and gastro-intestinal complaints), and convenience (intake frequency, food restrictions, pill intake, International Normalized Ratio (INR) blood monitoring), and out-of-pocket costs. The Analytical Hierarchy Process method was used to elicit preferences from a sample (n=45) of patients with non-valvular atrial fibrillation (AF) from the United Kingdom, Germany, France, Italy and Spain. **RESULTS:** Overall, drug effectiveness (59%) and side-effects (25%) have the most impact on the perceived value of OACs compared with drug convenience (9%) and out-of-pocket costs (6%). Within the attribute convenience, reducing the need for monthly INR monitoring was the most important (59%), followed by reducing diet restrictions (29%), reducing intake frequency (18%) and improving the pill intake (14%). The most important side effect was major bleed (71%), followed by minor bleed (18%) and gastro-intestinal complaints (11%). Furthermore, once-daily pill intake was preferred by the majority (73%) of focus group participants. **CONCLUSIONS:** Differences between various non–vitamin K antagonist oral anticoagulants and vitamin K anticoagulants in effectiveness and side-effects are relatively small, but also more difficult to assess by patients themselves. Although the relative impact of convenience on overall drug value was small, the largest difference in perceived performance of the available OACs was found on the attributes of convenience. Therefore, it is recommended that besides considerations on safety and effectiveness, physicians also discuss attributes of convenience with patients.

PCV117: THE IMPACT OF BELIEFS TOWARDS ILLNESS AND MEDICATIONS ON ADHERENCE AND CLINICAL OUTCOMES IN ACUTE CORONARY SYNDROME PATIENTS IN HONG KONG

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**OBJECTIVES:** To assess the impact of beliefs towards illness and medications on adherence and readmission in acute coronary syndrome (ACS) patients. **METHODS:** A phone interview that evaluated beliefs towards illness using the Brief Illness Perception Questionnaire (BIPQ), beliefs towards medications using the Beliefs about Medicines Questionnaire (BMQ) and adherence using a self-reported scale was done. Patients discharged for 1, 6, and 12 months were recruited and surveyed. 1-month, 6-month and 12-month readmission data was collected. Spearman’s rank correlation was used to show correlation between belief scores, adherence and readmission, while ordinal regression was used to adjust for covariates. **RESULTS:** Seventy-nine patients were surveyed; 30, 22, and 27 were discharged from the index ACS admission for 1, 6 and 12 months respectively. Significant positive correlations were found between adherence score with BMQ-Specific Necessity score (rs=0.287, p=0.010), necessity-concerns differential (rs=0.539, p<0.001), and an inverse correlation between adherence and BMQ-Specific Concerns score (rs=-0.443, p<0.001). Higher BMQ Specific-Necessity scores (aOR=1.404, 95% CI:1.147-1.719) and a monthly income less than HKD$10,000 compared to HKD$10,000 or greater (aOR=4.540, 95% CI: 1.761-14.311) was associated with higher adherence, while higher BMQ Specific-Concerns scores were related to lower adherence (aOR=0.774, 95% CI: 0.672-0.892). Total BIPQ score (OR=1.134, 95% CI: 1.005-1.278) and number of previous ACS episodes (OR=19.000, 95% CI: 2.029–177.932) predicted 6-month all-causereadmissions and 12-month cardiac readmissions respectively. **CONCLUSIONS:** Patients’ perceived necessity and concerns towards medications and an income less than HKD$10,000 were significantly associated with adherence. Illness perceptions and history of ACS predicted readmissions. These findings are useful for developing interventions to improve adherence in ACS patients.

PCV118: HETEROGENEOUS PREFERENCES IN THE ADJUNCT DRUG TREATMENT OF SEVERE HYPERCHOLESTEROLEMIA: A LATENT-CLASS ANALYSIS

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**OBJECTIVES:** New adjunctive drug therapies in severe hypercholesterolemia considerably reduce apheresis frequency and thus improve quality of life. So far it is unknown, if this reduction generates highest benefit for all patients. Prior analyses using mixed logit showed high standard deviations in patients’ preferences. **METHODS:** A discrete choice experiment (DCE) analyzed the impact of treatment attributes on patients’ preferences and how preferences varied according to socio-demographic, attitudes or experiences. The DCE included seven attributes with three levels each. A latent class analysis was used to model heterogeneity in preferences. **RESULTS:** N=348 patients participated. Based on the review of the model accuracy, a model with 3 classes was identified as suitable to reflect heterogeneities. For one class (N=126) “reduction of LDL-C level” (Level Difference/LD: 5.097) was most important and dominated all other attributes. This class focuses solely on this treatment outcome independent of apheresis frequency or additional injections. Preference patterns of the second class (N=106) are characterised by a focus on “frequency of apheresis” (LD: 2.323), “risk of myopathy” (LD: 1.577) and “reduction of LDL-C level” (LD: 0.893). Respondents clearly consider higher frequency of apheresis to have a negative impact. The objective ranking of attributes in the third class (N=116) is identical to the second one. However, the principle “the more the better” seems to apply - the highest frequency of apheresis is preferred most (LD: 0.750). These patients have adjusted to
apheresis for more than ten years and prefer it. CONCLUSIONS: The three groups show differences in the assessment of treatment attributes. As assumed, reduction of apheresis is important, but only for a sub-segment (30%) of patients. One third wants effective LDL-reduction by whatever means necessary. Most strikingly, another 30% postulate higher frequencies of apheresis and seem to reject adjunctive drug therapies even if outcomes are the same.

PCV119: ASSESSING THE BURDEN OF CHRONIC HEART FAILURE ON CAREGIVERS OF PATIENTS IN COLOMBIA

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OBJECTIVES: To understand the burden of chronic heart failure (HF) on informal caregivers in Colombia. METHODS: A Disease Specific Program was conducted to assess the impact of chronic HF in Colombia. Caregiver self-completion (CSC) questionnaires were completed by caregivers (n=58) of chronic HF patients. CSC questionnaires focused on the demographics and activities/responsibilities of caregivers, and the emotional and financial burden of caregiving. RESULTS: Based on CSC questionnaires, 80% of caregivers were females, and mean age was 55.1 years. Caregivers spent approximately 47.5 hours per week caring for the patient. Nearly 75% of patients lived with the caregiver, and the main caregiver was often the spouse (59%) or child (27%) of the patient. Caregiver Activities: The most frequently reported activities/tasks were reminding patients to take medication (67%), providing emotional support/encouragement, and driving the patient to work/hospital/appointments (61% each). Caregivers most frequently asked doctors about the best care for patients (67%), diet/lifestyle (56%), and treatment (56%) for the patient. Emotional Burden: Due to caregiving responsibilities, caregivers reported a decrease in social activities (23%), and reported suffering from sleeping problems (22%), depression (16%), and stress (16%). Financial Burden: Only 6% of caregivers reported a reduced income from a change in job or reduction of working hours due to caregiver responsibilities. Only 9% of caregivers reported paying for the patients’ chronic HF prescriptions, and 5% covered some of the cost of rehabilitation. Nearly 65% of caregivers were not financially responsible for any hospitalizations of the chronic HF patient. Travel: On average, caregivers accompanied the patient five times per year to chronic HF appointments, spending a mean of 67.5 minutes travelling to and from the hospital. Of those who reported travel costs (n=39), an average of COL$ 21 was incurred. CONCLUSIONS: These data show that caring for chronic HF patients inflicts a significant burden on informal caregivers in Colombia.

PCV120: PERSONALISED HEALTH DEFINITIONS – A NEW SUPPLEMENTAL FRAMEWORK TO INTERPRET INDIVIDUALS’ RESPONSES ON THE EQ-5D-VAS

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OBJECTIVES: Responder definitions are frequently used to quantify the meaningfulness of changes in a patient’s health status. These present a definition derived from a population for application to all individuals in that population. However, a change corresponding to the responder definition may not reflect a meaningful shift in how individual patients evaluate their personalized health. The objective of this study was to explore a personalized interpretative framework for examining changes over time on the EQ-5D visual analog scale (VAS); a widely used 0-100 number line on which patients rate their health. The personalized framework asks patients to create segments on the EQ-5D-VAS indicating areas corresponding to different health categories (e.g., “excellent,” “poor”). Qualitative interviews were conducted to assess comprehension of the framework, explore patient-defined health categories, and identify how they map onto the EQ-5D-VAS. METHODS: A draft framework asked patients to divide and label the EQ-5D-VAS into different categories of health. This was tested through in-person, semi-structured interviews with individuals self-reporting cardiovascular disease diagnoses. Interviews were conducted in three waves, with the framework revised between waves. RESULTS: Analyses included fourteen individuals with sEQ-5D VAS scores ranging ranging from 40 to 90; mean(SD)/median of 66.7(13.0)/63.5. Eight participants (57.1%) felt that four categories of health were appropriate and there was general agreement on the labels; Poor, Fair, Good, and Excellent. There was substantial variability in where patients drew lines on the EQ-5D-VAS to indicate the categorical boundaries; Poor ranged between 0 and 50; Fair 10-75; Good 40-91; Excellent 60-100. In wave 3, all participants demonstrated appropriate comprehension of the framework. CONCLUSIONS: The framework was well understood. The wide range of margins and the extent of overlap between the categories provide strong evidence for a personalized EQ-5D-VAS evaluation framework to better understand and interpret each individual’s response to the item.
PCV121: PRO INSTRUMENTS USED IN STUDIES OF PULMONARY HYPERTENSION SINCE 1960

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OBJECTIVES: To create an evidence map of the different patient-reported outcome instruments used in studies of patients with pulmonary arterial hypertension (PAH), the geographical settings in which these studies were conducted and the interventions assessed. METHODS: We searched the hecro.com database (www.hecro.com) for PRO studies on PAH published between 1960 and May 16 2017, and analysed the abstracts identified by the search to determine the different PRO instruments cited across the range of geographical locations and interventions. We presented the findings as an evidence map. RESULTS: We found a total of 70 abstracts that reported the use of 30 different PRO instruments. Of these, seven instruments were specific for PAH, two were designed for use in any respiratory disorder and three in heart failure. 13 were general instruments used to evaluate quality of life or utilities, one assessed the impact of treatments, and nine assessed symptoms or comorbidities of people with PAH or its underlying diseases. The most frequently used tool was the SF-36 in 41 abstracts, followed by the Minnesota Living with Heart Failure Questionnaire (9), CAMPHOR (8), Borg Dyspnoea Index, EQ-5D and St George’s Respiratory Questionnaire (6 each). Studies generally recruited patients with any PAH (40 abstracts) or CTEPH (10), but some studies focused on PAH only in patients with COPD (3), congenital heart disease (7) or systemic connective tissue/intestinal diseases (12). The USA was the most frequent location for the studies, with 14 abstracts, followed by the UK (10) then Australia, Canada and France (4 each). The main interventions assessed were bosentan (12 abstracts) and sildenafil (6). CONCLUSIONS: A wide range of PRO tools have been used in studies of PAH, but most used the SF-36, with the US or UK the most common locations.

PCV122: REDUCTION OF LDL-C LEVELS IS MOST IMPORTANT - PATIENT PREFERENCES FOR DRUG TREATMENT ADJUNCT TO LDL-C APHERESIS IN SEVERE HYPERCHOLESTEROLEMIA

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OBJECTIVES: Severe hypercholesterolemia is a major cause of death from coronary heart disease. Statins have been the cornerstone of lipid therapy for the last two decades. New adjunctive drug therapies (PSCK9-inhibitors) passed authorization processes in EU and US and have been launched recently. The aim of the empirical study was to document patients’ preferences with regard to the adjuvant drug therapy of apheresis-treated patients with severe familial hypercholesterolemia. METHODS: A systematic literature search was conducted to identify patient-relevant outcomes. Within N=10 semi-structured interviews the decision model was generated. Seven patient relevant characteristics were identified and described by three levels. For the discrete choice experiment (DCE), an experimental design (7*3) was generated using Ngene-Software. The design consisted of 96 choices, which were divided into 8 blocks. The survey was conducted between November 2015 to April 2016 with computer-assisted personal interviews. RESULTS: N=348 apheresis-treated patients participated (64.9% male). The preference analysis (random parameter logit estimation) showed that patients had clear preferences for all attributes included and that the efficacy criterion “reduction of LDL-C level in blood” (Level Difference/LD: 2.808) was the most significant characteristic in the treatment of hypercholesterolemia. The second rank was taken by “risk of myopathy” (LD: 1.239). In third place was “frequency of apheresis” (LD: 0.821) followed by “risk of cognitive impairment” (LD: 0.554), “number of additional injections” (LD: 0.526) and “risk of hypotension” (LD: 0.341). Within the random parameter logit estimation all coefficients proved to be significant at the level of p≤0.01. CONCLUSIONS: This study ascertained the essential decision criteria for an optimal therapy from the patients’ perspective. It seems that clinical efficacy is dominant from the patients’ perspective. Hence “reduction of lipoprotein (LDL-C) in blood” is ranked highest above the patient relevant mode of administration (apheresis frequency, additional injections) and side effects characteristics.

PCV123: ASSESSING THE BURDEN OF CHRONIC HEART FAILURE ON PATIENTS IN COLOMBIA

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OBJECTIVES: To understand the burden of chronic heart failure (HF) on patients in Colombia. METHODS: A Disease-Specific Program was conducted to assess the impact of chronic HF. Patient record forms (PRF) were completed by 30 cardiologists for 8 consecutive patients with CHF. The same patients were invited to complete a patient self-completion (PSC) questionnaire. RESULTS: PSC Data (n=116) revealed that the mean patient age was 70.1 years, and the majority of patients were male (63%). Three fifths of patients had a Body Mass Index (BMI) ≥25
kg/m². Half of patients were retired (0% due to chronic HF), 10% were unemployed (33% due to chronic HF), and 10% worked full-time. The majority (64%) of patients lived with their spouse/partner. The overall EQ5D utility score amongst patients was 0.62 (n=110). EQ5D results indicated that 63% of patients experienced moderate to extreme pain or discomfort, 60% had moderate to extreme anxiety or depression, and 43% reported some problems performing usual activities. One fourth of patients reported that chronic HF causes a severe disruption to their everyday life; only 30% of patients were always able to leave the house. Household income: 65 (63%) of respondents reported a household income less than COL$2,100,000 per month. Insurance: 81 (72%) of patients reported being covered by Colombia’s Contributive regime, while 18% were under the Subsidized regime, and 11% the special regime. Travel/Accommodation: Patients on average spent 77 minutes travelling to and from the hospital. For patients who reported transport costs (n=77), a mean cost of COL$21 per trip was incurred. Professional Caregiver: 4% of patients received assistance from a professional caregiver. Patients paid a mean of COL$1,033 per month, and required assistance for a mean of 42.3 hours per week. CONCLUSIONS: These data are significant for understanding the burden of chronic HF on patients in Colombia.

**PCV124: THE COMPARISON OF EQ-5D-5L VERSUS DISEASE/TREATMENT-SPECIFIC MEASURES IN PULMONARY EMBOLISM AND DEEP VEIN THROMBOSIS**

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OBJECTIVES: EQ-5D-5L has been developed from its parental measure, EQ-5D-3L, moving from 3 to 5 levels, aiming to improve sensitivity, discriminative power and limit ceiling effects. The use of 5L has grown rapidly in recent years. However, the use of EQ-5D-5L in pulmonary embolism (PE) and deep vein thrombosis (DVT) populations have not been validated. Furthermore, there is a lack of performance comparisons for EQ-5D-5L against disease-specific quality of life measures. The aim of this study was therefore to compare the measurement properties of EQ-5D-5L against PEmb-QoL and VEINS-QOL/Sym (disease-specific), and PACT-Q2 (treatment-specific) in both PE and DVT populations. METHODS: PREFER in VTE,a non-interventional disease registry, was conducted between 2013 and 2014 in primary and secondary care across seven European countries. Consecutive patients with acute PE/DVT were documented and followed up over 12 months. Patients who completed all above-mentioned questionnaires at baseline were included in the study sample. The psychometric properties examined included acceptability (missing, ceiling and floor effects), validity (convergent, discriminant, and known-groups validity), and responsiveness. Known group validity and responsiveness were assessed using both effect size (Cohen’s d) and relative efficiency (F-statistic). RESULTS: A total of 1,054 and 1,537 complete cases for PE and DVT were identified. A ceiling effect in EQ-5D-5L was observed (14% and 10% in PE and DVT, respectively), while a higher proportion of missings was observed in PACT-Q2 (19% and 18%). EQ-5D-5L was low to moderately correlated with other measures (r<0.5). Low correlations (r<0.2) between each QOL measure against age and gender were observed, supporting the discrimination validity. EQ-5D-5L was associated with larger effect sizerelative efficiency in most of known group comparisons in both groups. Similar results were observed for responsiveness. CONCLUSIONS: The results suggest that EQ-5D-5L is similar to PEmb-QoL, VENS-QOL/Sym and PACT-Q2 in terms of acceptability, validity and responsiveness in both PE and DVT populations.

**PCV125: QUALITY OF LIFE IN PATIENTS WITH CHRONIC HEART FAILURE IN SLOVK REPUBLIC**

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OBJECTIVES: The prevalence of chronic heart failure (CHF) in Slovak Republic is about 100 000 cases. No study was published about the impact of CHF on quality of life (QoL) and work ability (WA) in Slovak Republic. METHODS: The sample consisted of 99 patients, 41 women and 58 men, with average age being 63.7 years. 15 patients were classified in NYHA I, 48 patients – NYHA II and 36 patients – NYHA III. The average duration of disease was 3.6 years. Primary method used for the analysis of QoL was a combined questionnaire consisting of 6 parts: A. Demography, B1. Clinical part filled out by physician, B2. Clinical part filled out by patient, C. Quality of life, D. Socio-economic part, E. EQ5DL. QoL and WA were evaluated on numeric scales from 0 - the worst to 10 - the best. Mann-Whitney, Wilcoxon, Kruskal-Wallis and Friedman tests and Spearman correlation were used in results evaluation. RESULTS: Significant statistical differences in QoL were found: in the time of best health - 9.18, without CHF – 8.15 in the time of diagnosis – 5.76, in the time of acceptance in hospital – 3.98 and in the time of full
treatment – 5.01. The results gained in WA were: 9.36 vs 8.43 vs 5.71 vs 3.69 vs 4.55. The results from QoL and WA were in strong correlation. Foreknowledge of disease (1-the worst, 5-the best) was 3.55, satisfaction with medical care – 3.7 and nursing care – 3.8. Willingness to pay was for full health without CHF was 67.9 € monthly by average monthly income 427.1 €. **CONCLUSIONS:** CHF has a significant impact on patients' QoL and WA. There are significant differences in both areas in duration of CHF. The treatment had positive impact on QoL and WA. Higher grade of NYHA had worse QoL and WA.

**PCV126: BURDEN OF CHRONIC HEART FAILURE ON CAREGIVERS: A MULTINATIONAL CROSS-SECTIONAL SURVEY IN REAL WORLD SETTING**

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**OBJECTIVES:** To assess the burden of chronic heart failure (CHF) on informal caregivers. **METHODS:** A cross-sectional survey was conducted across 10 countries (Argentina, Brazil, China, Colombia, France, Japan, Mexico, Russia, Saudi Arabia and Turkey). A total of 563 cardiologists were surveyed to complete patient record forms for 4903 CHF patients. Those patients informal caregivers (n=1316) were invited to complete a caregiver self-completion questionnaire which included the EQ-5D and Heart Failure Caregiver Questionnaire (HF-CQ). **RESULTS:** The mean (SD) caregiver age was 57.9 (14.0) years. Two-thirds of caregivers were female (67%) and were most commonly either a spouse (64%) or child (24%). Caregivers spent an average of 28 (30.2) hours/week caring for the patient. The mean caregiver EQ-5D utility score was 0.87 (0.19) and moderate to severe anxiety/depression and pain/discomfort was reported by 32% and 29%, respectively. The three most frequent caregiving activities reported were providing emotional support/encouragement to patients (62%), reminding patients to take CHF medication (60%) and help in administering the medicines (44%). On a scale of 0 (best) to 100 (worst), mean emotional and physical wellbeing scores were 30.6 (17.4) and 25.0 (20.7), respectively. Due to caregiving responsibilities, 35% of caregivers suffered from stress, 33% were emotionally drained and 31% were mentally tired. Furthermore, caregiving was reported as being physically tiring and physically hard work for 33% each respectively. Considerable impact on own health (score of ≥5 on a scale of 1–10) was reported by 38% of caregivers. Reduced income due to job change or reduction of working hours owing to caregiving responsibilities was reported by 21% caregivers. On average, caregivers accompanied a patient 7 times a year to CHF appointments. **CONCLUSIONS:** CHF results in substantial burden on informal caregivers and has emotional, mental, physical and financial impact.

**PCV127: BURDEN OF DISEASE ON CHRONIC HEART FAILURE PATIENTS: A MULTINATIONAL CROSS-SECTIONAL SURVEY IN REAL WORLD SETTING**

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**OBJECTIVES:** To understand the burden of CHF on patients. **METHODS:** A cross-sectional survey was conducted and patient record forms (PRF) were completed by 563 cardiologists for 4903 CHF patients. The same patients were invited to complete a patient self-completion questionnaire which included the EQ-5D and Heart Failure Caregiver Questionnaire (HF-CQ). **RESULTS:** The mean (SD) patient age was 66.7 (11.9) years; 58% patients were male and mean BMI was 25.9 (4.6) kg/m2. The most common symptoms were dyspnoea when active (67%) and fatigue (58%). Considerable disruption in everyday life (score of ≥5 on a 1–10 disruption scale) was reported by 56% patients with a mean score of 4.9 (2.4). Of the 2452 patients, 17% were employed; and of the 85 unemployed patients responding, 44% reported CHF as the reason for their unemployment. Mean EQ-5D score (n=2398) was 0.71 (0.29); the most affected domain (moderate to severe) was pain/discomfort (55%) followed by problems in performing routine activities (46%), anxiety/depression (43%) and difficulty in walking about (43%). On average, patients spent 64.9 (148.8) minutes/visit travelling to and from the hospital. Assistance from a professional caregiver (n=2417) was reported by 9% of patients with a mean of 24.1 (28.9) hours/week of required assistance (n=200). PRF data showed that 41% of patients were hospitalised at least once for CHF in the year prior to the consultation, and of those hospitalised, 24% were readmitted within the same year. At least one emergency room visit was reported by 26% patients and 81% of patients had at least one outpatient visit with a mean of 4.9 (5.4) in the 12 months prior to the survey. **CONCLUSIONS:** CHF adversely affects patients’ quality of life and introduces considerable disruption due to (repeated) hospitalisations.

**PCV128: FACTORS ASSOCIATED WITH QUALITY OF LIFE(QOL) IN PERIPHERAL ARTERIAL DISEASE(PAD) PATIENTS IN KOREA: RESULTS FROM PAD OUTCOMES RESEARCH(OR)**
OBJECTIVES: Even though PAD is known to have significant effect on QoL, due to its asymptomatic nature, it is often underdiagnosed and undertreated. Therefore, in this study, we investigated factors associated with patients’ change of QoL (ΔQoL) in Korea. METHODS: Data in this analysis was from PAD OR, which was a prospective, observational study conducted from June 2013–August 2014 in 23 participating tertiary-hospitals. Patients with age≥20 years, ankle-brachial index (ABI) ≤0.9, and lower-extremity artery stenosis ≥50% on CT-angiography or peak-systolic-velocity-ratio (PSVR) ≥2.0 on duplex sonography were included. Clinical characteristics were collected through medical chart review, and QoL was assessed via patient survey using EQ-5D and EQ-VAS measures. Data were collected at the time of study enrollment and at 6-month follow-up (FU). Multiple linear regression analysis was conducted to assess factors associated with ΔQoL after 6-month. RESULTS: Total of 1,260 patients (mean age 69.76±9.94, male 77.0%) were included in the analysis. Patients’ mean EQ-5D index scores significantly increased by 0.04±0.20 (p<0.0001) after 6 months (baseline:0.64±0.24, 6-month FU:0.68±0.20). As a result of multivariable analysis, factors associated with ΔQoL was change of Fontain stage where ‘Improvement of Fontain stage’ compared to ‘No change’ (B=0.06646, p<0.0001) had positive effect on ΔQoL and ‘Deterioration of Fontain stage’ compared to ‘No change’ (B=-0.03902, p=0.0246) had negative effect on ΔQoL. Underlying conditions such as diabetes (B=0.02299, p=0.0469) had a positive effect, while cardiovascular comorbidities (B=-0.03132, p=0.0101) had a negative effect. Others such as treatment with pharmacotherapy (B=0.05257, p=0.0356) and patients’ smoking status of no smoking for the past 6 months compared to current smoking (B=-0.03254, p=0.0399), had a positive effect on ΔQoL. CONCLUSIONS: Since PAD is often diagnosed after symptom deterioration, patients’ QoL is more likely to be have been impacted even before the disease diagnosis. Therefore, more attention to the disease for earlier diagnosis and provision of timely pharmacotherapy is critical in management of patients’ QoL.

PCV129: COMPARING QUALITY OF LIFE OF (RT-PA) WITH NO-(RT-PA) IN STROKE ATTACKED PATIENTS

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OBJECTIVES: Stroke has been considered as one of the most common neurological disease life-threatening and a global health problem. It causes disability in adults and ranked as the third leading causes of human mortality worldwide. The aim of this study was to compare the quality of life in Stroke’s patients in both treated and not treated groups with (rt-PA). METHODS: We conducted a cohort study on 126 stroke attacked patients, 42 and 84 patients treated and not treated with (rt-PA) respectively. We used a disease specific questionnaire for stroke (SSQOL) and generic questionnaire (EQ5D). The patients were studied from the first week of treatment and continued up to 3 months after completion of the therapy (treatment with and without rt-PA), followed up and then complete the questionnaires. Both groups were tested for significant differences regarding socio-demographic. A multiple linear regression model was implemented to find out the factors affecting different aspect of QOL among the patients. RESULTS: Stroke attacked group was differ in physical and mental health, composite scores as well as relative scales. There was a significant difference between the MRS and NIHSS scores in the two groups Stroke’s patients treated and not treated with (rt-PA) after 3 months (p<0.05). Quality of life in patients treated with (rt-PA) was .67 and in patients treated with No-(rt-PA) was .07. CONCLUSIONS: By this study, we can conclude that a significant differences between QOL of patients were occurred when treated with (rt-PA) in compare with not treated with (rt-PA). In over all we can say (rt-PA) improved the quality of life in stroke attacked patients significantly. This study suggests that (rt-PA) improved the quality of life in stroke attacked patients by improving the sleep patterns, physical, social and psychological conditions.

CARDIOVASCULAR DISORDERS - Health Care Use & Policy Studies

PCV130: HYPERTENSION MEDICATION ACCESS AND SELF-MANAGEMENT AMONG THE ELDERLY BY EDUCATION: INSIGHTS FROM THE 2013 USA MEDICARE CURRENT BENEFICIARY’S SURVEY

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OBJECTIVES: Hypertension, a major risk-factor for cardiovascular disease and stroke, is a global public health problem...
problem. Effective antihypertensive medication use can decrease morbidity/mortality, yet medication access may vary by factors beyond insurance coverage. We measured educational disparities in hypertension medication access and adherence in hypertension self-management among the elderly with Medicare coverage in the USA. METHODS: The sample included those age 65 years or older with hypertension in the 2013 Medicare Current Beneficiary Survey (n=6652). We examined satisfaction with access to hypertension medications and adherence in hypertension self-management by education: less than high school, high school graduate, and some college or more (comparison group). Multivariable logistic regression was used to model the outcomes of being very satisfied, or very confident, controlling for age group, gender, income, race/ethnicity, comorbidity, health status, and type of prescription drug coverage (Medicare Part D, private, Medicare Advantage, Medicaid dual eligible, none). Significance was set at p<.05. RESULTS: For education: 21.1% had less than high school, 35.9% were high school graduates, and 43.0% had at least some college. In multivariable models, having less than a high school education was negatively associated with satisfaction in: the amount paid for medication (OR:0.68; 95%CI:0.56-0.83), the list of drugs covered (OR:0.69; 95%CI:0.56-0.85), and finding a pharmacy that accepted their drug plan (OR:0.58; 95%CI:0.47-0.72), compared to those with some college education. Both those with less than a high school education (OR:0.64; 95%CI:0.53-0.77) and with a high school degree (OR:0.70; 95%CI:0.62-0.80) were significantly less confident in managing their hypertension than those with some college education. CONCLUSIONS: This nationally representative sample revealed gaps in access to prescription medications by educational attainment, as well as less confidence in self-management, even after controlling for prescription drug coverage and other sociodemographic factors. Those with low education may lack drug coverage and/or chronic care management plans that meet their needs.

PCV131: PHARMACOLOGICAL ADHERENCE TO CLINICAL GUIDELINES IN ACUTE CORONARY SYNDROME IN HOSPITALS

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OBJECTIVES: Pharmacological adherence is critical by cardiologists in Acute Coronary Syndrome. In this study the extent of pharmacological adherence by cardiologists from updated clinical guidelines were conducted in cardiac patients on admission and at discharge in 4 hospitals in Isfahan, Iran. METHODS: A retrospective cross sectional study was conducted on medical records of Acute Coronary Syndrome (unstable angina and myocardial infarction). A range of clinical data including prescribed medications on admission and at discharge, disease background, laboratory tests and biomarkers were extracted from patients' medical records. The researcher's focus was more on prescription of recommended medications from clinical guidelines utilizing aspirin ± clopidogrel, beta blockers, statins, ACEI (angiotensin-converting enzyme inhibitor) or ARB (angiotensin II receptor blockers). Patients regarding cardiologist's pharmacological adherence were divided into two groups of good-adherence equals or above %75 (4/3, 4/4) and poor-adherence below %75 (1/4, 2/4). RESULTS: A total of 200 medical records of ACS patients was extracted and reviewed. %67 of population was male and 33% was female; %19.5 was young (equal and below 50 years old) and %80.5 was old (above 50 years old). Patients with ST segment elevation myocardial infarction accounted for %18.5 whereas the ones with non ST segment elevation myocardial infarction were %23. On admission and at discharge %99, %80, %58 and %96.5 of patients received antiplatelet, beta blockers, ACEI/ARB and statins respectively. In general the extent of adherence to updated clinical guidelines on admission was 58.5 and at discharge 53.9 which was poor. CONCLUSIONS: Poor adherence to updated clinical guidelines by cardiologists due to secondary prevention of Acute Coronary Syndrome (ACS) is very worrisome. It is necessary to investigate the reasons of non-adherence regarding aging society and the prevalence of cardiac disease.

PCV132: PENETRATION OF PERIPHERAL VASCULAR INTERVENTIONS IN HUNGARY

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OBJECTIVES: Our investigation aimed to analyse the penetration of peripheral vascular interventions among Hungarian hospitals, with special respect to the Clinical Center of the University of Pécs, a tertiary level university teaching hospital. METHODS: Data analysed were taken from the database of the Hungarian National Health Insurance Fund Administration, covering the year 2015. We identified the patients with the Hungarian Diagnosis Related Groups (DRG) categories. We investigated the following DRG groups: 190 C, 190 D, 190 E, 190 F, 190 G, 190 H. Hospitals that had reported patients with these DRG codes were involved into the study. Our investigation focused on case numbers and percentage ratio. RESULTS: The general market share of the Clinical Center of the University of Pécs (CC-UP) was 5.0 % from all the active inpatient care services in 2015. Institutions performing 190C Percutaneous and other vascular surgeries (with the implantation of one or more stents or homograft) reported a total 1111 cases, out of which 135 (12%, which is the second largest market share: 2nd place) was reported by the CC-
UP. Institutions performing 190D Percutaneous and other vascular surgeries without stent implantation reported a total 592 cases, according to reported performance, the CC-UP had 229 cases (38.7%, 1st place). Regarding 190E Percutaneous vascular surgeries with further treatment (with one or more stents) the reported number was a total of 1288 cases, out of which the CC-UP carried out 7 (0.5%, 28th place). The total number of 190F Percutaneous vascular surgeries without further treatment including stent implantation amounted to 822, and the CC-UP had 29 cases (3.5 %, 9th place). CONCLUSIONS: The case numbers and percentage ratio of peripheral vascular interventions performed at hospitals showed considerable differences, even in a tertiary level teaching hospital. Penetration rate of peripheral vascular interventions should be increased in Hungary.

**PCV133: INTERMEDIATE EVALUATION OF VIVOPTIM : THE MGEN (FRENCH INSURER) PREVENTION PROGRAM FOR CARDIOVASCULAR RISKS**

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OBJECTIVES: VIVOPTIM is an innovative prevention program for cardiovascular (CV) risks designed and financed by the French insurer MGEN Union. It is a personalized program based on digital services, telemedicine devices and direct coaching. A pilot program was launched in 2015 in two French regions (Midi Pyrénées and Bourgogne). A total of 15 different prevention programs were proposed: obesity, atherosclerosis, hypertension, physical activity… based on their CV risk profile. An evaluation of VIVOPTIM after 10 months of follow up was conducted. METHODS: The clinical data collected longitudinally and routinely during the program was described and analyzed. Evolution of risk factors between ‘highly active’ participants and ‘weakly active’ participants were compared with univariate and multivariate analyses. The participation was measured by the time spent with a coach or connected to the web platform. VIVOPTIM results were compared with results of other published prevention programs. RESULTS: 5,852 insured persons participated in the program and 2,352 of them gave the consent for participating in the evaluation. 66% lived in the Midi-Pyrénées region and 34% lived in the Burgundy region. Mean age was 62 years, 39% were women, 11.5% had a history of CV disease and 1.1% had a history of chronic kidney disease. After 10 months of follow-up, we observed a significant decrease (p<0.05) in systolic blood pressure (-3.48 mmHg), weight (-1.4 kg), BMI (-0.48 kg/m\(^2\)) and LDL-c (-0.06 g/L). Non-significant decrease in smoking and HbA1C was observed. Multivariate analyses did not show a significant dose-effect. CONCLUSIONS: VIVOPTIM shows similar efficacy results as already published programs. Extrapolation of these results with standard risk scores (SCORE and Framingham equations) shows that this pilot program conducted in two regions could have avoided 29 cardiovascular events.

**PCV134: REAL-WORLD EVIDENCE ON CLINICAL USE OF A NOVEL ORAL ANTICOAGULANT FOR THE TREATMENT OF ATRIAL FIBRILLATION**

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OBJECTIVES: This study was aimed to examine the clinical characteristics of patients with non-valvular atrial fibrillation (NVAF) treated with apixaban in a real world setting. METHODS: In this multi-center, retrospective, observational study, we collected data from 5 hospital databases (North, Center and South Italy) on consecutive patients with a diagnosis of NVAF who had initiated apixaban from 1 January 2014 up to 31 March 2016. Protocol and Case Report Form were submitted and approved by Ethics Committees; patient anonymized data were uploaded by clinicians; statistical analyses were performed by University of Milan-Bicocca. RESULTS: Data from 766 patients affected by NVAF from five Italian Centers were analyzed. The mean age was 74.2 years, 53.5% of patients were women and the median CHADS2 and CHA2DS2VASc scores were respectively 2.0 and 4.0. The most frequent comorbidities were cardiovascular diseases (hypertension [84%]; previous vascular disease [34%]; heart failure [22%]), renal impairment [34%], diabetes mellitus [22%] and anemia [12%]). In the whole cohort, half patients (50.7%) were naïve to oral anticoagulants, while 219 patients had been previously treated with warfarin, 66 with heparin, 52 with acetylsalicylic acid, 1 with clopidogrel and 40 with a novel oral anticoagulant (NOAC). At treatment initiation, 76.5% of patients was prescribed apixaban at the recommended daily dose of 10 mg, while the remaining patients (23.5%) received the reduced daily dose of 5 mg. During the follow-up period, apixaban dose was reduced only in 2.0% of patients at V1, in 3.2% at V2 and in 4.8% at V3. Switching to another anticoagulant occurred in 5.3% of patients at V1, in 8.3% at V2 and in 9.5% at V3. CONCLUSIONS: Patient characteristics observed in this study were very similar compared to clinical trials population, while the use of the reduced daily dose of 5 mg seemed to be higher in real life.

**PCV135: DRUG UTILIZATION IN A CARDIOLOGY UNIT OF A REFERRAL HOSPITAL IN NIGERIA**

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**OBJECTIVES:** This study described the utilization pattern of cardiovascular drugs to generate information for interventions and evidence based approach in rational use of cardiovascular drugs. **METHODS:** The study was a retrospective analysis of prescriptions covering two years period. Study lasted from October 2015 to August 2016. The outcome measures were based on World Health Organization (WHO) recommended drug use indicators adapted for cardiovascular health. Data were analyzed using descriptive statistics. **RESULTS:** 1827 prescriptions were analyzed. Antihypertensives were the most prescribed 844.0 (46.2%), followed by analgesics and anti-inflammatory agents 343.0 (18.8%), anti diabetes 53 (2.9%), anti infectives 49.0 (2.7%) among other. Diuretics were the most prescribed antihypertensive monotherapy 367.0 (43.6%), followed by angiotencin converting enzyme inhibitors (ACEI) 227.0 (26.9%), calcium channel blockers (CCB) 158.0 (18.7) while vasodilators were the least prescribed 4.0 (0.47%). Furosemide 126.0 (34.3%) was the most prescribed diuretic 126.0 (34.0%). Lisinopril was the most prescribed ACEI 223.0 (98.2%) and amiodipine was the most prescribed CCB 138.0 (87.3%). The most prescribed combination agent was ACEI and diuretics 71.0 (29.2%), followed by CCB+ACEI+Diuretics 38.0 (15.6%). The number of antihypertensives per prescription were one= 135.0 (35.6%), two= 180.0 (47.5%), and three= 64.0 (16.9%). The duration of therapy were 1 week: 446.0 (24.4%), 2 weeks: 917.0 (50.2%), 4 weeks: 22.4%, and >4weeks: 55.0 (3.0%). The most prescribed dosage form was solid (oral) preparations 1795.0 (98.2%). Number of drugs per prescription were four= 98.0 (25.9%), five= 78.0 (20.6%), and three= 63.0 (16.6%). **CONCLUSIONS:** Diuretics were the most prescribed antihypertensives. Outstanding antihypertensive combinations suggest scope for improving their utilization. High number of drugs per prescription was an indication for polypharmacy and irrational use of antihypertensive drugs with its implications on cost, and quality of life. This underscores the need for regular utilization studies to provide timely information for promoting rational use of cardiovascular drugs.

**PCV136: VALIDATION OF A SCREENING TOOL (ICUSI QUESTIONNAIRE) FOR AF PATIENTS RECEIVING VITAMIN K ANTAGONIST THERAPY**

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**OBJECTIVES:** To design and validate a simple, reliable and easy to use questionnaire to identify patients under vitamin K antagonists (VKA) treatment with sub-optimal time in therapeutic range (TTR; without needing the TTR values), in order to allow a closer follow-up of the actual anticoagulant treatment or guiding a possible treatment changes. **METHODS:** Non-interventional, cross-sectional, multicenter design. A cardiologist expert panel identified those clinical variables capable of forecasting a good TTR control. The 5 proposed indicators (ICUSI) were included in an electronic clinical record form along with thromboembolic (CHADS2 & CHA2DS2-VASc) and hemorrhagic (HAS-BLED) risk indexes. A patient diary collecting last 6 month INR measures was also included. Discriminant capabilities were assessed using binary logistic regression respect to TTR control (Rosendaal or direct methods), and discriminant validity using the area under the curve (AUC) of the ROC curve. A total of 870 patients with documented AF diagnosis, receiving VKA, and meeting the selection criteria were included. Patients were recruited at 54 Cardiology departments covering all the Spanish territory. **RESULTS:** The final sample contained 777 (88.9%) of assessable cases: 45% women, 13% lived alone, and 67% did not have caregiver. Mean age was 75.3±9.2 years, mean TTR=66.0±19.8% and 46.7% attained INR control between 2-3 (Rosendaal TTR>65%). Individually, ICUSI indicators were statistically significant (p<0.05) respect to Rosendaal or Direct non-optimal control, but one item was discarded in the overall estimation. The ICUSI index was statistically discriminant with respect to 6 months TTR<65% with AUC=0.705 (SE=0.018). Using the cut-off value ICUSI≥1 the risk of TTR<65%: sensitivity=80.9%, specificity=44.9%, positive predictive value=62.6%, and negative predictive value=67.4%. **CONCLUSIONS:** Initial evidences on the ICUSI validity support a good predictive behavior on screening patients with bad anticoagulant control.

**PCV137: PRIMARY PREVENTION OF HYPERLIPIDEMIA: TREATMENT AND COMPLIANCE IN REAL WORLD PRACTICE**

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**OBJECTIVES:** Hyperlipidemia is a major cause of disease burden globally due to its role in cardiovascular disease (CVD). Primary prevention and treatment of hyperlipidemia has been a major focus in public health over the last decade. We aimed to describe a cohort of individuals with hyperlipidemia taking pharmacological treatments for primary prevention, their adherence to treatment, and the proportion achieving target lipids levels. **METHODS:** We built a population-based cohort of Clalit members with hyperlipidemia (without indications for CVD) first diagnosed...
between 2012 and 2013, using integrated electronic medical record data. We present the annual number of individuals who purchased lipid lowering medications in 2014 and 2015. Adherence was assessed using the proportion of days covered (PDC), and proportion of individuals meeting lipid target goals were evaluated one year after treatment. RESULTS: During 2014 and 2015, among 61,650 individuals who were newly identified with hyperlipidemia, 26% purchased lipid lowering medications. Members who purchased lipid lowering agents had a higher risk for CVD compared for those who did not purchase (mean Framingham 10-year score 13.9% vs. 8.9%). HMG-CoA reductase inhibitors were the main pharmaceuticals purchased and only one-third adhered to this treatment regimen during the year following initiation. One year after treatment initiation, only half of the treated population achieved LDL-C, non-HDL-C, and total cholesterol targets (47.7%, 48.9% and 44.1%, respectively). CONCLUSIONS: Based on real-world data, we found that a low proportion of individuals with hyperlipidemia without indication for CVD consume lipid-lowering therapy. Furthermore, adherence to treatment is low and only half of those on medication achieve the recommended lipid target levels within a year. There is much that can be improved in clinical decision-making to achieve lipid targets in the majority of at-risk patients, including using the right medication at an appropriate dosage and focusing efforts in improving adherence to treatment.

| PCV138: POOR OUTCOMES ASSOCIATED WITH ANTITHROMBOTIC POTENTIAL UNDERTREATMENT IN PATIENTS WITH ATRIAL FIBRILLATION: A RETROSPECTIVE COHORT STUDY |
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OBJECTIVES: To measure the adequacy of antithrombotic medication use and to investigate the impact of potential antithrombotic undertreatment, on ischemic stroke and/or all-cause mortality in patients with AF. METHODS: The study was conducted from January 7, 2016 to April 30 2017 at Gondar University Hospital (GUH). A census using a retrospective cohort study design was conducted on medical records of patients with AF attending GUH between November 2012 and September 2016. Descriptive statistics were used to summarize baseline information. Patients receiving appropriate antithrombotic management and those on potential undertreatment, were followed for development of ischemic stroke and/or all-cause mortality. Kaplan-Meier and a log-rank test was used to plot the survival analysis curve. Cox regression was used to determine the predictors of guideline-adherent antithrombotic therapy. RESULTS: The final analysis included 159 AF patients with a median age of 60 years. Of these, nearly two third (64.78%) of patients were receiving potential undertreatment for antithrombotic medications. Upon multivariate analysis, history of ischemic stroke/transient ischemic attack (TIA) was associated with lower incidence of antithrombotic potential undertreatment. A significant increase (HR: 8.194, 95% CI: 2.911-23.066) in the incidence of ischemic stroke and/or all-cause mortality was observed in patients with potential undertreatment. Up-on multivariate analysis, only increased age was associated with a statistically significant increase incidence of ischemic stroke and/or all-cause mortality, while only history of ischemic stroke/TIA was associated with a decrease in the risk of ischemic stroke and/or all-cause mortality. CONCLUSIONS: Adherence to antithrombotic guideline recommendations was found to be crucial in reducing the incidence of ischemic stroke and/or all-cause mortality in patients with AF without increasing the risk of bleeding. However, potential undertreatment to antithrombotic medications was found to be high (64.78%) and was associated with poorer outcomes in terms of ischemic stroke and/or all-cause mortality (HR: 8.194, 95% CI: 2.911-23.066).

| PCV139: MANAGEMENT OF ATEROGENIC DYSLIPIDEMIA IN THE PRIMARY CARE SETTITING IN SPAIN |
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OBJECTIVES: To describe the management of atherogenic dyslipidemia (AD) in routine clinical practice in the Primary Care (PC) setting in Spain. METHODS: Observational, descriptive, cross-sectional study, based on a structured questionnaire designed for this study. The questionnaire content was based on a literature review and was validated by 3 experts in AD. It included 23 items divided in 4 dimensions and was addressed to PC physicians with experience in AD management in the Spanish healthcare system. RESULTS: A total of 1,029 PC physicians participated in the study [mean age:53.49(SD 7.78); clinical experience: 26.5(SD 8.29)]. Most physicians (76.68% and 93.00%) reported that AD is characterized by low HDL-C, elevated TGs and elevated small, dense LDL-C particles, and that metabolic syndrome, early coronary disease and T2DM are phenotypes associated with it. 96.99% indicated that AD is a determinant factor for cardiovascular risk, even if LDL-C levels are appropriate. Most physicians (98.43%) evaluated residual cardiovascular risk in their clinical practice, however, only 27.89% of them evaluated it in secondary prevention. Regarding diagnosis, 82.22% reported that TC, TG, HDL-C and non-HDL-C are essential measures when evaluating AD. Physicians often/very often used TC/HDL-C (53.06%) and LDL-C/HDL-C (49.56%) lipoprotein ratios, considering them useful/very useful (86.30% and 85.04%, respectively). Almost all
physicians reported that they can request fractionated cholesterol to assess HDL-C and LDL-C, however 3.69% could not. Physicians(95.63%) considered that the first step in AD treatment should be diet, regular exercise, smoking cessation along with pharmaceutical treatment, if necessary. 69.97% stated that pharmaceutical treatment should start with the combination of a statin and a fibrate (being fenofibrate the most appropriate one). CONCLUSIONS: Physicians have access to guidelines and recommendations regarding AD management, however, it is necessary to continue rising awareness about the importance of early detection and optimal control of AD to reduce patients’ cardiovascular risk.

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PCV140: USING TICAGRELOR TO ENHANCE OUTCOMES FOR ACUTE CORONARY SYNDROMES (ACS) PATIENTS AT LOW MIDDLE INCOME COUNTRIES

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OBJECTIVES: For low middle income country like Egypt characterized with high prevalence of hypertension in (26%) which an important driver of adverse cardiovascular outcomes (19%) acute coronary syndromes (ACS) could be considered be as an economic burden on health system. The objective for this study is evaluating introducing Ticagrelor to national formulary and its impact on outcomes for (ACS) patients for better resource management. METHODS: The study adopted a two-part cost-utility model comprising a short-term decision tree and a long-term Markov structure was utilized to estimate long-term costs and health outcomes. The aim of the modeling exercise was to adhere closely to the PLATO study and the model structure is based on the key clinical outcomes of PLATO. Data from PLATO were used to estimate rates of cardiovascular events, health-care costs, and health-related quality of life for the 12 months of therapy Event Risk. Quality of life were from PLATO To test the robustness of our results to variation in the estimates of the input model parameters, we performed various one-dimensional sensitivity analyses Time horizon was 12 months Results obtained in form of QALY. RESULTS: During the life-time horizon, total costs, QALY gained for Ticagrelor plus ASA was (9.5 QALY) versus (9.3) QALY for Clopidogrel plus ASA. This leads treatment with Ticagrelor is associated with highest effectiveness and accepted costs Ticagrelor was the preferred option in 90% of simulations at Egyptian national formulary CONCLUSIONS: Ticagrelor was the most cost-effective agent when used as part of dual antiplatelet therapy this will support introducing Ticagrelor to national formulary and treatment guidelines to enhance (ACS) outcomes and better resource utilization.

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PCV141: DOES THE REAL-WORLD USE OF PHARMACOLOGICAL THERAPY FOLLOW GUIDELINES IN CORONARY ARTERY DISEASE PATIENTS IN FINLAND?

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OBJECTIVES: Optimal medical therapy (OMT) is essential for symptom control and primary and secondary prevention of coronary artery disease (CAD). Guideline-recommended OMT in CAD consist of at least acetylsalicylic acid, lipid lowering drugs and beta blockers. In addition, angiotensin-converting enzyme -inhibitors or angiotensin receptor blocking agents may be indicated for some patients, and adenosine diphosphate (ADP) receptor inhibitors for patients having undergone a percutaneous coronary intervention (PCI). We studied how well the purchases of the most important OMT drugs followed guidelines in CAD patients before and after elective revascularization by PCI or coronary artery bypass grafting (CABG). METHODS: Clinical data from Kuopio University Hospital revascularization registers (years 2007-2014) were linked to national registers on mortality, hospital discharges, and prescription drugs purchased by the patients. Drugs were classified according to the Anatomical Therapeutic Chemical (ATC)-classification system and cardiovascular drugs were identified as any ATC-code C drug. RESULTS:85.2% of altogether 1557 PCI patients and 88.1% of 1768 CABG patients had purchased lipid-modifying agents during the three years before, and 94.9% and 96.8% during the year after the procedure, respectively. Beta blocking agents were purchased by 84.9% of PCI patients before and by 87.9% after the procedure, and by 86.3% of CABG patients before and 97.1% after the operation. In CABG patients the purchase of organic long acting nitrates fell from 59.7% before to 10.1% after the operation but remained almost constant in PCI patients (64.3% vs. 54.4%). Use of ADP receptor blocking agents increased in PCI patients from the pre-intervention 26.3% to the post-intervention 83.9%. Greater use of hospital services before and after the interventions had an incremental effect on medication purchases. CONCLUSIONS: Based on information on drug purchases, real-world use of recommended pharmacological therapy before and after revascularization complied both in PCI and CABG patients surprisingly well with current guidelines.

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PCV142: POTENTIAL MORTALITY REDUCTION WITH OPTIMAL USAGE OF SACUBITRIL/VALSARTAN THERAPY FOR THE TREATMENT OF HEART FAILURE IN BRAZIL

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OBJECTIVES: PARADIGM-HF, a phase III trial conducted in patients with heart failure with reduced ejection fraction (HFrEF), showed that sacubitril/valsartan, a first-in-class angiotensin receptor neprilysin inhibitor, provided incremental cardiovascular and overall survival benefit compared with enalapril. This analysis aims to quantify the number of all-cause deaths that potentially could be avoided with optimal usage of sacubitril/valsartan in the treatment of HFrEF in Brazil. METHODS: Data from Instituto Brasileiro de Geografia e Estatística was used to quantify the target population. A literature review was conducted to determine the prevalence of HF, the proportion of NYHA Class II-IV and finally, the proportion of HFrEF patients. The number needed to treat (NNT) to avoid one death due to any cause, standardized to 12 months, was derived from the PARADIGM-HF trial. The number of all-cause deaths that might be potentially prevented or postponed as a result of treatment with sacubitril/valsartan was estimated along with multiple-sensitivity analysis. The main outcome measure was all-cause mortality. RESULTS: The 2017 population (≥20 years) in Brazil was estimated at 144,323,520 and the estimated prevalence of HF was 2%, which was applied to determine the number of HF patients. The percentage of diagnosed HF patients was 60%. Of these, 85% were NYHA Class II-IV; 41% of these patients had HFrEF. This equated to 603,561 patients with HFrEF NYHA class II-IV. Finally, absolute reduction in all-cause mortality in PARADIGM-HF was 2.8% over an average follow-up time of 27 months. This translates into a NNT, standardized to 12 months, of 80.3; thus, optimal usage of sacubitril/valsartan therapy was estimated to prevent 7,516 deaths each year. CONCLUSIONS: The findings suggest that a substantial number of deaths could potentially be prevented by optimal implementation of sacubitril/valsartan therapy. Implementation of sacubitril/valsartan into routine clinical practice is important, and may substantially improve clinical outcomes among HFrEF patients in Brazil.

PCV143: DIRECT ORAL ANTICOAGULANT (DOAC) ADOPTION IN PRACTICE: UTILIZATION, EXPENDITURES, SWITCHING AND ADHERENCE

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OBJECTIVES: To compare prescription trends, costs, switch patterns, and mean adherence among oral anticoagulants (OACs) in the Texas Medicaid population. METHODS: Texas Medicaid prescription claims data from July 1, 2010 to December 31, 2015 were analyzed. All OAC prescriptions for patients aged 18-63 with ≥1 prescription claim for an OAC were included in utilization and expenditure trend analyses. Switch patterns and adherence, measured by the proportion of days covered (PDC), over 1 year were analyzed for patients newly initiated on OAC therapy between January 1, 2011 and December 31, 2014 and having ≥2 prescription claims. Adherence was measured only for direct oral anticoagulants (DOACs) as frequent dosage adjustments for warfarin limit PDC estimation accuracy. RESULTS: Over the 5.5-year study period, DOAC use increased steadily and the proportion of OAC prescription expenditures accounted for DOACs increased substantially. By December 2015, DOACs accounted for a third of anticoagulant prescription claims and >90% of total oral anticoagulant prescription expenditures. Mean cost per prescription was 30 times higher for DOACs than warfarin. A higher proportion of patients with a DOAC as an index drug switched drugs (dabigatran = 17.9%, rivaroxaban = 24.5% and apixaban = 15.6%), compared to warfarin (9.2%) [X2(3, N = 7,397) = 190.9, p < 0.001]. The overall mean PDC was 0.71±0.21, with no significant difference between patients on dabigatran, rivaroxaban and apixaban. Using an PDC cutoff point of 0.80 to indicate adherence/non-adherence, 42% of patients were categorized as adherent. CONCLUSIONS: Texas Medicaid prescription data show a gradual increase in DOAC use with a rapid increase in prescription expenditures. Further exploration of the causes of higher switch rates among DOAC initiators as compared to warfarin initiators and non-adherence to DOACs is needed to understand the challenges related to DOAC adoption in practice and to improve patient outcomes.

PCV144: UTILIZATION OF LIPID-LOWERING DRUGS IN SLOVAKIA: COMPARISON OF DATA FROM DIFFERENT SOURCES

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OBJECTIVES: Even though cardiovascular mortality decreased over the last decades, their prevalence has paradoxically increased. Therefore analyses of cardiovascular drug utilization have great importance and impact on health policies. Slovakia has reached the highest consumption of lipid-lowering drugs among all OECD countries since 2013. Defined Daily Dose (DDD) is the internationally recognized unit for reporting of drug utilization. Additionally, in Slovakia also the Standard Drug Dose (SDD) is used. In this study we analysed drug utilization data from two different sources. METHODS: We have analysed the utilization of lipid-lowering drugs in Slovakia between 2010-2015 using: 1) data provided by drug distributors to the State Institute for Drug Control (SIDC) which are...
The most common physician reported reason for treatment discontinuation was intolerance (31% and 4% from 65% to 84%). About 25% had previously received statins and/or ezetimibe. More PCSK9i users reported good medication adherence, ranging from 44% to 73%. They had a higher LDL-C level at diagnosis (196–210 mg/dL) and were more likely to have familial hypercholesterolemia (27–44%), and/or coronary heart/artery disease (32–43%). 63–73% had previously received statins and/or ezetimibe. More PCSK9i users reported good medication adherence, ranging from 65% to 84%. About 25%–49% of PCSK9i users were statin intolerant. 38–53% were on monotherapy, while 19–31% and 4–8% received concomitant statins or ezetimibe respectively, and 14–25% received statins and ezetimibe. The most common physician-reported reasons for initiating PCSK9i (related to prior regimen) were lack of efficacy.

**PCV145: ANALYSIS OF WARFARIN USAGE AND INR CONTROL IN ATRIAL FIBRILLATION: A RETROSPECTIVE STUDY**

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**OBJECTIVES:** To find the mean time in therapeutic range (TTR) of warfarin and to determine the INR control in patients with atrial fibrillation (AF) who were administered warfarin as primary anticoagulant.

**METHODS:** Retrospective Observational study: The data were analyzed using descriptive statistics in Microsoft Excel and also by utilizing the Rosendaal method of calculating TTR and CHA2DS2-VASc scoring for stroke risk analysis.

**RESULTS:** The mean age of 183 patients was 58±14 years. The male to female ratio was 0.86:1. The predominant co-morbidity was hypertension (34.43%, n=63) and anti-hypertensives were the most common concomitant medication (86.34%, n=158). The average CHA2DS2-VASc score was 2.74 ± 1.72 with a yearly stroke risk of 3.32 ± 2.71 (%). There were 29 cases of bleeding, with 5 recorded UGI bleeds, in which 17 cases were treated with Vitamin K as monotherapy. The mean TTR was concluded to be 17.37±22.67(%) using the Rosendaal method, and 17.59±20.73(%) using the traditional method. 40% patients were identified to be having a TTR of 0%. Out of 1337 hospitalized days, the INR of the patients were fou...
(72-86%) and muscle-related symptoms (myalgia/myopathy; 35-78%). **CONCLUSIONS:** PCSK9i patients were frequently from higher risk groups or were statin intolerant. Use of concomitant treatments varied. Further subgroup investigation will better characterize use of PCSK9i therapy.

**PCV147: POTENTIAL MORTALITY REDUCTION WITH OPTIMAL USAGE OF SACUBITRIL/VALSARTAN THERAPY FOR THE TREATMENT OF HEART FAILURE IN COSTA RICA**

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**OBJECTIVES:** PARADIGM-HF, a phase III trial conducted in patients with heart failure and reduced ejection fraction (HFrEF), showed that sacubitril/valsartan, a first-in-class angiotensin receptor-neprilysin inhibitor, provided incremental cardiovascular and overall survival benefit compared to enalapril. This analysis aimed to quantify the number of potential all-cause deaths that could be avoided with optimal usage of sacubitril/valsartan for the treatment of HFrEF in Costa Rica. **METHODS:** Data from Instituto Nacional de Estadística y Censos was used to identify patients with HFrEF for whom sacubitril/valsartan could be indicated. A literature review was conducted to determine the prevalence of HF, and the proportion of HFrEF patients classified as NYHA Class II-IV, in Latin America. The number needed to treat (NNT) to avoid one all-cause death, standardized to 12 months, was derived from the PARADIGM-HF trial. The potential number of all-cause deaths prevented or postponed with sacubitril/valsartan treatment was estimated using multi-way sensitivity analysis. The main outcome measure was all-cause mortality. **RESULTS:** The entire 2017 population (‡20 years) was estimated at 3,435,930 and the estimated prevalence of HF was 1.0%. Physician interviews indicated that 60% of patients with chronic HF are diagnosed, yielding approximately 20,616 patients. Half of diagnosed patients had HFrEF, 80% of whom were classified as NYHA Class II-IV, equating to 8,246 patients with HFrEF NYHA II-IV. The absolute reduction in all-cause mortality in PARADIGM-HF was 2.8% over an average follow-up of 27 months with a NNT of 80.3, standardized to 12 months. Thus, optimal usage of sacubitril/valsartan therapy was estimated to prevent 103 deaths each year. **CONCLUSIONS:** This analysis suggests that a significant number of all-cause deaths could potentially be prevented with optimal implementation of sacubitril/valsartan therapy into routine clinical practice in Costa Rica. However, one limitation of this analysis is the lack of current epidemiology data available specific to HF prevalence in Costa Rica.

**PCV148: ANTITHROMBOTIC TREATMENTS IN PATIENTS WITH ACUTE ISCHEMIC STROKE AND NON-VALVULAR ATRIAL FIBRILLATION BEFORE INTRODUCTION OF NON-VITAMIN K ANTAGONIST ORAL ANTICOAGULANTS INTO PRACTICE IN KOREA**

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**OBJECTIVES:** This multicenter observational study aimed to describe patterns of long-term antithrombotic use in acute ischemic stroke (AIS) patients with non-valvular atrial fibrillation (NVAF) in Korea and their impacts on clinical events before introduction of non-vitamin K antagonist oral anticoagulants (NOAC) into practice in 2015. **METHODS:** Patients with NVAF who were admitted due to the AIS and discharged no later than 2008 were enrolled retrospectively. Information on antithrombotic use and clinical events was collected at 11 time points during the 3 years of follow-up. The primary outcome was a composite of stroke recurrence, major bleeding, and death. Vitamin K antagonist (VKA) users were categorized into a well-controlled INR group and a poorly-controlled INR group using a median modified iTTR (47.0%). **RESULTS:** Of 1,350 patients enrolled in this study, 95% were on antithrombotic medications at discharge. The rate of VKA usage decreased over time (77% and 40% at discharge and 3 years, respectively). Among 26 identified treatment patterns, maintaining VKA-only was most common (47.5%), followed by maintaining antiplatelet-only (12.4%), VKA-only changed to antiplatelet-only (5.1%), and maintaining VKA in combination with antiplatelet (5.0%). The proportions of patients who experienced primary outcome differed by treatment patterns. Among the 10 most frequent treatment types, the highest outcome rate was observed in patients who started VKA-only therapy and discontinued it without any more antithrombotic therapy (70.2%); this was followed by those starting with antiplatelet-only therapy and stopping it without any further antithrombotic treatment (66.7%).
The 3-year cumulative primary outcome rates were higher in poorly-controlled groups than well-controlled groups (24.5% vs 15.7%; p = 0.015). CONCLUSIONS: Our study revealed that, in pre-NOAC era, there was a wide spectrum of long-term antithrombotic use in AIS patients with NVAF in Korea. The incidence of the composite outcome (stroke recurrence, major bleeding, and death) varied by patterns of antithrombotic use.

**PCV149: ANTIHYPERTENSIVE DRUG PRESCRIPTION PATTERNS AND THEIR IMPACT ON OUTCOME OF BLOOD PRESSURE IN ETHIOPIA: A HOSPITAL-BASED OBSERVATIONAL STUDY.**

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OBJECTIVES: Irrational prescription is strongly associated with poor control of hypertension. The present study aimed to evaluate antihypertensive drug prescription trends and to measure their impact on the level of blood pressure (BP) control in Gondar University Hospital, Gondar, Ethiopia. METHODS: A hospital-based retrospective cross-sectional study was conducted from May 30 to June 30, 2016. All hypertensive patients on medication were included. A structured data abstraction form was prepared to gather the necessary information. The prescription patterns and BP level were measured retrospectively. A binary logistic regression was computed to determine the effect of different prescription patterns on BP control. RESULTS: A total of 596 hypertension patients were recruited for the study; of them, 561 (94%) met the study criteria. The mean age of the respondents was 55.96±14.6 years. Females constituted 58.2% of the study population. Approximately fifty percent of the prescriptions were monotherapies. Twice-daily dosing was associated with lower risk of uncontrolled hypertension (crude odds ratio [COR] = 0.51[0.15–0.73], adjusted odds ratio [AOR] = 0.69[0.16–0.91]). Monthly appointment was linked with a nearly 90% reduced incidence of uncontrolled BP (COR = 0.15[0.04–0.73], AOR = 0.093[0.024–0.359]). CONCLUSIONS: Monotherapies were the most frequently prescribed regimens. Twice-daily dosing and monthly appointments were associated with low incidence of uncontrolled BP. Clinicians should be vigilant in adjusting the frequency of dosing and should fix appointment date in consultation with their patients.

**PCV150: POTENTIAL MORTALITY REDUCTION WITH OPTIMAL USAGE OF SACUBITRIL/VALSARTAN THERAPY FOR THE TREATMENT OF HEART FAILURE IN MEXICO**

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OBJECTIVES: PARADIGM-HF, a phase III trial conducted in patients with heart failure (HF), showed that sacubitril/valsartan, a first-in-class angiotensin receptor neprilysin inhibitor for treatment of HF with reduced ejection fraction (HFrEF), provided incremental cardiovascular and overall survival benefit compared with enalapril. This analysis aims to quantify the number of all-cause deaths that could be avoided with optimal usage of sacubitril/valsartan in the treatment of HFrEF in Mexico. METHODS: Data from INEGI Population 2010 Report and Projections was used to quantify the target population. A literature review was conducted to determine the prevalence of HF, and the proportion of HFrEF patients classified as NYHA Class II-IV, in Mexico. The number needed to treat (NNT) to avoid one death due to any cause, standardized to 12 months, was derived from the PARADIGM-HF trial. The potential number of deaths prevented or postponed with sacubitril/valsartan treatment was estimated along with multiple-way sensitivity analysis. The main outcome measure was all-cause mortality. RESULTS: The 2017 population (≥18 years) in Mexico was estimated at 82,206,974 and the estimated prevalence of HF was 2.3%. Further, the percentage of HF registered episodes in the National Health System was 41.1%, yielding approximately 765,668 patients. Half of these patients had HFrEF; 85.0% of whom were NYHA Class II-IV. This equated to 326,986 patients with HFrEF NYHA II-IV. Finally, the absolute reduction in mortality in PARADIGM-HF was 2.8% over an average follow-up time of 27 months. This translates into a NNT, standardized to 12 months, of 80.3. Thus, optimal usage of sacubitril/valsartan therapy was estimated to potentially prevent 4,072 deaths each year. CONCLUSIONS: The findings from this analysis suggest that a substantial number of all-cause deaths could potentially be prevented with optimal implementation of sacubitril/valsartan therapy. Implementation of sacubitril/valsartan into routine clinical practice is important, and may substantially improve clinical outcomes among HFrEF patients in Mexico.

**PCV151: GENERIC COMPETITION AND ITS IMPACT ON REFERENCE PRICING SYSTEM AND MEDICINES UTILIZATION IN THE GROUP OF SARTANS**

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OBJECTIVES: Analysis of the impact of new medicines inclusion in the Positive Drug List (PDL) on medicines reference prices and utilization in the group of sartans. METHODS: Retrospective, observational and statistical analysis of the inclusion of new INNs and generic products in the Bulgarian PDL during 2009-2015. The changes in reference prices that is the lowest price per DDD are calculated after every new products inclusion. Medicines utilization is measured through DDD/1000/ inh/day = ((Sales data in mg/ DDD)/(N inhabitans*365)). Statistical significance of corresponding changes is tested with t-test. Prices are collected from the official price register and sales data from drug agency. RESULTS: Two new INNs irbesartan and olmesartan were included in the PDL in 2011 and 2013 with following inclusion of 3 and 2 generic competitors. To already existing INNs 36 new generic products were added, and out of them 11 were with INN valsartan, 9 candesartan, 9 telmisartan, 2 losartan. The reference price decreases significantly for all INNs. The highest was the decrease in reference price for valsartan (from 0.4523 to 0.09464 BGN) and candesartan (from 0.6191 to 0.01567 BGN), where high number of new products was included. In contrast the utilization in DDD/1000/ inh/day increases significantly for candesartan (0.39 vs. 5.58) and telmisartan (1.81 vs. 8.18). For Losartan (7.23 vs. 4.23) and Valsartan (43.24 vs. 12.44) the utilization decreases significantly probably due to transfer to other INNs. CONCLUSIONS: Inclusion of new INNs and new generics impacted both prices and utilization of sartans. New products decrease the reference price but changes in utilization are not following the same logic. This pointed out that in general the generic and therapeutic competition improves a patients' access to treatment.

PCV152: MARKET DYNAMICS OF STATIN MEDICATIONS

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OBJECTIVES: It is not clear whether the introduction of low-cost generics have actually reduced pharmaceutical spending, especially when the definition of target population is rather vague. We sought to describe market dynamics of statins, where in-patent and off-patent drugs are mixed and whose demand is relatively elastic. METHODS: We utilized IMS Health Analytical Link databases from 2012 to 2016 in Italy, Japan, Germany, France, UK, US, Switzerland, Taiwan, Korea, and Australia. We refer to the volume (in Standard Unit, SU), price per SU, and the market share of the generics vs. originator where patents had expired in 2012 in most countries (simvastatin, atorvastatin), and have partly expired (rosuvastatin, pitavastatin). Their market expansion was measured as CAGR (compound annual growth rate) and relative market share was illustrated. RESULTS: 7 statins were observed, and 5 statins (atorvastatin, rosuvastatin, pravastatin, fluvastatin, simvastatin) were observed in all 10 countries. Generic market share was dominant in US, UK, and countries where reference pricing system has been implemented (Australia, France, Germany). The volume of statin was increased in all observed countries except US, yet the volume of atorvastatin and rosuvastatin increased in most countries whereas that of simvastatin decreased. For rosuvastatin, its patent expired in 4 countries (Korea, Taiwan, Australia, US) during the study period, and the generic replaced originator without market expansion in US and Australia, whereas market expanded dramatically without generic replacement in Korea and Taiwan. Recently launched statins (rosuvastatin & pitavastatin) are frequently priced highest, whereas mature statins (simvastatin) were tend to be priced lowest among statins. CONCLUSIONS: Statin volume has expanded, yet its expansion differ dramatically based on the price, patent status, and the country characteristics.

PCV153: POTENTIAL MORTALITY REDUCTION WITH OPTIMAL USAGE OF SACUBITRIL/VALSARTAN THERAPY FOR THE TREATMENT OF HEART FAILURE IN CHILE

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OBJECTIVES: PARADIGM-HF, a phase III trial conducted in patients with heart failure (HF), showed that sacubitril/valsartan, a first-in-class angiotensin receptor neprilysin inhibitor for treatment of HF with reduced ejection fraction (HFrEF), provided incremental cardiovascular and overall survival benefit versus enalapril. This analysis aims to quantify the potential number of all-cause deaths that could be avoided with optimal usage of sacubitril/valsartan in the treatment of HFrEF in Chile. METHODS: Data from the Instituto Nacional de Estadísticas was used to identify patients with heart failure for whom sacubitril/valsartan would be indicated, and a literature review was conducted to determine the prevalence of HF, the proportion of those NYHA Class II-IV and finally, the proportion of patients with HFrEF. The number needed to treat (NNT) to avoid one death, standardized to 12 months, was derived from the PARADIGM-HF trial. The potential number of deaths prevented or postponed as a result of sacubitril/valsartan treatment was estimated along with multi-way sensitivity analysis. The main outcome measure was all-cause mortality. RESULTS: The 2017 population (≥ 20 years) in Chile was estimated at 13,413,474 and the estimated prevalence of HF was 2%. The percentage of patients diagnosed with HF in Chile was 80%. Of these, 75% were
Patients with symptomatic peripheral artery disease (PAD) may be at increased risk for atherothrombotic events. In this study, we evaluated treatment patterns for patients at high risk for PAD and atherothrombotic cardiovascular disease (ASCVD) who were initiated on statin and/or ezetimibe therapy within 12 months before index date. Index date was defined as the date of first prescription for statin and/or ezetimibe. Patients were classified into following groups: patients with ASCVD (defined as myocardial infarction, angina, coronary revascularization, peripheral artery disease, ischemic stroke, and transient ischemic attack) and patients with hypertension, and 22.1% of patients with diabetes. The average MPR was 69.0% for statin and 61.0% for ezetimibe. During the follow-up period, 50.9% of patients with ASCVD, 51.6% of patients with hypertension, and 53.4% of patients with diabetes had a previously developed algorithm of treatment modifications. Treatment modification rate in lipid-lowering therapies and increased possible statin intolerance highlights an unmet need in the prevention and management of ASCVD.

**PCV154: ANTIHYPERTENSIVE DRUG TREATMENT PRESCRIBED FOR ESSENTIAL HYPERTENSION IN A PRIVATE HOSPITAL IN SOUTH SUMATRA, INDONESIA**

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**OBJECTIVES:** To assess antihypertensive drug treatment prescribed for essential hypertension in the Internal Medicine Polyclinic in a private hospital in South Sumatra, Indonesia. **METHODS:** This cross-sectional study included outpatients diagnosed with essential hypertension in the Internal Medicine Polyclinic in a private hospital in South Sumatra, Indonesia during the period of July 2013 until December 2015. Patients’ characteristics and antihypertensive drug treatment data were collected from the polyclinic medical records and hospital pharmacy records. Antihypertensive drug treatment was assessed based on the number of antihypertensive drugs prescribed per prescription, generic classification, antihypertensive drug classes, antihypertensive drug combinations, and the agreement with the National Formulary. **RESULTS:** A total of 345 patients with essential hypertension and 1126 prescriptions were included in this study. The average number of antihypertensive drugs per prescription was 1.03±0.18. Most (67.9%) of the antihypertensive drugs were prescribed as generics. Calcium channel blockers (74.8%) and antihypertensive agents acting on the renin-angiotensin system (20.3%) were most commonly prescribed. Many patients received combination antihypertensive drugs, with hydrochlorothiazide and captopril as the most often combination (47.5%). Only 66.5% of the drugs in the prescriptions were in agreement with the list of drugs in the National Formulary. **CONCLUSIONS:** The treatment of essential hypertension in a private hospital in South Sumatra was improving. Attention needs to be directed to comply more with the National Formulary and generic prescribing.

**PCV155: UTILIZATION PATTERNS OF LIPID-LOWERING THERAPIES IN PATIENTS AT HIGH RISK FOR OR WITH ATHEROSCLEROTIC CARDIOVASCULAR DISEASE: A POPULATION-BASED STUDY IN SOUTH KOREA**

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**OBJECTIVES:** To explore the utilization patterns of lipid-lowering therapies in patients at high risk for or with atherosclerotic cardiovascular disease (ASCVD). **METHODS:** A retrospective cohort study was conducted using the Korean Health Insurance Review & Assessment (HIRA) Service database. Patients aged ≥18 years were included if they initiated statin and/or ezetimibe between January 1, 2012 and December 31, 2014 without previous claims for statin and/or ezetimibe within 12 months before index date. Index date was defined as the date of first prescription for statin and/or ezetimibe. Patients were classified into following groups: patients with ASCVD (defined as myocardial infarction, angina, coronary revascularization, peripheral artery disease, ischemic stroke, and transient ischemic attack) and patients with hypertension or diabetes without a history of ASCVD. Patients were followed for 1 year after the index date to assess treatment patterns like discontinuation, switching, reinitiation, and augmentation. Medication adherence was measured as medication possession ratio (MPR). Possible statin intolerance was assessed based on a previously developed algorithm of treatment modifications. **RESULTS:** Among 2,600,810 patients who initiated statin and/or ezetimibe, 746,421 (28.7%) were with ASCVD, 956,356 (36.8%) were with hypertension, and 605,198 (23.3%) were with diabetes. The average MPR was 69.0% for statin and 61.0% for ezetimibe. During the follow-up period, 50.9% of patients with ASCVD, 51.6% of patients with hypertension, and 53.4% of patients with diabetes had ≥1 treatment modification including permanent discontinuation (19.4%, 21.6%, and 21.1%, respectively), reinitiation (6.1%, 6.7%, and 7.6%, respectively), switching (12.4%, 11.5%, and 12.3%, respectively), and augmentation (1.4%, 1.4%, and 1.7%, respectively). Possible statin intolerance was observed in 21.6% of patients with ASCVD, 21.1% of patients with hypertension, and 22.1% of patients with diabetes. **CONCLUSIONS:** High treatment modification rate in lipid-lowering therapies and increased possible statin intolerance highlights an unmet need in the prevention and management of ASCVD.

**PCV156: QUALITATIVE EVALUATION OF HEALTHCARE PROVIDER TRUST (AND MISTRUST) AMONG PATIENTS WITH SYMPTOMATIC PERIPHERAL ARTERY DISEASE**
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OBJECTIVES: Communication between patients and providers is required for shared decision making, and their interpersonal interaction directly impacts treatment choices. We conducted a focus group study of patients with symptomatic peripheral artery disease (PAD) to identify factors relevant for treatment decisions. This analysis specifically explores provider trust and communication as an important, process-related theme. METHODS: Patients with symptomatic PAD were recruited to participate in moderated focus groups. Focus groups lasted for approximately one hour, used a structured moderator’s guide, and were audio recorded. Verbatim transcripts were imported into a qualitative analytic software program and analyzed to identify key attributes and themes. Comments related to patient-provider interaction, communication, and trust were extracted and analyzed using thematic analysis, word frequency coding, and hierarchy charts. RESULTS: 51 participants with symptomatic PAD were recruited. Mean participant age was 66.2 ±13.9 years, 35% were women, and 43% were white. Provider trust and interaction emerged as unanticipated but important themes. Interpersonal interaction was discussed in terms of provider specialty, treatment venues, and information sharing. Provider trust was discussed in terms of need for second opinions, disclosure of treatment alternatives and risks, and access to outpatient clinic visits and specific treatments. Participants expressed positive attitudes toward involvement in shared decisions, receipt of educational information, detailed counseling, and discussion of treatment options under consideration. Negative attitudes were expressed toward treatment in the emergency room, delay of appropriate treatment, provider misinformation or withholding of information, inconsistent recommendations between providers, patient abandonment, and pain medication as a treatment. Attitudes about provider specialty, provider trust, and experienced decision roles were mixed. CONCLUSIONS: Provider trust is inconsistent among patients with symptomatic PAD and may be affected by a variety of factors, some of which are not provider-specific. Understanding barriers to patient-provider trust may identify opportunities to improve interaction, facilitating shared decision-making.

PCV157: EXAMINING HEALTH CARE UTILIZATION AND COSTS AMONG ATHEROSCLEROSIS PATIENTS IN THE US VETERAN HEALTH ADMINISTRATION POPULATION

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OBJECTIVES: To compare health care utilization (HRU) and costs between patients with and without atherosclerosis in the US veteran population. METHODS: Patients with ≥1 medical claim for atherosclerosis (International Classification of Diseases, 9th and 10th Revision, Clinical Modification [ICD-9-CM; ICD-10-CM] diagnosis codes [ICD-9-CM code 440; ICD-10-CM code I70]) were identified from 01JAN2012 through 31DEC2016 using the Veterans Health Administration datasets. The first diagnosis date was designated as the index date. Each control patient (without atherosclerosis) was matched with an atherosclerosis patient of the same age, region, gender, and index year. A random index date was chosen for the control cohort to reduce selection bias. All patients were required to have continuous health plan enrollment for 12 months pre- and post-index date. One-to-one propensity score matching (PSM) was performed to compare follow-up HRU and costs between the cohorts, adjusting for demographic characteristics and the pre-index Charlson comorbidity index (CCI) score. RESULTS: In each cohort, 65,933 patients were identified. The mean age was 72 years for controls and 71 years for cases. The mean CCI score was 3.0 for both cohorts. After applying 1:1 PSM, a total of 41,233 patients were matched from each cohort, and baseline characteristics were well-balanced. Atherosclerosis patients incurred higher HRU compared to controls, including inpatient (17.1% vs 3.3%), outpatient (99.6% vs 70.4%), and pharmacy (91.5% vs 70.9%) (all p<0.001) visits. Consistent with the trend of HRU, inpatient ($8,485 vs $1,014), outpatient ($6,156 vs $2,430), pharmacy ($998 vs $595) and total ($15,639 vs $4,040) (all p<0.001) costs were significantly higher among atherosclerosis patients compared to control patients. CONCLUSIONS: Patients diagnosed with atherosclerosis incurred significantly higher HRU and costs compared to control patients in the US veteran population.

PCV158: AN EVALUATION OF THE UTILISATION AND EXPENDITURE ON DUAL ANTIPLATELET THERAPY (DAPT) IN IRELAND

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OBJECTIVES: To investigate utilisation of dual antiplatelet therapy (DAPT) with regards treatment combinations, duration of use, co-prescribing with high-risk medicines and associated expenditure from 2012-2015. METHODS: A retrospective, cross-sectional study of DAPT using pharmacy claims database for the means tested General Medical Services (GMS) scheme from January 2012 to December 2015. The GMS scheme over-represents elderly, female
and younger aged populations. DAPT combinations were identified using ATC codes and the duration was measured in a ‘new-user’ cohort. Descriptive statistics was used to analyse data using SPSS® and Microsoft Excel®. RESULTS: A total of 19,771 individuals received DAPT over the study period, 61% male and 39% female with a median age of 74 years (IQR 66-80). Aspirin and clopidogrel was the most commonly prescribed with 15,584 (78.8%) individuals followed by aspirin and prasugrel with 1,059 (5.4%) and aspirin and ticagrelor with 947 (4.8%) individuals. Aspirin and clopidogrel remained the most commonly prescribed DAPT combination over the study period but aspirin and ticagrelor prescribing increased 100 fold over the same period. Regarding duration of use, 45.8% received treatment for 0-6 months, 21.7% for 6-12 months and 32.5% for >12 months. The mean duration was 306 days (10.2 months) [95% CI for mean 301.5-309.9]. Co-prescribing with non-steroidal anti-inflammatory drugs decreased from 10.9% to 7.3% and anticoagulants from 3.3% to 3.1% from 2012 to 2015 respectively. Total expenditure increased from €1,519,142 in 2012 to €2,022,131 in 2015. CONCLUSIONS: Despite reference pricing of clopidogrel in 2013, total expenditure on DAPT is increased over the study period due in part to an increased use of patent-protected medicines i.e. ticagrelor. The high proportion of short (0-6 months) and extended (>12 months) duration of DAPT identifies a lack of adherence to international best practice guidelines. Further analysis into the reasons for these prescribing practices in Ireland is warranted.

PCV159: CLUSTER-RANDOMIZED, CROSSOVER TRIAL OF HEAD POSITIONING IN ACUTE STROKE

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BACKGROUND The role of supine positioning after acute stroke in improving cerebral blood flow and the countervailing risk of aspiration pneumonia have led to variation in head positioning in clinical practice. METHODS: In a pragmatic, cluster-randomized, crossover trial conducted in nine countries, we assigned 11,093 patients with acute stroke (85% of the strokes were ischemic) to receive care in either a lying-flat position or a sitting-up position with the head elevated to at least 30 degrees, according to the randomization assignment of the hospital to which they were admitted; the designated position was initiated soon after hospital admission and was maintained for 24 hours. The primary outcome was degree of disability at 90 days, as assessed with the use of the modified Rankin scale (scores range from 0 to 6, with higher scores indicating greater disability and a score of 6 indicating death). RESULTS: The median interval between the onset of stroke symptoms and the initiation of the assigned position was 14 hours (interquartile range, 5 to 35). Patients in the lying-flat group were less likely than patients in the sitting-up group to maintain the position for 24 hours (87% vs. 95%, P<0.001). In a proportional-odds model, there was no significant shift in the distribution of 90-day disability outcomes on the global modified Rankin scale between patients in the lying-flat group and patients in the sitting-up group (unadjusted odds ratio for a difference in the distribution of scores on the modified Rankin scale in the lying-flat group, 1.01; 95% confidence interval, 0.92 to 1.10; P = 0.84). Mortality within 90 days was 7.3% among the patients in the lying-flat group and 7.4% among the patients in the sitting-up group (P = 0.83). CONCLUSIONS: Disability outcomes after acute stroke did not differ significantly between patients assigned to a lying-flat position for 24 hours and patients assigned to a sitting-up position with the head elevated to at least 30 degrees for 24 hours.

PCV160: PATIENT CARE PATHWAY FOR POST-STROKE SPASTICITY AND BONT MANAGEMENT IN FRENCH HOSPITALS THROUGH THE PRISM OF PMSI DATA

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OBJECTIVES: Stroke is the leading cause of spasticity in adults, with a significant impact on patients’ quality of life. This study explores the incidence of spasticity post-stroke, its management with botulinum toxin (BoNT), and describes the patient care pathway over several years. METHODS: The data were extracted from the French national PMSI (Programme Médical de Systemes d’Information) database MCO (Medecine-Chirurgie-Obstetrique) and SSR (Soins de Suite et de Readaptation) chained 2009-2014. The analysis describes the care pathway for stroke between 2009 and 2011; patients who died within 6 months of stroke were excluded. The coding of spasticity was analyzed, as were the frequency of BoNT treatments. A correlation coefficient of treatment rates was calculated by age group. RESULTS: In total over the 2009-2014 period, 271,586 stroke cases were monitored. A diagnosis of spasticity was made in the hospital in 9.1% of cases, with a median time to spasticity diagnosis of 24 days post-stroke. Among spastic patients, 18% benefited from BoNT treatment. The median time to first injection was 11 months post-stroke. The rate of treatment was different between age groups, with 31% of 40-59 year olds (+/- 1.1%) treated, compared to 11% of 70-79 year olds (+/- 0.8%). For patients with follow-up post-treatment of ≥2 years, only 9.5% were treated with ≥3 injections per year, and 29% received only one injection. For patients with ≥2 injections, the mean time between 2 injections was 198 days (standard deviation: 171 days). CONCLUSIONS: This analysis shows that only 1.8% of post-stroke patients were treated with BoNT. Given the impact of spasticity on the quality of life of patients, it
is important that additional work is performed to identify which of the patient care pathways or clinical decisions defined a patients’ care and the therapeutic interventions used.

**PCV161: THE DISEASE BURDEN OF HEART FAILURE IN PORTUGAL**

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**OBJECTIVES:** The objective of this study is to estimate the disease burden of Heart Failure (HF) in Portugal for 2014. **METHODS:** The HF burden was measured in Disability Adjusted Life Years (DALY) resulting from the sum of Years Lost due to Disability (YLD) and Years of Life Lost (YLL) due to premature death. YLL were estimated based on the mortality rates reported by the European Detailed Mortality Database. For YLD, the three disability weights (mild moderate and severe) presented by the Global Burden of Disease Study (2015) were considered. Patients in the first class of the New York Heart Association (NYHA) Functional Classification, where considered to have no disability associated to HF. The average total disease duration by age group and the overall incidence were estimated using the software DisMod II, calibrated with the prevalence of NYHA class II-IV, relative risk of mortality and a remission rate of zero. Prevalence was estimated using the microdata of a previously conducted national community-based epidemiological survey while relative risk of mortality came from the international literature. It was assumed that incidence by severity class followed the same pattern as prevalence and that duration was independent from severity. **RESULTS:** In 2014, HF incident cases in NYHA class II-IV were estimated to be 38,960 (394.74/100,000 inhabitants). The deaths for HF patients amounted to 4,688, 4.7% of overall deaths, with women being responsible for 66.7% of HF mortality. Overall, DALY totaled 21,162, with 53.8% due to YLL and 46.2% due to YLD. Women contributed to most of the overall disease burden in terms of DALY (57.0%) with YLL and YLD estimated at 6.944 and 5.118, respectively. **CONCLUSIONS:** Heart Failure is an important cause of disease burden in Portugal. Heart Failure should be an important target for health policy interventions.

**PCV162: SOCIO-ECOLOGICAL CONTEXTUAL FACTORS ASSOCIATED WITH HYPERTENSION MEDICATION AND CONTROL AMONG THE ELDERLY IN THREE MIDDLE-INCOME COUNTRIES (ALBANIA, BRAZIL, AND COLOMBIA)**

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**OBJECTIVES:** Hypertension medication and control are understudied among the elderly in middle-income countries, particularly as contextualized within social and community factors. **METHODS:** We used 2012 International Mobility in Aging Study data of community-dwelling adults 65-74 years across three study sites (Tirana, Albania n=394; Natal, Brazil n=402; Manizales, Colombia n=407; N=1,203). The study framework was the socioecological model, positing that individual-level health outcomes are influenced by interpersonal (e.g., family, friends), organizational (e.g., health system), community (e.g., neighborhood safety), and policy levels. Logistic regression models identified factors associated with uncontrolled (vs. controlled) hypertension among those with diagnosed hypertension. Of particular interest was the role of antihypertensive medication contextualized within other factors specified by the socioecological model. **RESULTS:** Among those with diagnosed hypertension, control was: Albania: 33%; Brazil: 30%; Colombia: 51%. At all sites, those not in control were less likely to have hypertension medications in their homes than those in control, but this difference only differed significantly in Brazil and Colombia. A high proportion of those not in control (>80%) had antihypertensive medications at all sites. In final models, distinct factors from the socioecological model were strongly associated with uncontrolled hypertension across sites: Perceived income insufficiency (OR:3.23,95% CI:1.79-5.82) in Tirana; hypertension medication (OR:0.38,95%CI:0.16-0.88) and religious participation (OR:0.36,95% CI:0.13-0.97) in Colombia; and hypertensive medication (OR:0.38,95% CI:0.16-0.88) and strolling shops and stores (OR:0.44,95%CI:0.21-0.94) in Brazil. No behavioral variables (e.g. smoking, exercise, alcohol) were associated with control once organizational and community factors were considered. **CONCLUSIONS:** In two of three middle-income study sites, all with low hypertension control, antihypertensive medication in the participants’ homes was significantly associated with a lower likelihood of uncontrolled hypertension. However, hypertension medication use was high across both controlled and uncontrolled hypertension. Contextualizing medication use within other socioecological factors is important to understand key predictors of hypertension control generally as well as variation across communities.
PCV163: COST-EFFECTIVENESS OF MECHANICAL THROMBECTOMY COMPARED WITH STANDARD TREATMENT IN PATIENTS WITH ACUTE ISAemic STROKE


OBJECTIVES: To determine the cost-effectiveness of mechanical thrombectomy, compared with standard treatment, from the perspective of the UK NHS and PSS. METHODS: We undertook a cost-effectiveness analysis alongside the Pragmatic Ischaemic Stroke Thrombectomy Evaluation (PISTE) trial. In addition, a decision-analytic model was developed to estimate the long-term cost-effectiveness of thrombectomy using all available trial evidence. Meta-analysis was used to estimate the clinical effectiveness; resource use and costs were sourced from the PISTE study and the broader literature. Value of implementation analysis was used to estimate the potential value of implementing this treatment into routine clinical practice within the UK NHS. As health budget responsibility is devolved within the UK, we plan to estimate the five-year budget impact of introducing mechanical thrombectomy into routine practice within the devolved NHS in Scotland. RESULTS: Compared with standard treatment, thrombectomy was not shown to be cost-effective within-trial/90-day period. However, the reverse was observed with the long-term model (ICER £3,857 per QALY gained). We estimate that 42,525 patients are potentially eligible to receive this treatment in the UK over a five year period. The net monetary benefit (health benefit in monetary terms) is £13,704 per patient. Assuming a five-year time horizon and full implementation, the value of implementation was £542 million. We estimate the “break-even” value of implementation activity point at approximately 26% implementation. CONCLUSIONS: Based on a lifetime horizon, mechanical thrombectomy is cost-effective compared with standard care. If implementation is greater than 26%, the value of implementation is greater than the cost of implementation.

PCV164: VENOUS THROMBOEMBOLISM PROPHYLAXIS: RISK ASSESSMENT COMPLIANCE WITH RESPECTED PATIENT RISK

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OBJECTIVES: VTE prophylaxis implementation remains to be a challenge at KFSH with deterrent patient risk and death. The purpose of this study is to measure the degree of physician compliance to KFSH 2013 VTE prophylaxis protocol and to identify the percentage of patients at risk of VTE. METHODS: 103 patients admitted to various medical wards were reviewed of which 69 were included in our study. Their risk was measured using the risk assessment sheet in accordance to KFSH VTE prophylaxis protocol. Physicians’ compliance was assessed on their degree of compliance to KFSH 2013 VTE prophylaxis policy. RESULTS: The overall compliance rate with 2013 VTE prophylaxis among physicians was 1.4% in the 69 hospital admissions that were reviewed. The majority of our patients 56.5% received prophylaxis but not in accordance to policy. 41.7% of our patients had highest risk of VTE (>5) according to their calculated risk. The highest risk 66.7% was observed in the Intensive Care Unit. CONCLUSIONS: There is no adherence to VTE protocol among KFSH physicians which stresses the importance of awareness of VTE implications to patient well-being across KFSH medical staff. Patient risk of VTE is high and proper implementation is a must to reduce overall risk.

PCV165: EVALUATING THE IMPACT OF PCSK9 INHIBITORS ON CARDIOVASCULAR DISEASE

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OBJECTIVES: Several outcome-based agreements (OBA) have been signed in the past years with health plans in the Unites States for the reimbursement of the PCSK9 inhibitor evolocumab. We developed a model to determine what factors may impact the outcome measured under these OBAs in patients with atherosclerotic cardiovascular disease. METHODS: A Bayesian model was built in HOPE (Health Outcomes Performance Estimator), a tool that predicts drug outcomes under different real world scenarios. Assumptions on efficacy of evolocumab versus placebo in terms of hazard ratio to time to first cardiovascular event, defined as cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization, came from a phase 3 randomised clinical trial (RCT). Two virtual cohorts of 10,000 patients: one approximating the health plan population, one with characteristics as in the RCT, were created with different distributions of baseline age, weight, smoking status, LDL and HDL cholesterol levels, type of atherosclerosis, use of cardiovascular medications, and other factors including adherence. The impact of factors on baseline risk was extracted from the literature. To account for variability in inputs, we performed 1,000 simulations of cardiovascular events in each of the virtual cohorts. RESULTS: The model
estimates provided a good fit to time to cardiovascular event reported in the RCT. The estimated event rate 6 months after drug initiation in the health plan population was predicted to be higher than in the Phase 3 trial on average, with more variability due to higher variability in drug use and population characteristics. CONCLUSIONS: We investigated how outcomes chosen to define the OBA terms on evolocumab could be affected in the population of health plan subscribers. Additional variability in population factors impacted the event rates which may in turn impact the financial results of the OBA, depending on the financial terms that were used.

PCV166: REAL-WORLD TREATMENT PATTERNS AMONG PATIENTS INITIATING ON STATINS IN ENGLAND

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OBJECTIVES: This study aimed to describe real-world patterns of statin use in England. METHODS: Patients in the Clinical Practice Research Datalink linked to Hospital Episode Statistics aged ≥18 years with a first-time statin prescription between 01/03/2008-31/03/2014, with ≥2 years of medical history and ≥12 months plus 90 days of available follow-up, were included. Treatment patterns assessed at 12 months after statin initiation included: persistence (no gap >90 days between subsequent statin prescriptions), discontinuation (absence of a prescription within 90 days following a prescription supply end), restart (subsequent statin prescription after discontinuation). Initial statin dose, upward and down-titration were also assessed. Results were stratified by history of atherosclerotic disease, familial hypercholesterolemia (FH), diabetes and chronic kidney disease (CKD). RESULTS: 128,586 incident statin users were included; 55.1% were male, mean age was 62.7 years, 55% had QRISK2≥20%. Cholesterol measurements were recorded for 80% of patients (N=104,772, mean total cholesterol: 6.3 mmol/L). A total of 81.3% (N=104,552) of patients had no history of atherosclerotic disease; 57.8% (N=74,287) had no atherosclerotic disease and no FH (with diabetes: 23.8%, with CKD: 13.7%). Most patients initiated a medium intensity statin (88.8%, N=114,217). During 12 months of follow-up, 68.8% (N=88,506) were persistent, 90.3% of those remained on the same statin intensity. Of patients with no history of atherosclerotic disease and no FH, 66.4% were persistent (N=49,306), and 25.8% (N=6434) of discontinuers, restarted. Of 24,034 patients with prior history of atherosclerotic disease, 78.2% (N=18,794) were persistent, whereas 27.3% of discontinuers restarted. CONCLUSIONS: Around two-thirds of incident statin users in this real-world study in England stayed persistent on treatment at one year after initiation, and around one-third of those who discontinued restarted. Although this was a descriptive analysis, patients treated for secondary prevention appeared more likely to persist on treatment compared to patients treated for primary prevention.

PCV167: PHARMACOLOGY FOR PERIPHERAL ARTERIAL DISEASE IN THE NETHERLANDS; PATIENT JOURNEY AND PLATELET AGGREGATION INHIBITOR PRESCRIPTION.

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OBJECTIVES: Pharmacological treatment of Peripheral Arterial Disease (PAD) comprises of antiplatelet therapy (APT), blood pressure control and cholesterol optimisation. Guidelines provide class-I recommendations on the prescription of these medications but there is little data on the actual use by PAD patients. Our study provides insights into the patient journey through primary and secondary care and the use of medication among patients with newly diagnosed PAD in the Netherlands, based on ‘real-world' information. METHODS: We conducted a retrospective cohort study among patients newly diagnosed with PAD from 2010-2014 with at least 1-year database follow-up. ‘Newly diagnosed’ was defined as no previous PAD diagnosis record in the database and no prescription of P2Y12-inhibitors or aspirin in the preceding year. Data were obtained from the PHARMO Database Network, a population-based network of electronic healthcare records from primary and secondary healthcare settings in the Netherlands. The source population for this study was defined by the combined catchment areas of the General Practitioner Database and the Outpatient Pharmacy Database and comprised 951,886 individuals. RESULTS: Between 2010-2014 3,929 newly diagnosed PAD patients were identified. Most patients (ca 90%) were diagnosed in primary care and <1% was referred to secondary care within the first 3 months climbing to 11% at the ≥12 months’ timeframe. Overall, half of the patients were prescribed APT (50%). For 1,544 (39%) aspirin with or without statins was recorded as mono-APT. From 418 patients (11%) with documented P2Y12-inhibitor prescription, 7% was as dual-APT with aspirin and 70% as aspirin and statins. The majority of patients were in primary care at the end of the study (83%). CONCLUSIONS: Although Dutch guidelines recommend APT for every PAD patient we observed that 26% of patients had no recorded APT use. This suggests that in the Netherlands daily clinical practice appears not fully congruent with guideline recommendations.
PCV168: LIPID-LOWERING TREATMENT PATTERNS AND POSSIBLE ASSOCIATED STATIN INTOLERANCE IN PATIENTS WITH CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD) OR DIABETES MELLITUS (DM) IN TAIWAN

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OBJECTIVES: To assess treatment patterns of statin and/or ezetimibe and possible statin intolerance among patients with clinical ASCVD or DM in Taiwan. METHODS: We conducted a retrospective cohort study using Taiwan’s 2005-2013 National Health Insurance Research Database (NHIRD). Patients with history of clinical ASCVD or DM (without previous clinical ASCVD) and newly initiating statin or statin plus ezetimibe during 2006 to 2012 were identified. The treatment initiation date was defined as index date. Treatment patterns (including discontinuation, re-initiation, subtraction, switching and augmentation), adherence (medication possession ratio, MPR) and persistence (gap no greater than 60 days) of statin and/or ezetimibe during 12-month post-index period were examined. Possible statin intolerance as per previously developed algorithm was estimated. All the analyses were conducted among clinical ASCVD cohort and DM cohort. RESULTS: Among patients initiating statin or statin plus ezetimibe, 11,092 patients with history of clinical ASCVD and 31,100 patients with DM but without clinical ASCVD were analyzed. The discontinuation, re-initiation and switching rates among patients with clinical ASCVD were 54.0%, 11.3% and 25.7% during the follow-up period, respectively. Among patients with DM, the rates were 57.5%, 14.2% and 28.5%. Only less than 1% patients of the overall study cohort encountered subtraction or augmentation. The MPR of statins among clinical ASCVD and DM cohort were 0.62 and 0.60, respectively. Persistence to statin treatment among ASCVD was 46.1% and among DM patients was 42.6%. Among ASCVD and DM patients possible statin intolerance was observed among 19.9% and 21.4% of patients, respectively. CONCLUSIONS: This national database analysis indicates that more than half of patients with clinical ASCVD or DM discontinued statin and/or ezetimibe within 12-month period and the adherence and persistence of statin therapy were suboptimal indicating unmet need of lipid control treatment.

PCV169: PATIENT CHARACTERISTICS AND TREATMENT PATTERNS IN CHRONIC HEART FAILURE: RESULTS FROM A MULTINATIONAL REAL-WORLD CROSS SECTIONAL SURVEY

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OBJECTIVES: To understand the patient characteristics and treatment patterns of chronic heart failure (CHF) patients in a real-world setting. METHODS: A cross-sectional survey was conducted and patient record forms were completed by 563 cardiologists for 4903 CHF patients. Treatment patterns for the following drug classes were described: angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor II blocker (ARB), beta blocker (BB), and mineralocorticoid receptor antagonist (MRA). Pooled data for 10 countries (Argentina, Brazil, China, Colombia, France, Japan, Mexico, Russia, Saudi Arabia and Turkey) is presented. RESULTS: The mean (SD) age of a CHF patient was 67.2 (12.5) years with a male predominance (57%). Mean age ranged from 58.1 (7.8) years in Saudi Arabia to 72.8 (13.3) years in Japan and male percentage from 51% (Turkey) to 69% (Saudi Arabia). Overall, 28% patients had HFrEF [LVEF<40%, inter-country range: 11% (Brazil)-57% (Turkey)], 42% had HfPEF [LVEF≥50%, 3% (Turkey)-53% (Brazil)]. The mean number of comorbidities was 3.5 (2.3); the most frequent two were hypertension (70%) and hyperlipidemia (34%). Three quarters of patients were classified as having mild symptoms (NYHA class I: 26%, NYHA II: 49%); 21% and 4% patients were NYHA III and IV, respectively. The most common treatment combination were ACEi/ARB+BB [41%, inter-country range: 25% (Russia)-53% (Saudi)], ACEi/ARB+BB+MRA [25%, 10% (Turkey)-47% (Russia)] and ACEi/ARB [16%, 4% (Saudi)-24% (Russia)] for the overall CHF population. Patients with HFREF were most frequently prescribed ACEi/ARB+BB+MRA [40%, 8% (Turkey)-68% (Argentina)] followed by ACEi/ARB+BB [31%, 13% (Russia)-50% (Turkey)] and ACEi/ARB [10%, 1% (Argentina)-24% (Russia)]. Whereas, the most common treatment combination for HFPEF patients was ACEi/ARB+BB [48%, 37% (Japan)-68% (Saudi)] followed by ACEi/ARB+BB+MRA [18%, 7% (Colombia)-41% (Russia)] and ACEi/ARB [18%, 9% (Saudi)-31% (Brazil)]. CONCLUSIONS: The two most frequent treatment combinations were ACEi/ARB+BB with or without MRA and the distribution across countries was heterogeneous.

GASTROINTESTINAL DISORDERS - Clinical Outcomes Studies
PGI1: ANGIOTENSIN II RECEPTOR BLOCKERS AND INTESTINAL MALABSORPTION: AN OBSERVATIONAL COHORT STUDY IN GERMANY AND ITALY

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OBJECTIVES: Treatment with the angiotensin II receptor blocker (ARB) olmesartan has been associated with sprue-like enteropathy (SLE), a gastrointestinal condition characterized by intestinal malabsorption (IM) and severe diarrhea. Although this phenomenon is not frequent, it is important to raise clinical awareness in order to avoid delay in taking proper actions. Whether the increased risk of SLE is substance specific or a class effect involving all ARBs is uncertain. This study aims to assess the risk of severe enteropathy associated with ARBs treatment in two European countries (Italy and Germany) using data from large administrative and claim databases. METHODS: We obtained data from five Italian Local Healthcare Units and a large German claim database and included patients treated with olmesartan, other ARBs and ACE inhibitors (ACE-i). In the absence of a specific diagnosis code for SLE, ICD codes for unspecified IM, coeliac disease and syndromes of malabsorption were used. Analysis implemented a Poisson regression with robust error variance procedure. RESULTS: Patients were divided into three groups: olmesartan (25.591, 5.5%), other ARBs (104.901, 22.5%) and ACE-i patients (334.951, 72.0%). Baseline characteristics were similar overall. The incidence of unspecified IM in ACE-i patients was different compared to the olmesartan group. In fully adjusted analysis, a higher rate ratio was observed when comparing ARBs patients with the olmesartan group (RR: 2.50, 95% CI 1.21 to 5.19, p 0.01). When ICD codes for coeliac disease were included, no differences were observed. CONCLUSIONS: In a large cohort of Italian and German patients, we found that SLE was more common in the group of ARBs patients and we could not confirm previous findings of a higher risk of SLE in olmesartan-only patients. This study suggests that drug-induced SLE should be considered the result of exposure to the class of ARBs rather than a specific drug-related effect.

PGI2: RISK OF COMPLICATIONS WITH MINIMALLY INVASIVE SURGERY IN LIVER RESECTION

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OBJECTIVES: The advantage of minimally invasive surgery (MIS) in reducing the incidence of complications has been widely recognized. The objective of this study was to assess the risk of complications with MIS in comparison with open procedures in liver resection using a real-world data set. METHODS: The study was conducted using the Premier Perspective® Database that contains a nationally representative sample of discharges from over 600 hospitals in the U.S. Included patients were \textsuperscript{3}18 years of age and had a liver resection from October 2015 to December 2016, when ICD-10 procedure codes were available for direct identification of MIS. All complications were reviewed, and those with highest frequencies were examined. To determine the association of MIS with complications, multivariable logistic regression models were built with a broad range of predictor variables, including surgical approach (MIS vs Open), demographics, procedure and hospital characteristics. RESULTS: A total of 1,097 patients underwent liver resection, 22.6% (N=248) received MIS and 77.4% (N=849) received traditional open surgery. Compared to Open patients, MIS patients had higher a proportion of female patients (58.1% vs. 48.3%) and lower proportion of patients with a cancer diagnosis (48.4% vs 67.4%). Bleeding was the most frequent complication with an incidence of 16.6%, followed by respiratory failure (10.4%), intestinal obstruction (5.7%), and pleural effusion (4.6%). In the logistic regression model, MIS patients were less likely to have bleeding events with odds ratios (OR) of 0.342 (95% confidence interval: 0.196-0.598, p=0.0002) compared to the Open group. Similar trends for other complications were observed. The odds ratios (95% CI, p value) for respiratory failure, intestinal obstruction, and pleural effusion were 0.178 (0.074-0.429, p =0.001), 0.309 (0.118-0.813, p=0.0173), and 0.236 (0.063-0.889, p=0.0328), respectively. CONCLUSIONS: This study suggests that MIS is associated with significantly lower risk of major complications in liver resection.

PGI3: LOSS OF RESPONSE OF ANTI TNF-Α AGENTS AS THE SECOND-LINE THERAPY IN INFLAMMATORY BOWEL DISEASE: BASED ON KOREAN NATIONAL INSURANCE CLAIMS DATA

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OBJECTIVES: Anti TNF-α agents (infliximab, adalimumab) are indicated for the second-line therapy in patients with inflammatory bowel disease (IBD). They are expected to achieve a sufficient treatment goal for IBD. However, we are not sure their clinical outcomes due to lack of evidences in Korean populations. This study aims to investigate treatment outcome such as loss of response (LOR) of anti TNF-α agents in real world settings. METHODS: In this retrospective, population-based observational study, 5-year National Health Insurance claim data from 2010 to 2014
were used. Patients with ulcerative colitis (UC) and Crohn’s disease (CD) (ICD 10 codes K51 or K50) who were newly diagnosed and recorded anti TNF-α agent prescriptions during the study period were enrolled. Index date was defined as the first prescription day of anti TNF-α agents during 2010 to 2012. Subjects were follow-up for their clinical outcomes till end of the study period. LOR of anti TNF-α agent was defined as follows: increasing dose or shortening dose interval, switching to other anti TNF-α agent, discontinuation for at least 1 year, IBD-related operation, or administration of total parenteral nutrition. All data were analyzed using SAS software version 9.3. RESULTS: During the overall study period (2010 to 2014), infliximab was more frequently used than adalimumab for UC and CD (85% and 81%). The numbers of anti TNF-α users during 2010 to 2012 were 807 and 2,119 patients for UC and CD, respectively. LOR was developed in 72.6% and 80.4% among anti TNF-α users with UC and CD during the study period. More than 60% of LOR was developed within the first year from index date. Among LOR criteria, anti-TNF-α discontinuation was top ranked in both UC and CD. CONCLUSIONS: High LOR rate of anti TNF-α agents in IBD requires further treatment strategies in patients developed LOR to anti TNF-α agents.

PGI4: INCIDENCE OF SURGERY FOR INFLAMMATORY BOWEL DISEASE WITHIN 12 MONTHS OF INITIATION OF VEDOLIZUMAB OR INFlixIMAB

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OBJECTIVES: To compare the incidence of inflammatory bowel disease (IBD)-related surgeries in patients with moderate-to-severe Crohn’s disease (CD) and ulcerative colitis (UC), respectively, following initiation of biologic therapy with vedolizumab (VDZ) versus infliximab (IFX). METHODS: All biologic-naïve adults with IBD who initiated VDZ or IFX therapy between 01/05/2014 and 22/02/2017 were identified in the US Explorys Universe database. The date of the earliest infusion was deemed the index date, and we selected those who: (1) transitioned to maintenance therapy (i.e., >3 infusions ≤98 days of index date); and (2) had medical history spanning ≥365 days before (“pre-index”) their index date. Patients were propensity matched (1 VDZ:3 IFX). We ascertained incidence rates per person-year (PY) of IBD-related surgeries during follow-up: incidence rate ratios (IRRs) (VDZ rate/IFX rate) were estimated using generalized estimating equation (GEE) models with negative binomial distribution. RESULTS: 105 VDZ initiators were matched to 315 IFX initiators; median time from diagnosis to index date was 2.4 years and 1.9 years, respectively. The incidence of surgery (patients who underwent surgery/PY at risk) was 0.023 (4/175.6) for VDZ initiators vs. 0.043 (24/563.7) for IFX initiators; among CD patients, rates were 0.028 (3/106.8) vs. 0.052 (18/344.9); and among UC patients, 0.015 (1/68.8) vs. 0.027 (6/218.7). Colectomy was the most common surgery in both groups. The adjusted IRR (95% confidence intervals) among all IBD patients was 0.36 (0.14-0.93) (p=0.03); for CD patients it was 0.31 (0.04-2.80) (p=0.29); and for UC patients it was 0.37 (0.15-0.92) (p=0.03). CONCLUSIONS: In clinical practice, rates of IBD-related surgeries tend to be lower among biologic-naïve patients who initiate VDZ versus IFX; surgeries were significantly lower among UC patients and the overall IBD cohort. Further studies are needed to better understand surgical outcomes of initiating biologic therapy with VDZ versus IFX in IBD.

PGI5: THE INCIDENCE OF LIVER COMPLICATIONS IN ISRAEL

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OBJECTIVES: To assess the incidence of liver complications in a large, nationally representative health fund in Israel. METHODS: The study utilized the computerized database of Maccabi healthcare services (payer-provider). All members without cirrhosis or cancer on January 1st 2000 (index date) were followed until death, disenrollment or January 2017. Incident cirrhosis, liver transplant and liver cancer were detected by documented diagnoses, procedures, and the national cancer registry. RESULTS: The cohort included 1,129,969 subjects with a mean follow-up time of 15.15 years (SD=4.17). The overall incidence rate of diagnosed cirrhosis was 1.85 per 10,000 person year (PY), ranging between 0.29 under the age 40 till 6.87 over age 60. The incidence of liver cancer was 0.75 per 10,000 PY, ranging between 0.07 and 3.62 for age<40 and >60 respectively. The incidence of liver transplant was 0.12 per 10,000 PY. After excluding patients with viral hepatitis or significant alcohol consumption (4.1%), the incidence reduced to 1.05 for cirrhosis, 0.58 for liver cancer and 0.05 for liver transplant. The incidence of all liver complications was significantly associated with BMI; with cirrhosis reaching a peak incidence of 6.69 for BMI of 35 or above, vs. 4.49 for BMI 30-34 or 3.53 for BMI 25-29, among patients aged 60+. The observed mean survival times from cirrhosis till liver cancer or transplant were 15.4 and 16.1 years respectively in the overall population, as compared with 16.3 and 16.7 years after excluding patients with viral hepatitis or alcohol-abuse. CONCLUSIONS: This population-based study demonstrates the burden of liver complications even in patients without viral hepatitis or alcohol disorders, likely caused by non-alcoholic fatty liver disease. Older patients with increased BMI had higher rates of cirrhosis. The next
Spain, Nuñez J

PGI8: is superior to other treatments in preventing CDI recurrence, and through reductions in recurrence, payers can expect efficiency upon introduction of fidaxomicin. The magnitude of cost savings varied, directionality remained consistent, indicating improved effectiveness and economic efficiency upon introduction of fidaxomicin. The results of this model demonstrate that fidaxomicin is superior to other treatments in preventing CDI recurrence, and through reductions in recurrence, payers can expect moderate cost savings over a 6-month time horizon.

PGI6: CLINICAL CHARACTERISTICS OF PATIENTS WITH CHRONIC HEPATITIS C INFECTION AT INITIAL PRESENTATION TO TERTIARY CARE IN AN ASIAN MIDDLE-INCOME COUNTRY

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OBJECTIVES: Chronic hepatitis C virus (HCV) infection is often asymptomatic until the occurrence of severe liver disease such as liver cirrhosis and liver cancer. These HCV-related clinical sequelae can cause significant clinical and financial implication. This study aims to describe the clinical characteristics of HCV-infected patients during initial presentation to tertiary care in Malaysia, a middle-income Asian country, to inform the development of a national guideline. METHODS: A descriptive cross-sectional study of a hospital-based case-series on consecutive HCV patients who presented in 2014 at the national referral centre was conducted. All patients with active viremia (detectable HCV RNA) during initial presentation were included. RESULTS: There were 741 HCV patients treated by the hepatology specialty in 2014 (n=741/5865). Mean age at initial presentation was 48 years (SD=11.5; median=49) with 541 (73%) being male. Prior known exposure to various HCV risk factors included: intravenous drug use (n=271/737), blood or blood products transfusion (n=237/737), multiple sexual partners (n=123/737), high-risk practices such as tattooing, cupping therapy, acupuncture and sharing of personal items with infected individuals (n=68/737), dialysis (n=38/737) and organ transplantation (n=13/737). Based on histology, fibroscan findings or aspartate aminotransferase-to-platelet ratio index (APRI), 327 (44.1%) patients had cirrhosis at initial presentation, with mean age 52 years (SD=8.86) compared to 44 years (SD=12.0) for non-cirrhotic patients. Decompensated cirrhosis was seen in 118 (36%) and HCC in 45 (13%) of the 327 cirrhotic patients. Only 262 (44%) of 595 patients who were clinically eligible for interferon-based therapy (patients with no cirrhosis or with compensated cirrhosis) received interferon-based HCV treatment. CONCLUSIONS: HCV-infected patients at initial presentation to tertiary care in Malaysia reflected delayed presentation to clinical care with disproportionately high number of cirrhotic patients. The low proportion of clinically eligible patients receiving HCV treatment need to be investigated further and addressed accordingly in future guidelines.

GASTROINTESTINAL DISORDERS - Cost Studies

PGI7: A BUDGET IMPACT ANALYSIS OF FIDAXOMICIN VERSUS VANCOMYCIN AND METRONIDAZOLE FOR THE TREATMENT OF CLOSTRIDIUM DIFFICILE

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OBJECTIVES: To estimate the health outcomes and financial impact to a private healthcare payer of treatments for mild/moderate and severe clostridium difficile infection (CDI) acquired from the hospital or community setting. METHODS: We developed a budget impact model from the U.S. payer perspective, which followed patients over a 6-month time horizon beginning with an initial CDI episode for up to two additional recurrent episodes. In severe CDI episodes, we model two index inpatient treatments – vancomycin and fidaxomicin; however, for mild/moderate cases, we added metronidazole to the treatment choices. The model explicitly incorporates drugs costs, hospital costs attributable to CDI, and costs associated with outpatient follow-up or prescription medications acquired in the community setting. Clinical outcomes are measured as the number/rates of clinical cures and recurrences. RESULTS: The base case model assumed a hypothetical private health plan with one million covered lives, 75% of which are below the age of 65, and indicated that use of fidaxomicin led to a lower incidence of CDI recurrence, with 174 fewer first recurrences and 66 fewer second recurrences. Total plan costs for the treatment of CDI were just under $34 million before introduction of fidaxomicin, and just under $33 million after its introduction, a savings of 3.16%. Total savings per-member per-month were $0.09. We conducted a series of one-way sensitivity analyses to test the impact of key assumptions on plan savings after introduction of fidaxomicin, and while the magnitude of cost savings varied, directionality remained consistent, indicating improved effectiveness and economic efficiency upon introduction of fidaxomicin. CONCLUSIONS: The results of this model demonstrate that fidaxomicin is superior to other treatments in preventing CDI recurrence, and through reductions in recurrence, payers can expect moderate cost savings over a 6-month time horizon.

PGI8: BUDGETARY IMPACT ANALYSIS OF THE NUTRITIONAL HOME CARE SERVICE

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OBJECTIVES: The aim of the study was to analyze the SNS budget impact of domiciliary administration of parenteral nutrition. METHODS: A retrospective digestive surgery patient cohort was analyzed. The variable costs associated with all reported cases that required parenteral nutrition have been extracted to estimate the hospital stay cost per patient. The group of patients susceptible to receiving the Nutritional Home Care Service (NHCS) has been estimated through a comparison of the hospital stay of patients who required parenteral nutrition versus the average hospitalization days of each Diagnostic Related Group (DRG) published by the Spanish National Health System (SNS). The budgetary impact of incorporating the nutritional assistance service outside the hospital setting has been estimated by calculating the daily cost and hospitalization days in which the patient could have received domiciliary parenteral nutrition care. The budgetary impact of the SNS has been estimated using a Markov model processed in 15,000 Monte Carlo simulations for the whole Spanish population, through the probability distributions of the variables: variable cost of the PN and Cost of stay, patients receiving PN, patients likely to receive NHCS (study population) and number of surgical procedures performed in the SNS in digestive surgery. RESULTS: The initial cohort was composed of 504 patients who required an average 10.26 days of hospitalization with parenteral nutrition consumption in 2015. The study population was estimated at around 120 patients. The health insurers that finance private health care would see savings in the private sector of 36,535.30€. In the National Health System, the budgetary impact would be estimated at a saving of 1,834,965.31 €. CONCLUSIONS: The Nutritional Home Care Service would reduce healthcare expenditure and lengthy hospital stays.

PGI9: BUDGET-IMPACT-ANALYSIS OF IRON TREATMENT USING INTRAVENOUS FERRIC CARBOXYMALTOSE IN PATIENTS WITH IRON DEFICIENCY ANEMIA IN AUSTRIA

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OBJECTIVES: Iron deficiency (ID) appears in 60-80% of patients with inflammatory bowel disease (IBD), out of which about one-third is affected by anemia. Anemia which depicts a frequent extra-intestinal manifestation of IBD has a significant impact on quality-of-life components such as emotional, physical and cognitive functions, the ability to work, hospitalization, as well as healthcare costs. Thus, the objective of this analysis is the evaluation of the cost saving potential through an increased use of intravenous iron therapy with ferric carboxymaltose (FCM) based on clinical trial evidence. METHODS: A budget-impact-analysis (BIA) with a four-year’s time horizon was developed from the payer’s perspective. IBD patients with IDA run into a Markov-model and receive different iron-deficiency strategies (FCM, Iron-Sucrose (IS), oral or no-treatment) according to current clinical practice. The model includes 6 states (treatment success, recurrent anemia, hospitalization, disease worsening and death) based on RCT-data of FERGIfcor and FERGIfmain. The objective of the model was to assess the influence of a higher percentage of treated patients (65%-74%) in general and an increased share of IV substances (49%-59%) on health-care budgets from the payers perspective. Input-data were derived via a systematic literature review. Direct costs were retrieved from published sources and were expressed in 2016€. RESULTS: The result of the BIA shows that an increased use of IV-therapy (+9%) and a shift towards IV-application (+10%) in IBD patients with IDA leads to a positive budget impact from the second year onwards (-44,075€ in the 3rd year). The additionally treated patients (+713) causes increased costs for iron medication and outpatient services (+51,175€ 1st year to +208,221€ in the 3rd year). Saving effects are achieved due to reduced hospital stays (-40,679€ in the 1st year to -252,296€ in the 3rd year). CONCLUSIONS: IV iron therapy with FCM in IDA patients are associated with cost-savings by reduced hospitalisations.

PGI11: ANALYZING THE TREATMENT COST OF LIVER CIRRHOSIS FROM HEALTHCARE PAYER’S PERSPECTIVE OF VIETNAM IN 2015

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OBJECTIVES: Cirrhosis is one of the leading causes of death worldwide and also a substantial economic burden for patient, healthcare system and society. However, researches concentrating on the cost of cirrhosis treatment in Vietnam are still limited. Therefore, the aim of this study was to estimate the inpatient treatment costs of liver cirrhosis and influencing factors on costs in Vietnam in 2015. METHODS: Descriptive cross-sectional study has been conducted based on retrospective data of all cirrhosis patient’s records in 2015 from two hospitals (HCMC Tropical Hospital and Bach Mai Hospital), satisfied inclusion and exclusion criteria. Descriptive and analytic statistics were performed with relevant statistical test (T-test, one-way ANOVA, correlation) and 95% confidence level. RESULTS: Study sample included 313 cirrhosis patients with average age of 56.86 ± 13.09 years, male: female ratio – 2.13:1; 72.5% decompensated cirrhosis and 27.5% compensated cirrhosis; 79.6% of patients with cirrhosis due to hepatitis and 11.2% of patients with alcoholic cirrhosis; average number of days in hospital of 8.29 ±
6.19 days. The median cost of treatment per session is 7,439,527.40 ± 5,251,403.97 VND; in the structure of total cost, 68.25% was covered by health insurance and 31.75% - by patients. In structure of treatment cost, drugs cost accounted for the highest proportion with 44.52%; the lower is the clinical test cost with 21.67% (3,376,153.70 and 1,643,644.83 VND respectively). The influential factors on costs of treatment included the place of residence, the number of days in hospital, the stage and the complications of cirrhosis. **CONCLUSIONS:** With the rising trend of liver cirrhosis in Vietnam and the high cost of treatment, national health policies and medical programs should be considered.

**PGI12:** EVALUATING COST OF REGIMENS IN HEPATITIS C TREATMENT FROM HEALTHCARE PAYER VIETNAM’S PERSPECTIVE

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**OBJECTIVES:** Chronic hepatitis C (CHC) is a global health problem with 130-150 million people infected worldwide. With chronic infectious characteristics and severe consequences such as cirrhosis and liver cancer, HCV causes high economic and disease burden for both society and healthcare system. This study aimed to estimate the direct treatment cost of CHC, genotype 1 in the Vietnam with different treatment regimens. **METHODS:** Decision-tree models were built to estimate the direct medical costs of CHC for the whole treatment course of different regimens with the real-world data in 2 specialized hospitals in Vietnam (Hospital of Tropical diseases in HCMC and Hanoi). Treatment costs include drug costs, healthcare service costs (including 5 components by circular of 37/MOH-VN). The treatment regimens included in the analysis were Peg-Interferon/Ribavirin (Peg-INF/RBV), sofosbuvir/ledipasvir (SOF/LDV). **RESULTS:** Based on decision-tree models, simulating the treatment process with different regimen for CHC patients, genotype 1, it has been shown that medical direct cost was higher in peg-INF/RBV regimen, which was 2.85 times than SOF/LDV regimen (141.46 VND million vs 49.58 VND million, respectively). In the structure of medical direct cost, the drug cost had predominated. **CONCLUSIONS:** Peg-INF/RBV regimen was costly than SOL/LDV regimen despite of the higher price of SOL/LDV compared to Peg-INF/RBV. The drug cost was the majority part of total medical direct cost. With the rising trend of hepatitis C chronic in Vietnam and the high cost burden of treatment, healthcare policies and national medical programs should be considered.

**PGI13:** COST OF TREATMENT FOR CHRONIC HEPATITIS C INFECTION AT A NATIONAL TERTIARY-CARE REFERRAL CENTRE IN AN ASIAN MIDDLE-INCOME COUNTRY

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**OBJECTIVES:** Disease burden due to chronic hepatitis C virus(HCV) infection is expected to increase in the coming decades in countries without comprehensive national treatment strategies with direct acting antivirals(DAA). Severe clinical sequelae of HCV, which includes end stage liver disease and liver cancer, will cause substantial financial implication. This study aims to estimate the healthcare cost of managing HCV at a tertiary-care referral centre in Malaysia, as an example of a middle-income country that has not yet adopted DAA drugs as standard HCV treatment. **METHODS:** A costing analysis was conducted from the healthcare provider perspective. Annual resource use of standard interferon-based HCV treatment pathways was obtained by face-to-face interviews of local clinical experts(n=4). Unit costs specific to the referral centre(price year 2014) were derived by combining top down and bottom up activity-based costing methods. Costs were reported in US dollars(USD). **RESULTS:** Estimated first year costs of managing non-cirrhotic chronic infection(NCCI), compensated cirrhosis(CC), decompensated cirrhosis(DC) and hepatocellular carcinoma(HCC) were USD7080, USD7295, USD7503 and USD7713 respectively which include interferon cost for NCCI and CC. Costs for subsequent years for NCCI and CC were USD243 and USD410 while costs for DC and HCC remain the same annually. Cost drivers for NCCI and CC was the cost of interferon(73% and 70%) in the first year, for DC was symptomatic clinical management of liver disease(47%) and for HCC was clinical management of cancer(33%). **CONCLUSIONS:** The estimated annual healthcare costs increased corresponding to the severity of HCV-related liver disease. Current interferon-based treatment may lead to substantial downstream implications due to the low clinical effectiveness and limited patient eligibility for treatment. Adoption of DAA as standard treatment may require substantial upfront investment but it can potentially reduce HCV-related clinical morbidity and mortality and lower the national clinical and economic burden of HCV infection.

**PGI14:** ECONOMIC AND CLINICAL IMPACT OF SERUM-DERIVED BOVINE IMMUNOGLOBULIN / PROTEIN ISOLATE (SBI) IN THE MANAGEMENT OF CHRONIC DIARRHEA IN INFLAMMATORY BOWEL DISEASE (IBD)

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OBJECTIVES: This study sought to evaluate the real-world economic and clinical impact of EnteraGam®—a medical food containing serum-derived bovine immunoglobulin/protein-isolate (SBI) for the management of chronic diarrhea. METHODS: Medical records were reviewed across nine US gastroenterology practices for patients diagnosed with either ulcerative colitis (UC) or Crohn’s disease (CD). Patients included in the study had at least six months’ treatment for IBD prior to a minimum of six months’ continuous SBI use. Patients were excluded if they were involved with an interventional clinical trial during the study period, had a history of malignant disease of the gastrointestinal tract, or were suspected of therapy non-compliance. Information abstracted from medical records included all IBD-relevant prescription medications, tests, procedures, adverse events and healthcare contacts. Resource utilization was compared prior-to and during SBI use. Patients’ costs were fit to a log-normal distribution to calculate expected values (means). Medication classes were evaluated for utilization differences between periods. Budget impact was extrapolated to a hypothetical plan with 1M covered lives. RESULTS: 32 of 170 potential subjects met eligibility criteria. Primary reason for exclusion was a lack of sufficient treatment time prior to SBI initiation and/or less than six months’ SBI use. Mean overall daily cost for IBD patients during SBI use was €110.46 versus €112.63 prior. Prescription medication costs were lower with SBI use ($98.55) compared to prior ($103.61). Medication class analysis showed reduced dosage ratios in several prominent classes. Budget impact analysis revealed annual net savings of €4,582,849 with SBI use for a plan with 1M lives. CONCLUSIONS: This retrospective real-world study suggests that inclusion of SBI for the management of chronic diarrhea in IBD can offer clinical benefits while also lowering the overall cost of treatment. Reduction in utilization of some notable medication classes can contribute to net savings.

PGI15: CROHN’S DISEASE IN GERMANY: A CLAIMS DATA ANALYSIS OF THERAPIES WITH BIOLOGICAL AGENTS

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OBJECTIVES: Crohn’s disease (CD) is a chronic inflammatory disease that is not curable at the moment. This study provides information on the current supply with biological agents and its related costs in Germany. METHODS: A retrospective claims data analysis was conducted utilizing the Institute for Applied Health Research (InGef) Berlin, formerly HRI Health Risk Institute, database including approximately 6.7 million insured anonymities originating from 63 statutory health insurances in Germany. Analyses were performed by the InGef institute. A sample with approximately 4 million insured persons was drawn and stratified by age and gender according to the official demographic structure of the German statutory health insured population (DeStatis, Dec 31st, 2013). Patient data from 2012 - 2016 were included if they met the following conditions: Main diagnosis of CD (ICD-10 code K50.-), and start / maintenance / switch of treatment with CD approved biological agent(s) (at least for three months). The study evaluated hospital admission, change in medication and direct medical costs (drug, outpatient care, hospitalization). RESULTS: Leading biological agents for 1st line treatment of CD are adalimumab and infliximab, however, at a low level of share of prescriptions. Both agents are administered mostly to patients already on treatment (in 2015 adalimumab 57.6 % vs. infliximab 39.9 %). The total costs of the included 1’721 patients add up to € 38’572’694 in 2015. The number of patients, number of hospital admissions and total treatment costs including all individual cost items (costs of biological agents / other medication / outpatient care / hospitalizations) grew yearly on average between 5.0 % and 21.8 % (2012 – 2015). CONCLUSIONS: Adalimumab and infliximab are those biological agents mainly used for treating MC. All cost items grew steadily over the last 4 years. Total costs in 2015 were € 38.6 million (on average € 22’413 per patient).

PGI16: ECONOMIC EVALUATION OF USING A COMBINATION OF HELICOBACTER PYLORI ANTIBODY AND SERUM PEPSSINOGEN LEVELS FOR GASTRIC CANCER-RISK SCREENING IN JAPAN

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OBJECTIVES: Helicobacter pylori infection and the degree of chronic atrophic gastritis are significant predictors for the development of gastric cancer, especially in the Japanese population. A combination of assays for serum anti-
Helicobacter pylori immunoglobulin G antibody (HPA) and serum pepsinogen (PG) levels can be used to identify gastric cancer risk. In Japan, this ABC method may be an effective approach for identifying high-risk individuals who should undergo gastric cancer screening. The present study's purpose was to estimate the long-term cost-effectiveness of the ABC method for assessing the gastric cancer risk in a Japanese population. METHODS: We constructed a Markov cohort model to compare the lifetime expected cost of and life-years saved by two strategies: 1) the ABC method, using a combination of HPA and serum PG levels for cancer-risk screening, and 2) scheduled endoscopy, the strategy of conducting endoscopic surveillance yearly for everyone. The target population was 40 to 60-year-old Japanese individuals, who had not received H. pylori eradication therapy. Clinical and epidemiological data, including the model, were obtained from published literature. Analyses were conducted from the Japanese health care payer perspective. RESULTS: According to cohort simulation, the ABC method cost less than annual endoscopic screening (128,970 vs. 276,561 Japanese yen) and saved more lives (25.55 vs. 25.50 life years) in Japanese individuals aged 40 years. The results of individuals aged 50 and 60 years indicated prolonged life-years and a reduced cost. CONCLUSIONS: A combination of HPA and serum PG assays plus scheduling endoscopy accordingly is a cost-effective strategy of screening for gastric cancer risk in Japan. The present study's result provides new evidence of the economic impact of H. pylori eradication and scheduled endoscopy on gastric cancer screening.

PGI17: THE COST-EFFECTIVENESS OF USTEKINUMAB IN MODERATE TO SEVERELY ACTIVE CROHN'S DISEASE IN SWEDEN

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OBJECTIVES: Human monoclonal antibody ustekinumab is a novel Crohn’s disease (CD) treatment option which blocks pro-inflammatory cytokines interleukins (IL)-12 and IL-23. The aim was to assess the cost-effectiveness of ustekinumab in moderate to severely active CD in Sweden. METHODS: A cost-effectiveness model with a decision tree structure for the induction phase and a Markov cohort structure for the maintenance phase was constructed. CD was represented by five health-states: remission, mild, moderate-severe, surgery and death. Ustekinumab was compared to adalimumab in a conventional-care-failure population and to vedolizumab in patients previously failing TNF-alpha-inhibitor treatment. Discontinuation probabilities, utilities and ustekinumab induction efficacy were sourced from phase III clinical trials. Maintenance and comparator efficacy came from a network meta-analysis and a treatment sequence analysis. Resource use and cost data were derived from the literature and validated by clinical experts. The analysis had a societal perspective, a life-time time-horizon, and a 2-year maximum treatment duration. The robustness of the results was tested in univariate and probabilistic sensitivity analyses (PSA). The cost-effectiveness was estimated using quality-adjusted life-years (QALYs). RESULTS: Ustekinumab dominated adalimumab in the conventional-care-failure population. The total cost was €6,984 lower for ustekinumab compared to adalimumab and the incremental QALY gain was 0.232. In the TNF-alpha-inhibitor-failure population, ustekinumab’s incremental QALY gain versus vedolizumab was 0.133, at an incremental cost of €4,023, yielding an incremental cost-effectiveness ratio (ICER) of €30,282. Results were sensitive to excluding indirect costs and to increasing the treatment duration. An increased treatment duration improved cost-effectiveness versus adalimumab but increased the ICER versus vedolizumab. PSA showed that at a Swedish reference willingness to pay of €63,000 (SEK 600,000), ustekinumab had 94% probability of being cost-effective versus adalimumab, and 72% versus vedolizumab. CONCLUSIONS: The results indicate that ustekinumab dominates adalimumab in the conventional-care-failure population, and is cost-effective versus vedolizumab in the TNF-alpha-inhibitor-failure population.

PGI18: WOULD A TWO-DOSE ROTAVIRUS VACCINE IMPROVE HEALTH OUTCOMES WHILE REDUCING COSTS IN THE SULTANATE OF OMAN?

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OBJECTIVES: Rotavirus is the most common cause of diarrhoea in young children. A recent study in Oman showed no significant disease reductions despite improved healthcare facilities and infection control measures. This study evaluated whether a paediatric vaccination programme with a two-dose Human Rotavirus Vaccine (HRV) would be cost-effective in Oman. METHODS: A previously published Markov cohort model, with monthly cycles, was used to follow-up the 2015 Oman birth cohort to the age of 80. Local epidemiology and cost data were obtained from published sources and acute rotavirus events were measured up to the age of 5. Publicly available two-dose vaccine tender price for the Gulf Cooperation Council states was used. The analysis was made from a healthcare payer and societal perspective with costs and benefits discounted at 3% per year. RESULTS: Without vaccination the Oman birth cohort would be exposed to an estimated 36,442 severe rotavirus diarrhoea events by the age of 5 years. Total disease cost was estimated to be 2,971,994 OMR, of which direct medical costs account for 1,947,331 OMR (65%)
and indirect costs for 1,024,263 OMR (35%). Vaccinating with a two-dose HRV would reduce the number of rotavirus-related hospitalizations by 92% (from 5,637 to 478) and medical visits by 77% (from 23,889 to 5,377). Total cost of the disease, including vaccine cost, would be reduced to 1,446,859 OMR (51%), of which 1,127,997 OMR (78%) are direct medical costs and 318,862 OMR (22%) indirect costs. The vaccination is estimated to result in 286 QALYs gained. The analysis showed HRV is cost-saving from the healthcare payer and societal perspective respectively. CONCLUSIONS: Universal paediatric vaccination against rotavirus with a two-dose HRV would lead to the improvement in health outcomes while reducing the disease cost in the Sultanate of Oman.

PGI19: COST-EFFECTIVENESS OF FERRIC CARBOXYMALTOSE (FCM) IN THE TREATMENT OF IRON DEFICIENCY ANEMIA IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE (IBD)

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OBJECTIVES: Anemia is the most common systemic complication and extra-intestinal manifestation of IBD. A meta-analysis has published an overall prevalence rate in IBD patients of 24% (95%CI, 18–31). As anemia is a serious medical condition that may become life threatening, preventive measures should be considered. Two pivotal studies (FERGIcor and FERGImain) showed clinical meaningful results of FCM regarding to Hb increase 2 g/dL and prolonged time to recurrence of anemia. The purpose of this study was to evaluate the cost-effectiveness of FCM versus Iron-Sucrose (IS) and no-treatment in IBD patients with iron deficiency anemia (IDA). METHODS: We developed a Markov-Model to simulate the treatment pathway of IDA in IBD patients. Patients with mild/moderate IBD and IDA run into the model and receive different strategies of iron-deficiency-management (FCM, IS or no-treatment). The model includes 6 states (treatment success, recurrent anemia, hospitalization, disease worsening and death) based on RCT-data of FERGIcor and FERGImain. The cohort definition was adapted from the FERGIcor study. Monte Carlo simulation accounted for uncertainty. Direct costs were retrieved from published sources for 2016 and were expressed in Euro from the payer’s perspective. QALYs and total costs were projected over a 5-year time horizon and discounted at 5% p.a. RESULTS: Over a 5-year timeframe, costs and outcomes associated with FCM would amount to 3,630€ and 3.22 QALYs. Costs associated with IS are 3,144€ and 3.18 QALYs (incremental-cost-utility-ratios ICUR: 11,780€). Costs and outcomes associated with no-treatment are 3,227€ and 2.97 QALYs (ICUR: 1,585€). At the study endpoint 22.95% of patients are anemic in the FCM-group, 32.23% in the IS-group and 99.86% in the group without treatment. CONCLUSIONS: IDA treatment with FCM compared with IS or no-treatment is clearly below the CE threshold of €22,200-€33,300/QALY typically used by the UK NICE and hence can be considered as a cost-effective treatment strategy.

PGI20: COST-EFFECTIVENESS OF VEDOLIZUMAB FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY-TO-SEVERELY ACTIVE ULCERATIVE COLITIS IN RUSSIA

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BACKGROUND: Vedolizumab is one of the biologic drugs recommended by current clinical guidelines for the treatment of moderately-to-severely active ulcerative colitis (UC) in Russia. OBJECTIVES: To estimate the cost-effectiveness of vedolizumab compared with alternative strategies in the management of patients with UC who have had an inadequate response with, lost response to, or were intolerant to conventional therapy without anti-TNF-α inhibitors. METHODS: The global UK Markov model was populated with the Russian-specific input data. The target model population included patients with moderately-to-severely active UC who had demonstrated an inadequate response, lost response or had been intolerant to a conventional therapy. The model compared vedolizumab with infliximab (originator and biosimilar) as well as conventional therapy from the perspective of the Russian healthcare system for the 5-year time horizon. A 5% discount factor was used for costs and outcomes. The incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) was calculated. RESULTS: Vedolizumab required additional costs per additional QALY gained of 3.19 million rubles (49,669 euro) when compared to conventional therapy in UC patients. There was a small reduction in medical costs after correcting for disease progression and adverse effects. Concurrently, patients who received vedolizumab had longer sustained clinical remission, higher general survival rate, and lower need for surgery. When compared to originator infliximab, who have not been treated previously with anti-TNF-α inhibitors, vedolizumab was associated with lower costs and higher effectiveness. When compared to equal-share use of original and biosimilar infliximab, vedolizumab incurred an additional cost of 577,869 rubles (8,990 euro) per QALY gained. CONCLUSIONS: Vedolizumab is a dominant alternative in anti-TNF-α-naive patients with UC, compared with originator infliximab. It is also a cost-effective option compared to equal-share use of originator and biosimilar infliximab.
OBJECTIVES: Fibrosis progression of chronic hepatitis C (CHC) may significantly influence treatment cost-effectiveness using HCV antiviral agents because advanced fibrosis more frequently leads to hepatocellular carcinoma and liver failure. The aim of this study was to evaluate the impact of treatment strategies initiated at different stages of liver fibrosis on the cost-effectiveness of three antiviral combinations for Japanese patients with chronic hepatitis C genotype 1. METHODS: We created a decision analytic model of HCV reflecting liver fibrosis progression to evaluate the cost-effectiveness of alternative therapeutic strategies for Japanese patients with genotype 1 CHC with different fibrosis stages. We compared six strategies: treatment of patients with all fibrosis stages (TA), those initiated at different liver fibrosis stages (F1S, F2S, F3S, F4S), and no treatment (NoRx). We examined three kinds of combination therapy with antiviral agents: sofosbuvir-ledipasvir (SOF/LDV), ombitasvir-paritaprevir-ritonavir(OPR), and daclatasvir-asunaprevir (DA). The proportion of initial liver fibrosis stages of the cohort was assumed to be the same as in a Phase III study of DA treatment for Japanese HCV patients. RESULTS: On base case analysis, TA yielded the most effective result and the ICER against the second most effective strategy, F1S, fell below 1.4 million Japanese yen per QALY with all antiviral agent combinations. F2S followed F1S for effectiveness, and the ICER of F1S against F2S with the three combinations fell below 1.1 million Japanese yen per QALY. NoRx, F4S, and F3S had higher lifetime costs and were less effective compared with F2S with all antiviral agent combinations. The accessibility curve of TA on treatment with SOF/LDV, OPR, and DA, with ICERs below 5 million Japanese yen per QALY, showed probabilities of 98.4, 99.1, and 99.8%, respectively. CONCLUSIONS: Our results suggest that treatment of all Japanese patients with genotype 1 CHC regardless of their liver fibrosis stage would be cost-effective.

PGI23: COST-EFFECTIVENESS OF ENTEREX® HPT, A SPECIALIZED NUTRITION SUPPLEMENT, FOR PATIENTS WITH LIVER DISEASE IN MEXICO

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OBJECTIVES: Malnutrition is very common in patients with liver disease. The underlying liver disease will cause anorexia, nausea, and a poor appetite. Early recognition of micro or macronutrient deficiencies is essential, because the use of nutritional supplements reduces the risk of complications. Nutritional supplements should aim to maintain an adequate protein and caloric intake and to correct nutrient deficiencies. Enterex® HPT is specially formulated to help promote positive nitrogen balance and improve the nutritional status of individuals with liver disease while minimizing the risk of hepatic encephalopathy. The objective of this study is to determine the cost-effectiveness of Enterex® HPT vs no treatment (not offering any specialized nutrition intervention) in Mexico, from the institutional perspective. METHODS: A cost-effectiveness analysis was conducted using a Markov model to assess the efficacy of the treatments, defined as the progression free of the disease and the costs associated. The time horizon was 12 months. RESULTS: Tha basecase analysis incates that Enterex® HPT is a dominant alternative. Enterex® HPT provides saving for $4,462 USD per patient per year ($5,676 vs $61,223), meanwhile most patients are likely to progress when no specialized nutrition supplement (Enterex® HPT) is used (0.79 vs 0.72). In a 5-year time horizon, for a cohort of 1,000 patients with liver disease, Enterex® HPT will generate savings reaching $2,231,000 vs no specialized nutrition supplement per patient, as about 350,000 patients will avoid progression. CONCLUSIONS: Patients with liver disease using Enterex® HPT as a specialized nutrition supplement obtain important benefits like decreasing the risk of developing hyperglycemia, fatty liver and avoid hepatic failure progression.

PGI24: A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS OF BIOLOGICAL THERAPIES FOR THE TREATMENT OF ULCERATIVE COLITIS

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OBJECTIVES: Biological therapies have an increasing role in altering the natural course of Ulcerative Colitis (UC), especially in patients with an inadequate response to conventional treatment. Biological therapies, due to their high cost, are a major target for economic evaluation, in an effort towards the efficient allocation of the healthcare scarce resources. This study aims to systematically review the literature on cost-effectiveness/utility analyses of anti-TNFα agents that had been approved by EMA for UC. METHODS: A systematic literature search with keywords was performed using Google Scholar and Pubmed for studies published between February 2006 and March 2017. All cost-effectiveness or cost-utility studies, comparing biological therapies with conventional treatment, another
biological therapy, surgery or placebo for the treatment of UC in adults were included in this review. An assessment of the quality of the included studies, using the Drummond checklist, was conducted, in order to improve the generalizability and transparency of the review. All the above-mentioned were evaluated by two authors independently. RESULTS: After full text screening, fourteen studies were included in the review. As shown by the content analysis of the studies, the use of approved biological therapies in UC leads to the shift of cost from hospitalization and surgery towards TNFα drugs. The majority of the results fall within the acceptable thresholds, however a significant proportion tends to exceed them. The variety of the study design, country of origin, scope of the study, lack of indirect costs in most of the studies and differences in willingness to pay thresholds restrict the generalizability of the results. CONCLUSIONS: Although biological therapies in UC seem to provide clinical benefits, the cost associated with these treatments could be perceived as high. Direct comparisons between the agents are necessary.

PGI25: COST-EFFECTIVENESS ANALYSIS OF ULINASTATIN FOR PATIENTS UNDERGOING HEPATECTOMY: A DISCRETE EVENT SIMULATION MODEL

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OBJECTIVES: It was demonstrated that various surgical complications and death cases are highly associated with the excessive inflammatory response after hepatectomy. Ulinastatin was recommended to inhibit the excessive inflammatory response, hence to reduce the risk of post-hepatectomy complications and mortality. Evidences also indicated the Ulinastatin’s ability of shortening the length of stay (LOS) after hepatectomy, illustrating potential economic value to be assessed. This study aimed to analyse the cost-effectiveness of Ulinastatin versus standard care for hepatectomy patients. METHODS: A discrete event simulation model was constructed from the payers’ perspective. The time-to-events were simulated using an exponential distribution, with the exception of LOS using a log-normal distribution. The complication and death costs were acquired through a KOL consultation. Other cost, efficacy and utility data were sourced from literature. All costs were inflation-adjusted to 2016. The quality-adjusted life-year (QALY) was calculated with area under curve technique. The model has run through with numerous sample sizes to determine the number of simulated entities needed to generate a stable result. One-way sensitivity analysis and probabilistic sensitivity analysis were conducted. RESULTS: The total cost for per patient who has received Ulinastatin is $1197.09, while the total QALY gained for 1 year after the surgery is 0.8895. Oppositely, for entity who has not been administrated, the total cost and total QALY gained are $1342.10, and 0.8884, respectively. Consequently, the use of Ulinastatin for patients undergoing a hepatectomy provides minor extra QALY gain (0.0011), and some cost saving ($145.01) during the hospitalisation. According to one-way sensitivity analysis, the most influencing parameter is the average daily inpatient expense. In probabilistic sensitivity analysis, using Ulinastatin had a 99.6% probability of being cost-effective versus not using it at a $23,745.91/QALY threshold (i.e. three times of Chinese national gross domestic product in 2016). CONCLUSIONS: Administering Ulinastatin is a dominantly cost-effective intervention for patients undergoing hepatectomy.

PGI26: THE ECONOMIC BURDEN OF COELIAC DISEASE IN NORTH AMERICA AND EUROPE: A SYSTEMATIC REVIEW

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OBJECTIVES: The prevalence of coeliac disease (CD) has rapidly increased over recent decades. Its economic burden can be substantial, but remains poorly understood. This systematic review assessed the economic burden of CD in North America and Europe. METHODS: Medline, Embase, EconLit, and Cochrane Library were systematically searched to identify English-language literature published during the last 10 years assessing costs, cost-effectiveness, and health resource utilization for CD. RESULTS: Thirty-three studies met inclusion criteria. Most (20) were from Europe, and most (18) reported or modeled costs of screening and diagnosis. Cost per positive CD diagnosis of screening patients already undergoing esophagogastroduodenoscopy (EGD) for other indications, such as anaemia or irritable bowel syndrome, ranged from $1,300 in Canada to more than €44,000 in the Netherlands. In these populations, screening was cost-effective with strategies combining diagnostic modalities, including serology then biopsy, versus no screening. Direct annual excess costs to a US payer per diagnosed CD patient totaled $6,000 (US $2013) more than for a person without CD, chiefly due to outpatient care, with higher costs among patients with poor disease control. Hospitalizations, emergency visits, and medication use were more common in patients with CD versus controls. After initiating a gluten-free diet (GFD), patients visited primary care providers less often, but used
more medications. Gluten-free (GF) foods cost 240-518% more than gluten-containing equivalents. Three Scandinavian studies on absenteeism found fewer days missed from school and work following GFD initiation. CONCLUSIONS: Most economic studies of CD assess screening and diagnosis costs, especially in Europe. Methods of screening generally are considered cost-effective when they combine diagnostic modalities in symptomatic patients. Most costs to a payer of managing CD derive from outpatient care, especially for patients with poorly controlled disease. Patients on a GFD lose fewer days from work and school but pay high costs for GF foods.

PG127: COST UTILITY ANALYSIS OF INFliximab AND ADALIMUMAB COMPARED WITH CONVENTIONAL THERAPY IN PATIENTS WITH CROHN DISEASE IN THE ISLAMIC REPUBLIC OF IRAN

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OBJECTIVES: In spite of expensive medication costs of Crohn Disease treatment, an economic evaluation has not been done locally in Islamic Republic of Iran yet, in order to assess this medications cost effectiveness. Therefore, prescribers can’t judge the cost-effective alternative. This study aims to implement a cost utility analysis for two most biologic medications used in severe non Fistulizing Crohn Disease from a societal perspective in Islamic Republic of Iran. METHODS: This study target population was adults’ patients with Non Fistulizing Sever Crohn Disease who did not reply to first line therapy. 109 patients were enrolled to study from Shariati Public Hospital and Masoud Clinic which both are referral centers. Study arms included Infliximab and Adalimumab as comparators. Model structure was based on disease natural history and clinicians’ consultations. All direct medical and non-medical costs were entered to model. Indirect costs were calculated through Human Capital approach. Patients’ utilities were extracted by EQ5D questionnaire through face to face interview. Mortality rates were derived from Iran National Statistics Database. Transition probabilities were extracted by a systematic review from published Randomized Clinical Trials. A markov model designed with 2 month length cycles and 5 year time horizon in Excel 2013 software. Probabilistic sensitivity analysis was done by Treeage 2011 software. RESULTS: Calculated Incremental Cost Effectiveness Ratios (ICERs) was -48,469 USD per QALY gained. CONCLUSIONS: Study results showed that due to difference between Infliximab and Adalimumab medications’ prices, Adalimumab is the dominant alternative in Islamic Republic of Iran, considering its threshold which is about 3,700 USD. Hence it is recommended that Adalimumab to be administered as the first choice of biologic therapy which is controversial to current approach of most Iranian gastroenterologists.

PG128: HEALTHCARE RESOURCE UTILIZATION IN PATIENTS WITH MODERATE TO SEVERE CROHN’S DISEASE: A BRAZILIAN REAL WORLD STUDY

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OBJECTIVES: Describe the use of health resources related to the management of moderate to severe Crohn’s disease (CD) in Brazil. METHODS: This was a retrospective analysis that collected data from patient medical records in multiple Brazilian centres in 2017. Healthcare resource utilization data related to the management of patients (≥18 years old) diagnosed with moderate to severe CD at least 6 months before the inclusion day were presented using descriptive statistics. RESULTS: A total of 264 patients with moderate to severe CD were included in this analysis. The mean age of the patients was 42.9±12.96 years and 54.2% were female. The mean weight and body mass index were 69kg ±14.52 and 25.1 kg/m2 (15.2-44 kg/m2), respectively. The time since diagnosis of moderate to severe CD was on average 8.0±6.3 years. Surgeries were required in 25.4% of patients and the average number of surgeries per patient was 1.6±0.9. The majority (20.4%) of surgeries were anal procedures (fistulectomy). The number of mean hospitalizations was 1.7±0.89 times for CD patients with a mean duration of 4.0 months. The mean medical appointments per patient was 12.1±6.81 during the period and more than 90% corresponded to an IBD specialist visit. The number of imaging and laboratory tests performed was on average 21.8±18.1 per patient. Hemogram was the most frequent test performed (40.8%), followed by C-reactive protein (31.2%). Biological therapy was the most common type of therapy (36.5%), followed by immunosuppressants (36.1%). Regarding biological treatment, 20.3% of dose changes were due to poor effectiveness. CONCLUSIONS: Moderate to severe CD was associated with substantial healthcare resource utilization in Brazil.

PG129: HEALTH ECONOMIC EVALUATIONS IN INFLAMMATORY BOWEL DISEASE IN BRAZIL: A SYSTEMATIC REVIEW
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OBJECTIVES: The objective of this study was to systematically review health economic evaluations (HEE) in Inflammatory Bowel Disease (IBD) in Brazil. METHODS: Electronic databases (MEDLINE, LILACS, SciELO, NHS EED, HTA) and the Brazilian Journal of Health Economics were searched with no restriction of population, language and period. Editorials, letters, commentaries, opinion papers and reviews were excluded. Two researchers examined titles, abstracts and full articles for criteria eligibility and carried out data extraction independently. A qualitative narrative synthesis was performed. RESULTS: Abstracts and titles were screened (n=260) and seven studies were included, two conference abstracts and five articles. Five complete HEE (three cost-minimization analyses, one cost-effectiveness analysis, one cost-utility analysis), one cost analysis and one budget impact analysis were included. The target population in all analysis was adults. Two studies compared mesalazine drugs (MMX vs conventional; Mesalazine once vs twice a day) in ulcerative colitis and five assessed the biologic treatment in Crohns Disease (two adalimumab vs infliximab and three certolizumab vs adalimumab vs infliximab). In the biologic treatments comparisons, three studies evaluated just the drug acquisition costs and two conducted additional analysis based on specialist opinions and international literature. The resource use for public and private systems was obtained from the Official Brazilian Administrative Database (DATASUS) and expert opinion, respectively. Costs were obtained from official sources (DATASUS and CMED). The cost-utility analysis used international utility data. CONCLUSIONS: IBD is a chronic disease with substantial financial and quality of life impact but currently there is a lack of studies evaluating the economic and societal burden of the disease in Brazil.

PGI30: HEALTHCARE RESOURCE UTILIZATION IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS: A BRAZILIAN REAL WORLD STUDY.

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OBJECTIVES: Describe the use of health resources related to the management of moderate to severe ulcerative colitis (UC) in Brazil. METHODS: This was a retrospective analysis that collected data from patient medical records in multiple Brazilian centres in 2017. Healthcare resource utilization data related to the management of patients (≥18 years old) diagnosed with moderate to severe UC at least 6 months before the inclusion day were presented using descriptive statistics. RESULTS: A total of 143 patients with moderate to severe UC were included in this analysis. The mean age was 45.9±13.83 years and 56.6% were female. The mean weight and body mass index were 70.1±14.33 kg and 25.7±4.63 kg/m², respectively. The time since diagnosis of moderate to severe UC was on average 6.1±4.85 years. Surgeries were required in 2.8% of patients and the average number of surgeries per patient was 1.8±0.5. Total colectomy and closure of enterostomy (any segment) corresponded (each one) to 28.6% of surgeries. The mean number of hospitalizations was 1.5±0.92 times for UC; the mean duration was 0.7 months. The mean number of medical appointments per patient was 10.8±6.56 during the period and 92.5% corresponded to an IBD specialist visit. The average number of imaging and laboratory tests was 17.8±14.02. Hemogram was the most frequent test performed (38.8%), followed by C-reactive protein (29.8%). Salicyl acid derivatives were the main type of therapy prescribed after the disease diagnosis (60.3%), followed by biological therapy (10.6%). CONCLUSIONS: Moderate to severe UC was associated with substantial healthcare resource utilization in Brazil.

GASTROINTESTINAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PGI31: PATIENT REPORTED OUTCOME OF CELIAC DISEASE

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OBJECTIVES: Statistics show that in Hungary, one in ten people has celiac disease, which means a significant burden for both the families, the health care system and the economy. Our research was designed to provide a comprehensive picture of all children diagnosed with celiac disease at the children's ward in Tolna County Hospital in 2016. We aimed to explore, identify correlations by reviewing the documents. METHODS: During the retrospective, quantitative study patient documents (final report, medical record, and nursing diary) of 132 persons (84 male and 48 female) were reviewed. Their average age was 7.74 years (SD ± 4.46). 28 questions based on the following variables - basic demographic data, symptoms, diagnostic tests, comorbidities, family – were analysed. Descriptive statistics and Chi-square test were used with 95% probability level, we used the SPSS statistics program. RESULTS: 79.5% of the patients were diagnosed with classical clinical symptoms, 17.4% were atypical and 3% did not show any
symptoms. Regarding diagnosed patients significantly more (65%) girls (p = 0.00) with classic symptoms occurred than boys (35%). Associated diseases occurred in 59%, these include anemia (34%), lactose intolerance (17%), diabetes (8%) and eczema (8%). The sample mainly had serological studies (60%), only four cases were negative results due to low levels of IgA, or lack IgA. In patients with IgA deficiency, a biopsy confirmed the disease in 100%. More invasive procedure, biopsy were made in 62.12%, which revealed villus atrophy in 96.23%. Due to the family involvement celiac disease occurred in 43.2%, 65% in siblings, 16% in mothers, and only some cases in fathers, grandparents and cousins. CONCLUSIONS: The investigation shown that celiac disease can appear not only in young children but later in life and need to pay attention to family history, because they can help in the rapid diagnosis.

PGI33: A SOCIETAL UTILITY STUDY TO ELICIT VALUES FOR ADVERSE EVENTS AND SURGICAL COMPLICATIONS IN MODERATE TO SEVERE CROHN’S DISEASE IN UK


OBJECTIVES: The impact of Crohn’s disease (CD) treatments and adverse events (AEs) has been previously researched and reported. However, less is known about their impact on health-related quality of life (HRQL) specifically for use in economic evaluations. The aim of this study was to elicit utility values for AEs related to biologic treatment and surgical complications for CD in the UK. METHODS: Health state selection and wording were informed by literature review and interviews with CD patients (N=6) and gastroenterologists (N=3). Draft health states were validated in cognitive debrief interviews with other CD patients (N=4) and gastroenterologists (N=2). Treatment AEs were described with moderate-severe CD (baseline state) and included hypersensitivity, injection site reactions, serious infection, lymphoma, and tuberculosis. Surgical complications were described with bowel surgery (baseline state) and included anastomotic leak, wound infection, prolonged ileus obstruction, and intra-abdominal abscess. The final health states (n = 11) were piloted to check UK general public understanding. For health state valuation, UK general public participants (n=100) completed background questions, EQ-5D, visual analogue scale and time trade-off (TTO) with lead time method for states worse than dead. RESULTS: The mean TTO value for baseline states ‘moderate to severe CD’ and ‘bowel surgery’ were 0.70 (SD=0.28) and 0.69 (SD=0.28). Participants rated moderate to severe CD+lymphoma as the worst state (0.44), then tuberculosis (0.47) and bowel surgery+anastomotic leak (0.48). Values of other states ranged from 0.76 (hypersensitivity) to 0.56 (intra-abdominal abscess). Overall, decline in utility was largest moving from ‘moderate to severe CD’ baseline state to also experiencing lymphoma (-0.26). CONCLUSIONS: This study provides novel utility estimates for health states not previously assessed in the context of CD, or at all. As biologic treatments help CD patients avoid future bowel surgery it has become important to incorporate surgical complications in assessment of benefit.

PGI34: IDENTIFYING A CLAIMS-BASED DEFINITION OF SATISFACTION WITH LINACLOTIDE TREATMENT AMONG PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) AND CHRONIC IDIOPATHIC CONSTIPATION (CIC)

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OBJECTIVES: This study aimed to develop and validate a claims-based definition of linacotide treatment success based on patient-reported survey data on treatment satisfaction, over 6 months, from the Chronic Constipation and IBS-C Treatment and Outcomes Real-world Research Platform (CONTOR), a longitudinal research platform combining administrative claims and patient survey data for IBS-C and CIC patients (Abel JL et al. Am J Gastroenterol 2016;111:S257). METHODS: This retrospective analysis identified CONTOR participants aged ≥18 years with evidence of IBS-C or CIC (by patient-reported physician diagnosis, treatment or symptoms) who reported current (≤7 days before survey date) or recent (8–180 days before survey date) linacotide use. Logistic regression models were used to determine which claims-based variables (eg medication use patterns [number of fills, days’ supply], healthcare resource use, patient characteristics and demographics) best predicted treatment success by examining concordance/discordance between the predicted satisfaction, based on claims, and patient-reported treatment satisfaction with linacotide. RESULTS: Of 627 eligible patients identified from CONTOR (mean age 46.0 years, 94.4% female), 64.6% (n=405) reported satisfaction with linacotide treatment. Patients who reported treatment satisfaction had significantly more linacotide fills compared to unsatisfied patients (mean 2.2 vs 0.5, respectively; p<0.001), as well as a higher number of days’ supply of linacotide (mean 71.5 vs 20.0 days, respectively; p<0.001). The number of linacotide fills was the strongest predictor of patient-reported treatment satisfaction (odds ratio=1.87; p<0.0001). For a cut-off point of ≥2 linacotide fills during the past 6 months, the satisfaction model had a sensitivity of 0.52 and a specificity of 0.89. CONCLUSIONS: A refill of a linacotide prescription is the best claims-based method of defining patient satisfaction with linacotide treatment, consistent with behavioural expectations.
PGI35: PREFERENCES FOR ROUTE OF ADMINISTRATION, FREQUENCY AND LOCATION - A TIME-TRADE-OFF STUDY IN THE ITALIAN GENERAL POPULATION

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OBJECTIVES: The objective of this study was to investigate preferences from the Italian general population for route, frequency and location of route of treatment, independent of disease area. METHODS: We developed eight health states varying the route of administration (subcutaneous injection/intravenous infusion), frequency (every 1/2/4/8/12 weeks), and location (hospital/home) to correspond with treatment regimens for a number of commonly used biologic compounds. The time-trade-off (TTO) method was applied to elicit utility values associated with each health state. Respondents were repeatedly asked to ‘trade off’ a portion of their remaining lifespan for perfect health until a point of indifference was found. 1,547 respondents (≥18 years old) from the Italian general population who were recruited through a representative internet-based survey panel completed the questionnaire. A utility value was assigned to each health state based on each individual’s response, derived from the midpoint of the indifference interval. RESULTS: Respondents preferred less frequent administration both for subcutaneous injections (weekly subcutaneous injections at home: 0.859; bi-weekly: 0.859; 8-weekly: 0.871; 12-weekly: 0.874) and infusions (infusions at the hospital 4-weekly: 0.831; 8-weekly: 0.838). Additionally, respondents prefer a subcutaneous injection at home rather than at the hospital (subcutaneous injections every 12 weeks at the hospital: 0.870; at home: 0.874) and subcutaneous injection to infusion (treatment every 8 weeks at the hospital, infusion: 0.838; subcutaneous injection: 0.856). Receiving a subcutaneous injection at home every 12 weeks was preferred over all other health states (however not significantly for subcutaneous injection at home every 4/8 weeks). CONCLUSIONS: Route, frequency and location of administration matter for members of the general public as they have an impact on convenience. The best combination of administration and frequency is receiving a subcutaneous injection every 12 weeks at home, showing that more convenient treatment regimens are associated with higher utility values.

PGI36: PREFERENCES FOR ROUTE OF ADMINISTRATION, FREQUENCY AND LOCATION – A TIME-TRADE-OFF STUDY IN THE UNITED KINGDOM GENERAL POPULATION

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OBJECTIVES: The objective of this study was to investigate preferences from the UK general population for route, frequency and location of route of treatment, independent of disease area. METHODS: We developed eight health states varying the route of administration (subcutaneous injection/intravenous infusion), frequency (every 1/2/4/8/12 weeks), and location (hospital/home) to correspond with treatment regimens for a number of commonly used biologic compounds. The time-trade-off (TTO) method was applied to elicit utility values associated with each health state. Respondents were repeatedly asked to ‘trade off’ a portion of their remaining lifespan for perfect health until a point of indifference was found. 1,645 adult respondents (≥18 years old) from the United Kingdom general population who were recruited through a representative internet-based survey panel completed the questionnaire. A utility value was assigned to each health state based on each individual’s response, derived from the midpoint of the indifference interval. RESULTS: Respondents preferred less frequent administration both for subcutaneous injections (weekly subcutaneous injections at home: 0.859; bi-weekly: 0.859; 8-weekly: 0.871; 12-weekly: 0.874) and infusions (infusions at the hospital 4-weekly: 0.831; 8-weekly: 0.838). Additionally, respondents prefer a subcutaneous injection at home rather than at the hospital (subcutaneous injections every 12 weeks at the hospital: 0.870; at home: 0.874) and subcutaneous injection to infusion (treatment every 8 weeks at the hospital, infusion: 0.838; subcutaneous injection: 0.856). Receiving a subcutaneous injection at home every 12 weeks was preferred over all other health states (however not significantly for subcutaneous injection at home every 4/8 weeks). CONCLUSIONS: Route, frequency and location of administration matter for members of the general public as they have an impact on convenience. The best combination of administration and frequency is receiving a subcutaneous injection every 12 weeks at home, showing that more convenient treatment regimens are associated with higher utility values.

PGI37: INTERROGATING SOCIAL MEDIA SOURCES TO GAIN INSIGHT ON OPIOID-INDUCED CONSTIPATION SYMPTOMS AS REPORTED BY PATIENTS

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OBJECTIVES: Opioid-induced constipation (OIC) is the most common adverse effect associated with prolonged use of opioids, and it can have a major impact on patient’s lives. This exploratory project employed text mining techniques to gather information from a range of social media sources, including patient forums, to better understand which
symptoms are associated with OIC. METHODS: A web crawler was seeded with the URLs of websites likely to contain the content we were looking for; this was then run to retrieve web-pages containing mentions of OIC. A machine-learning application was developed to extract patient-reported symptoms relating to OIC from the web-pages. The performance of the model was evaluated and tuned using standard cross-validation techniques. The narrative content of the posts was anonymised and analysed manually. RESULTS: Of the 42,000 web-pages retrieved, we found 128 posts that described symptoms of OIC as reported by patients. Some posts mentioned more than one symptom. The most common symptoms were having pain (39 posts), feeling blocked (37 posts), evacuation issues (22 posts) and bloating (22 posts). There were a range of other symptoms which included: anal spasm, weight change, cramps, nausea/sickness, tenderness, stomach pressure, headache, urge, stitch, leakage, anus not closing, gassy, brain fog, bleeding and feeling tired. Patients also reported a fear of rupture (4 posts) and of piles (1 post). CONCLUSIONS: A range of symptoms were reported by patients with OIC. More generally, this research project shows that social media can be an important source of insight on patient symptoms; which could be invaluable when designing further qualitative or quantitative research or in better understanding the burden of a condition.

PGI38: PATIENT-REPORTED OUTCOMES OF OPIOID-INDUCED CONSTIPATION AS IDENTIFIED THROUGH SOCIAL MEDIA

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OBJECTIVES: The aim of this exploratory project was to better understand the patient-reported impact of opioid-induced constipation (OIC) as discussed in social media. METHODS: In this project, we applied text mining and machine-learning techniques to interrogate social media data. A web crawler was seeded with some initial URLs of websites likely to be relevant to the content we were seeking; further websites were then identified by the crawler. A machine-learning application was developed to extract from the web-pages anonymised patient-reported concepts relating to the burden of OIC on patients. RESULTS: Of the 42,000 web-pages retrieved, 122 described the patient-reported impact of OIC. There were 40 posts that spoke about the impact of OIC on dietary habits or the need for laxatives (with an additional 6 posts speaking about the need for enemas or manual excavations). There were 36 posts describing the emotional impact (including worry) associated with OIC, with 23 posts describing how OIC had necessitated a change in opioid use. The impact of OIC on general health and everyday functioning (including work) were other topics that patients discussed (9 and 8 posts, respectively). CONCLUSIONS: Social media posts can offer an important source of data on patient experiences of disease. In this exploratory study, these posts have indicated that OIC impacts a number of different aspects of people’s lives, including general health, daily functioning, and emotional well-being. OIC also impacts behaviour (dietary change, change in opioid use, and need for procedures) as patients attempt to reduce its burden. Findings from this study could be used as an input to the development of a conceptual model, or to supplement other qualitative research on the patient-reported impact of OIC.

PGI39: DEVELOPMENT OF A NEW PATIENT-REPORTED OUTCOME MEASURE FOR NON-ALCOHOLIC STEATOHEPATITIS: NASH-CHECK

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OBJECTIVES: Nonalcoholic steatohepatitis (NASH) is the most advanced form of nonalcoholic fatty liver disease, characterized by excessive liver fat accumulation, inflammation, cell injury and fibrosis. Here we report on the initial development of the NASH-CHECK, a new NASH-specific patient-reported outcome (PRO) measure. METHODS: Content for the NASH-CHECK was generated via thematic analyses of semi-structured, concept elicitation (CE) interviews conducted with NASH patients in Virginia, USA. Item selection was guided by a task-force group including clinical experts, patient representatives and PRO researchers. The content validity of the draft measure was assessed through cognitive debriefing (CD) interviews. RESULTS: Twenty-three CE interviews were conducted (females=18[78%]; age: mean[SD] age=55.9[10.0]; range: 31.0-73.0 years). Sixteen patients (69.6%) had biopsy-diagnosed NASH (fibrosis grade:F1=1[4.3%]; F2=5[21.7%]; F3=10[43.5%]); 7 patients (30.4%) had phenotypic-diagnosed NASH. Mean(SD) years since diagnosis=3.9(2.9). Key symptoms reported included pain in upper right abdomen (n=14; 60.9%), fatigue (n=18; 78.3%), poor sleep quality (n=12; 52.2%), cognition problems (impaired memory [n=13; 56.5%]; reduced focus [n=11; 47.8%]) and pruritus [n=10; 43.5%). Key health-related quality-of-life (HRQOL) impact included; impaired physical functioning, relationships, emotions (low mood and anxiety), stigma and self-consciousness. The first draft NASH-CHECK included 52 items (16 symptoms/36 HRQOL); duplicate items were included to allow patient-selection of most appropriate item phrasing. Fifteen CD interviews
were conducted (females=7[46.7%]; age: mean[SD]= 53.6[8.9];range 31.0-68.0 years). Eleven patients (73.3%) had biopsy-diagnosed NASH (fibrosis grade: F1=3[20.0%];F2=2[13.3%];F3=6[40.0%]); 4 patients (26.7%) had phenotypic-diagnosed NASH. Mean (SD) years since diagnosis=3.2(2.8). The NASH-CHECK was reduced to 31-items based on patient preferences for item relevance, acceptability and comprehension. Minor changes were made to the instructions and item wording. The final version was considered relevant and acceptable to the CD interview patients. **CONCLUSIONS:** The study was successful in producing a US-English NASH-specific PRO measure assessing symptoms and HRQOL suitable for further psychometric evaluation.

GASTROINTESTINAL DISORDERS - Health Care Use & Policy Studies

PGI40: A WEB-BASED HUB & SPOKE MODEL FOR THE MANAGEMENT OF HCV PATIENTS AND INNOVATIVE TREATMENTS: THE RESIST - HCV SICILY NETWORK EXPERIENCE

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**OBJECTIVES:** To develop a web-based platform for connecting hub and spoke centres, gastroenterologists, infectivologists and general practitioners for identifying patients with HCV chronic diseases, characterizing pathology and patients profile and for managing drug prescriptions in accordance with guidelines and ensuring therapeutic appropriateness. **METHODS:** The Sicily HCV Network and CINECA Interuniversity Consortium have designed and implemented an online system for data collection and analysis to support the management and treatment of chronic hepatitis and cirrhosis. The network includes 42 centres, 96 gastroenterologists or infectivologists and around 300 general practitioners connected by a web platform in which patients registration, disease evaluation, validation (if applicable), therapeutic plans, follow-up visits and ADR data are collected. The web platform, through an electronic agenda system, also guarantees fibroscan and therapies booking from Spoke to Hub centres (enabled to prescribe antiviral therapy). **RESULTS:** In just over two years (from March 2015 to June 2017), over 12,000 patients (57% male, mean age 63 years) have been recorded in the web platform; more than 50% of patients was included in the Registry for Chronic hepatitis and genotype 1b has been the most frequent observed in the population (64%); 4,754 patients completed the treatment, and 3,697 completed the 12 weeks of follow-up. The Sustained Virological Response (SVR) was achieved in 3,499 patients (94.6%). **CONCLUSIONS:** The HCV Sicily Network is an effective system for managing HCV chronic diseases that need a complex diagnostic and therapeutic approach and represents a Health Value Added for all stakeholders: it facilitates Regional Health Department in monitoring drug consumption and related costs, it helps specialists in prescribing a more appropriate therapy, it improves both continuity of care and equity of access to innovative medicines and, moreover, it allows the collection of a huge amount of real-world data for epidemiological estimations, pharmaco-economical evaluations and other scientific purposes.

PGI41: BARRIERS TO ACCESS AND PRICING NEGOTIATIONS CRITERIAL SELECTION FOR NOVEL TREATMENTS FOR HEPATITIS C IN THE GREEK HEALTHCARE CONTEXT

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**OBJECTIVES:** Novel treatments with direct-acting antivirals (DAAs) against Hepatitis C (HCV) address the issue of limited clinical efficacy with previous treatments at the individual and population level. However, the use of DAAs is accompanied by implications of affordability and equity in access to treatment. The present study aimed to identify a) real-world barriers to treatment access, as well as b) criteria on potential pricing/negotiation decisions for DAAs from the physicians’ perspective in Greece, a country under financial constraints. **METHODS:** A panel of physician experts in the management of HCV with geographical distribution representative of national clinical practice provided the primary data for the analysis. A two-step Delphi process was used to achieve consensus on the relative importance (scale 0-100) of a series of criteria on the two above-mentioned policy issues. **RESULTS:** According to the Delphi process, the major barriers in access to treatment for Greek patients include patient ineligibility in meeting treatment criteria (restricted to F3 treatment experienced and F4 only) (90.0), limited patient awareness on the available treatments and their efficacy (58.8), lack of system capacity for the management of the disease (46.3) and lack of specialized medical personnel (26.8). Major criteria highlighted for pricing/negotiation process for DAAs were therapeutic efficacy of medicines (96.87), lack of alternative effective treatment (unmet need) (94.87), cost-effectiveness (93.37) and severity of the disease (91.62), followed by parameters such as safety, incidence of the disease etc. **CONCLUSIONS:** According to physicians in Greece, main barriers to access to HCV treatment were strict criteria ineligibility, system capacity and patient awareness. With respect to the factors that should be taken into...
account during negotiations for DAAs, both economic and clinical criteria should be incorporated in the decision algorithm.

**PGI42: THE VALUE OF REAL-WORLD EVIDENCE TO SUPPORT VALUE-BASED DECISION-MAKING: EXAMPLES FOR VEDOLIZUMAB IN INFLAMMATORY BOWEL DISEASE**

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**OBJECTIVES:** Efficacy of interventions from randomised controlled trials (RCTs) forms the backbone of reimbursement submissions. However, RCTs have limited external validity, providing insufficient insights for payers to make resource-allocation decisions for their populations. Real-world evidence (RWE) provides a more accurate representation of drug utilisation and healthcare expenditure in clinical practice, and can inform on comparative effectiveness in the absence of head-to-head trials. We present examples of vedolizumab (VDZ) outcomes in inflammatory bowel disease (IBD) to demonstrate how RWE can support value-based decision-making by payers. **METHODS:** MEDLINE-, Cochrane-, Embase-indexed publications and conference abstracts were systematically searched from 1/5/2014–10/1/2017 for studies reporting real-world VDZ effectiveness, safety, healthcare resource utilisation, and treatment patterns. Reports for patients <18 years or off-label VDZ use were excluded. **RESULTS:** The review identified 116 RWE studies (>6,500 VDZ patients). VDZ demonstrated long-term effectiveness (1-year) in ulcerative colitis and Crohn’s disease (pooled clinical remission: 49% and 31%, respectively; pooled corticosteroid-free remission: 46% and 26%; mucosal healing: 59% and 58%), in some cases exceeding efficacy observed in the RCTs. Compared to anti-TNF therapy, VDZ was less frequently dose-escalated (5% versus 26%, after 30 weeks) and showed greater reductions in healthcare resources (after 26 weeks, ≥1 IBD-related hospitalisation: 8% versus 16%; surgeries: 1% versus 6%). The evidence synthesised has been utilised to strengthen a number of submission packages, refine cost-effectiveness and budget impact models, develop field-based tools to support local access as well as inform risk-sharing agreements and facilitate pricing negotiations in multiple countries. **CONCLUSIONS:** RWE can supplement the evidence package of new, innovative drugs beyond RCTs, providing payers with insights on expected utilisation, outcomes, and helping them plan population budgets. At a time when payers are increasingly expected to make trade-offs based on limited information, RWE is fundamental in supporting the decision-making process at national and local levels.

**PGI43: IRON DEFICIENCY ANEMIA IN PATIENTS WITH CHRONIC INFLAMMATORY BOWEL DISEASE (IBD): A SYSTEMATIC LITERATURE REVIEW**

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**OBJECTIVES:** Iron-deficiency-anemia (IDA) is highly prevalent in chronic inflammatory disease (IBD) patients and imposes a significant disease burden for IBD patients with enormous impact on their outcome. For this reason, this study was designed to identify epidemiological data, screening and treatment guidelines, costs as well as outcome of intravenous iron treatment in patients with IBD and IDA. **METHODS:** A comprehensive literature review was undertaken for all publications from 1997 to March 2016 using Medline, EMBASE, Central-Cochrane, Science Direct and Pubmed databases, comprising English and German articles. The review focused on studies based on patients with chronic inflammatory disease and iron deficiency, with or without anemia. Articles were systematically selected if they included data for iron deficiency on at least one of the following criteria: epidemiology, screening and treatment guidelines, costs, clinical outcomes. **RESULTS:** Database search yielded 8,342 articles, 265 additional articles were identified via secondary hand searches. Of the 68 eligible articles 22 provided information on epidemiological data, 25 on screening and treatment guidelines, 11 on costs and 10 on clinical outcomes. Findings exhibit a prevalence-rate of IBD in the European population. Out of these, 35-90% suffer from iron deficiency. The prevalence of anemia in IBD patients ranges between 18% and 40.27%. European cost studies have calculated yearly per-patient costs of IBD between 1,043€ and 4,533€. Health care costs for Crohn’s disease is higher compared to ulcerative colitis. An IBD patient with IDA induces 2.5 times higher healthcare costs per year compared to a non-IDA patient. IDA is responsible for a reduction in quality of life (~0.0845 Utilities=1 month in perfect health). **CONCLUSIONS:** The presence of anemia iron deficiency is associated with poorer quality of life and performance in patients with IBD. The IV iron therapy can be an option to improve outcome (patient status) and reduce health care costs.

**PGI44: REPORTING OF THE USE OF RESEARCH AND PUBLICATION GUIDELINES IN HEALTH ECONOMIC AND OUTCOMES RESEARCH PUBLICATIONS IN INFLAMMATORY BOWEL DISEASE – A SYSTEMATIC LITERATURE REVIEW**

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OBJECTIVES: Several best practice guidelines exist for the conduct and communication of health economic and outcomes research (HEOR) studies. Few studies have assessed the reporting of the use of research and publication guidelines in HEOR publications developed by clinical/academic and pharmaceutical company authors. We performed a systematic literature review to investigate the trends in HEOR publications for inflammatory bowel disease (IBD: ulcerative colitis or Crohn’s disease) and the reporting of the use of research/publication guidelines. METHODS: The electronic databases MEDLINE® and Embase were searched to identify all real-world evidence (RWE), patient-reported outcomes (PROs), epidemiology and economic modelling publications related to IBD published between January 2011 and September 2016. RESULTS: A total of 1100 publications were identified; from which 254 manuscripts were included for analysis (66 [26%] RWE; 98 [39%] PROs; 45 [18%] epidemiology; 45 [18%] economic modelling). The annual number of HEOR manuscripts increased over 6 years (2011, n=28; 2016, n=51). Only 16/254 included studies were published in HEOR-specific journals; most studies were published in medical journals. The majority of manuscripts (219/254, 86%) listed only clinical/academic authors, whereas 24/254 (10%) were authored by pharma. The involvement of professional medical writers was declared in 17 papers (7%), all of which were funded by pharma. Only 15 studies (6%) reported the use of research/publication guidelines; none of which received medical writing support. Most reported guidelines were country-specific guidance for economic evaluation or health technology assessment. No publication reported the use of ISPOR or EQUATOR network (MOOSE, CHEERS and STROBE) guidelines. CONCLUSIONS: Few HEOR publications in IBD report the use of research/publication guidelines. Greater use and/or reporting of the use of such guidelines for HEOR studies is required. Most HEOR publications in IBD do not report the involvement of pharma or medical writers. This analysis was limited by sample size.

PGI45: THE UNKNOWN BURDEN OF CELIAC DISEASE IN THE US AND GLOBALLY

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OBJECTIVES: Awareness of the prevalence and burden of celiac disease is increasing globally. This study summarizes the latest estimations of celiac disease prevalence and burden disease, including impact on quality of life, of celiac disease in the US and around the world, comparing methods used and reliability of data. METHODS: Meta-review of literature and comparison of methods and estimations from peer-reviewed studies in 68 countries. RESULTS: The reliability of estimations of prevalence and burden of celiac disease vary greatly in the US and around the world, with the exception of Northern Europe. Variability in estimations are due in part to failure of primary healthcare providers to suspect, screen for and accurately diagnose celiac disease, and multiple misdiagnoses due to diverse symptomatology of the disease. Confounders of accurate estimation of prevalence and burden of disease include lack of access to diagnostics and genetic biomarkers, avoidance of consumers, providers and governments to perform confirmatory biopsies, self-diagnosis by consumers, and gluten free diet. CONCLUSIONS: Celiac disease continues to be poorly understood, underdiagnosed and mismanaged in most countries of the world, resulting in significant burden of disease and impact on quality of life. Advances in less invasive diagnostics and better electronic health data analytics, along with increased education of primary care practitioners and new therapeutic choices should improve diagnosis and lessen overall burden of disease.

RESPIRATORY-RELATED DISORDERS - Clinical Outcomes Studies

PRS1: AGE AND GENDER RELATIONSHIPS WITH SYSTEMIC CORTICOSTEROID INDUCED MORBIDITY IN ASTHMA: A CASE-CONTROL STUDY

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OBJECTIVES: Treatment of severe asthma may include high dose systemic-corticosteroid therapy which is associated with substantial additional disease burden. In this study, we examine the relationships between steroid exposure and disease burden as well as heterogeneity in this related to age and gender. METHODS: Patients with severe asthma (n=808) (high corticosteroid exposure) were matched by age and gender with patients with mild asthma (n=3,975) (low corticosteroid exposure) and a non-asthma control cohort (with a diagnosis of rhinitis; n=2,412) (no corticosteroid exposure) from nationally representative primary care database - the Optimum Patient Care Research Database (OPCRD). Regression analysis was used to investigate the odds of a number of corticosteroid related comorbidities and how this varied by corticosteroid exposure, age and gender. Prescribed drugs
and publicly funded healthcare activity were monetised. Annual costs per patient estimated and patterns related to corticosteroid exposure examined. RESULTS: Younger patients with high oral corticosteroid (OCS) exposure had a greater odds of a range of conditions (osteopenia, osteoporosis, glaucoma, dyspeptic disorders, chronic kidney disease, cardiovascular disease, cataracts, hypertension and obesity (p < 0.01)) relative to those with low OCS exposure in this age group. This difference in odds was much less evident in older patients. Both males and females with high OCS exposure compared to low OCS exposure have greater odds of most comorbidities. This differential pattern of comorbidity prevalence was also reflected in mean healthcare costs per patient per year. CONCLUSIONS: This data demonstrates important differential prevalence of corticosteroid induced morbidity by age and gender which is paralleled by differences in healthcare costs. This is important for cost-effectiveness analysis of corticosteroid-sparing therapies as these therapies may exhibit different incremental cost-effectiveness ratios for specific subgroups notably younger patients.

PRS2: LONG-TERM IMPACT OF GRASS-POLLEN (GP) SUBLINGUAL IMMUNOTHERAPY TABLET (SLIT) ON ALLERGIC RHINITIS (AR) AND ON ALLERGIC ASTHMA (AA) ONSET AND PROGRESSION

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OBJECTIVES: To assess the long-term effectiveness of grass-pollen (GP) sublingual immunotherapy (SLIT) tablet on allergic rhinitis (AR) and asthma in France. METHODS: A retrospective analysis using real-world data from IMS Longitudinal Prescriptions (LRx), a database including one-third of French retail pharmacies was performed over 4.8 years (March 2012 to December 2016). Two cohorts of patients with GP AR were selected: patients treated with GP SLIT tablet for at least 2 successive GP seasons (SLIT Tablet group (STG)) were compared with patients treated with symptomatic treatments (Control group (CG)), matched on age and index year (i.e.: year of SLIT tablet initiation). Multiple regressions were used to compare changes over time in symptomatic AR medication deliveries (MD), asthma MD, and asthma onset in the two groups. RESULTS: 1,099 and 10,990 patients were included respectively in STG and CG. In both cohorts, 43.2% were aged between 6-17, 47.3% between 18-45 and 9.5% > 45. A ratio between symptomatic AR MD before treatment and after treatment cessation highlighted that symptomatic AR MD were reduced by 80% in SLIT tablet group versus 20% in CG. A linear regression showed that this reduction was significantly higher in STG (p<0.0001). In STG, asthma occurred in 13.7% of patients without asthma before index versus 20.6% in the CG and a logistic regression allowed to conclude that this rate was significantly lower in STG (p<0.0001). For patients with asthma, with a median reduction of 50% of asthma MD during analysis period, STG presented a significant reduction compared to CG which remained stable over time on this endpoint (p<0.0001). CONCLUSIONS: GP SLIT tablets significantly reduced AR progression after treatment cessation, asthma occurrence and progression during and after treatment cessation, as assessed by MD. These real-life data confirms a previous German study and reinforces SLIT tablets overall value.

PRS3: EVALUATION OF ANTI-ASTHMATIC POTENTIAL OF ARTEMISIA PALLENS WALLS IN OVALBUMIN-INDUCED AIRWAY HYPERRESPONSIVENESS IN LABORATORY RATS

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OBJECTIVES: To evaluate the anti-asthmatic potential of Artemisia pallens methanol extract (APME) in ovalbumin (OVA)-induced airway hyperresponsiveness (AHR) in laboratory rats. METHODS: The methanolic extract of aerial parts of Artemisia pallens (APME) was prepared. The AHR was induced in the male Wistar rats by intraperitoneal (i.p.) injection of OVA. Rats received treatment of either APME (100, 200, and 400 mg/kg, p.o.) or vehicle from next 28 day. Various behavioral, biochemical, molecular and histopathological parameter were assessed. RESULTS: Treatment with APME (200 and 400 mg/kg) showed the significant restoration (p < 0.001) in altered lung function test, hematology, and bronchoalveolar lavage fluid (BALF) cellular count. OVA-induced alteration in oxido-nitrosative stress and IgE level was significantly restored (p < 0.001) by APME treatment. APME (400 mg/kg) treatment significantly up-regulation (p < 0.001) in nuclear factor erythroid 2-related factor 2 (Nrf2) mRNA expression, whereas it significantly down-regulated (p < 0.001) tumor necrosis factor-α (TNF-α), interleukin (IL)-1β, IL-4, IL-6 and Transforming growth factor-beta (TGF-β) mRNA expressions. Histological alteration induced in the lung by OVA was ameliorated by APME. CONCLUSIONS: APME has suppressive properties for the pathogenesis of AHR through modulation of oxido-inflammatory genes.

PRS4: EFFICACY OF INDACATEROL/GLYCOPYRRONIUM IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: SYSTEMATIC REVIEW AND META-ANALYSIS
OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is the fourth most common cause of death globally, and is expected to be the third by 2030. New therapies have been recently included for its treatment highlighting the need to compare their efficacy and safety. We wanted to establish the efficacy and safety of indacaterol/glycopyrronium (IND/GLY) as maintenance therapy for moderate to severe COPD. METHODS: Following local (IETS) guidelines, 8 databases were searched; free terms and controlled vocabulary were used. A meta-analysis of direct comparisons between IND/GLY and other first line drugs was performed. Main outcomes were Trough FEV1, health status (SGRQ), dyspnea (TDI) and adverse events. The outcomes were compared using risk ratios (RR) weighted by sample size. 95% confidence intervals (95% CI) were calculated for each comparison. RESULTS: Of the 85 references evaluated, 12 were included for data extraction. Statistically significant differences were found between IND/GLY and tiotropium for Trough FEV1 70.7 ml (95% CI: 40.4-101.0) vs 64.2 ml (95% CI: 36.4-92.1) and SGRQ -2.68 (95% CI: -3.92--1.44). Compared with salmeterol/fluticasone, IND/GLY had a statistically significant difference in Through FEV1 90 ml (95% CI: 60-120). IND/GLY showed higher efficacy over other first line therapies. Compared to monocomponents, IND/GLY showed statistically significant advantage. No differences were found on safety. No serious risk of bias was identified in the trials included. CONCLUSIONS: IND/GLY showed favorable differences in efficacy compared with all comparators. There were no statistically significant differences in safety. IND/GLY demonstrated higher efficacy than standard therapy for moderate to severe COPD.

PRS5: CLINICAL EFFECTIVENESS OF SMOKING CESSATION THERAPY DURING PREGNANCY

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OBJECTIVES: This aim of this study is to assess the clinical effectiveness of smoking cessation interventions available to women during pregnancy, both pharmacological and non-pharmacological (psychosocial). METHODS: Searches were carried out for recent systematic reviews of eligible smoking cessation interventions in women during pregnancy. Two systematic reviews relevant to this HTA were identified, both Cochrane Reviews. These reviews were subsequently updated with additional studies that have emerged since the original review was published. Electronic searches were conducted in Medline, Embase and the Cochrane Register of Clinical Trials to identify RCTs comparing any eligible smoking cessation intervention in women during pregnancy to another eligible intervention or to no treatment. RESULTS: A total of 73 relevant studies were identified, published between 1976 and 2016. The studies broadly support the view that smoking cessation interventions are effective in pregnancy. NRT is the only pharmacotherapy licensed for use in pregnant smokers who wish to quit, and its efficacy appears to be lower in pregnant smokers than in non-pregnant smokers. Eight trials investigated NRT use as a smoking cessation aid in pregnancy, and they were deemed of high quality. Some evidence of a beneficial effect was found for NRT in this group with a 41% increase in cessation rates, but this did not reach statistical significance. The review identified 64 studies evaluating psychosocial interventions for smoking cessation in pregnancy. However, these were rated as being of low quality. There was some evidence to suggest that counselling, health education and financial incentives increase cessation rates in pregnant smokers. CONCLUSIONS: Pregnant smokers should be offered a psychosocial intervention in the first instance. However, due to the limited effectiveness of interventions in pregnancy, smokers should be encouraged to quit prior to conception when more treatment options are available and therapy is more likely to succeed.

PRS6: CLINICAL OUTCOMES OF THEOPHYLLINE USE AS ADD-ON THERAPY IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A PROPENSITY SCORE MATCHING ANALYSIS

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OBJECTIVES: To examine clinical outcomes of theophylline use in COPD patients receiving ICS+LABA. METHODS: Electronic data from 5 hospitals located in northern Thailand between January 2011 and December 2015 were retrospectively collected. Propensity score matching (2:1 ratio) technique was used to minimize confounding factors. Primary outcome was overall exacerbations. In addition, secondary outcomes were all-cause hospitalizations, and pneumonia were also evaluated. Cox’s proportional hazards models with potential confounders adjusted were used to estimate adjusted hazard ratio (aHR) and 95% confidence interval (CI). RESULTS: After propensity score matching, of 711 patients with COPD; 474 used theophylline and 237 non-theophylline users (mean age, 70.1 years; 74.4% male, 60.8% severe COPD) were included. Mean follow-up time was 2.26 years.
Theophylline was significantly increase risk of overall exacerbation (aHR 1.48, 95%CI 1.11-1.96; p=0.008), and tend to increased pneumonia (aHR 1.28, 95%CI 0.89-1.84; p=0.185) and all-cause hospitalizations (aHR 1.03, 95%CI 0.80-1.33; p=0.795). CONCLUSIONS: Theophylline use as add-on therapy to ICS and LABA in COPD patients was increased risk of overall exacerbation. Therefore, prescribing of theophylline in COPD patients should be caution. Further large prospective study of theophylline use in both safety and efficacy issues was warranted.

**PRS7: COMPARING INHALED CORTICOSTEROIDS AND LONG-ACTING BETA AGONISTS COMBINATION TO INHALED CORTICOSTEROIDS ON RISK OF ISCHEMIC CARDIOVASCULAR DISEASES IN PATIENTS WITH ASTHMA**

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OBJECTIVES: Despite inhaled corticosteroids and long-acting beta agonists (ICS-LABA) combination treatment is commonly practiced for patients with asthma, only randomized controlled trials (RCT) on safety in ischemic cardiovascular diseases (ICVD) were conducted while real-world studies are scarce. This study aimed to compare the ICVD risk in ICS and ICS-LABA treatment groups using real-world data. METHODS: Retrospective cohort study was conducted using National Sample cohort data provided by the South Korea National Health Insurance Service. Study patients included those from the age of 40 with new diagnosis of asthma and prescriptions of ICS or ICS-LABA between January 1, 2010 and September 30, 2013. Patients were excluded if they were prescribed with ICS or ICS-LABA or diagnosed with ICVD within one year prior to their index dates, which was the date of first prescription of ICS or ICS-LABA. Eligible patients were observed for 90 days from their index dates. The incidence rate and crude and adjusted odds ratios (OR) of ICVD associated with ICS-LABA compared to ICS were estimated with 95% confidence intervals. Patients were adjusted for CCI, hypertension, age group, and gender. RESULTS: The cohort included 1,839 patients: 1,401 patients (76.2%) treated with ICS-LABA and 438 patients (23.8%) treated with ICS. The crude incidence rate was 1,273.7/10,000 person-years for ICS-LABA group while that of ICS group was 1,018.5/10,000 person-years. Compared to ICS, crude OR for ICVD was 1.259 (95% CI: 0.644-2.458), while adjusted OR was 0.965 (95% CI: 0.487-1.915) in ICS-LABA group. The result showed no statistical significance. CONCLUSIONS: The unadjusted and adjusted risk of ICVD in ICS-LABA group compared to ICS group did not show significant difference, which corresponded to the result from previous study that systemically reviewed RCT's. More real-world studies considering patients' pre-existing cardiovascular diseases should be conducted in order to reflect various conditions in patients with asthma.

**PRS8: ESTIMATING THE PROPORTION OF PATIENTS DIAGNOSED WITH ALLERGIC RHINITIS, AT RISK OF DEVELOPING ASTHMA**

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OBJECTIVES: Continuous exposure to allergens can trigger the development of allergic rhinitis (AR) and asthma. This study estimates the proportion of patients with AR at risk of developing asthma, and how many of those patients have allergen specific diagnoses. METHODS: The study was performed using The Health Improvement Network (THIN), a UK primary care database. Patients were selected using Read codes indicating a diagnosis of AR, and included if they had at least 12 months medical history prior to AR diagnosis. Patients were excluded if a Read code indicated diagnosis of asthma prior to that of AR. The medical notes of 200 randomly selected patients were examined for the mention of key terms and their misspellings, to identify allergen-specific AR. RESULTS: The THIN population comprised 13,217,187. In total, 940,259 (7.1%) patients had ever been diagnosed with AR. Of these, 786,727 (83.7%) were registered in THIN for at least 12 months prior to AR diagnosis date. There were 593,471 (75.4%) patients identified as being at risk of developing asthma. Ten of the 200 randomly sampled patients (5.0% (95% confidence interval (CI) 2.7-9.0) had a record of sensitization to any specific allergens included in free text fields, and four (2.0% (95% CI 0.8-5.0)) denoted sensitization to grass pollen. CONCLUSIONS: A large number of patients with AR are at risk of developing asthma. Only a small proportion of patients with AR at risk of developing asthma, have allergen-specific diagnoses.

**PRS9: FACTORS ASSOCIATED WITH MULTI-DRUG RESISTANT TUBERCULOSIS INCIDENCE IN GHANA: A 1:2 UNMATCHED CASE CONTROL STUDY, 2017**


Theophylline use as add-on therapy to ICS and LABA in COPD patients was increased risk of overall exacerbation. Therefore, prescribing of theophylline in COPD patients should be caution. Further large prospective study of theophylline use in both safety and efficacy issues was warranted.
OBJECTIVES: Multi-drug resistant TB has emerged a major threat to global TB control efforts with high reported cases in Ghana in recent times. However, limited epidemiological information to guide decision making in our context exist. This study aimed to determine factors associated with MDR-TB incidence to inform policy. METHODS: We conducted 1:2 unmatched case-control study. MDR-TB case patient was MDR-TB client diagnosed by Culture and Drug Sensitivity Testing between January 2013 to December 2016 and alive at time of study. Control was susceptible TB client diagnosed January 2013-December 2016 who completed treatment, cured and alive at time of study. We interviewed participants on socio-demographic, treatment compliance, social support, Health system support and program protocol adherence exposures using digitized structured questionnaire on TBcare mobile app (Davies-Teye et al, 2016) and geospatially mapped residence of participants. Data collected was sent to an online platform from where excel template exported to STATA 13/SE was managed and multiple logistic regression analysis done. RESULTS: The cumulative Incidence of MDR-TB in Greater Accra region, Ghana 2013 – 2016 was 1.4/100,000 population with Case fatality of 14.5%. Logistic regression analysis (95% confidence interval) showed clients previously treated for drug sensitive TB (AOR=308.52, CI 4.51 – 21097.65), interrupting CAT1 treatment ≤ 2months (AOR= 20.61, CI 1.50-283.19), defaulting CAT1 treatment > 2months (AOR=0.016, CI 0.0019-1.3333), previous treatment with only CAT1 medication (AOR=0.092, CI 0.0116-0.7384) and having end of treatment sputum testing (AOR=0.0582, CI 0.0107-0.3180) were associated with MDR-TB infection. However, males (OR=2.5, CI 0.811-8.612), loss of job (OR= 2.7, CI 1.07- 6.99) and receiving both CAT 1 & 2 medications (OR= 19.94, CI 4.01-99.26) only associated with bivariate analysis. CONCLUSIONS: Contrary to school of thought that physician errors are main factors to MDR-TB development, this study showed patient non-compliance to medication as major factor to disease infection our setting.

PRS10: RISK OF ACUTE EXACERBATION AND SEVERE ACUTE EXACERBATION ASSOCIATED WITH DIFFERENT SEVERITIES OF COPD AT DIAGNOSIS: A PROSPECTIVE COHORT STUDY IN KOREA

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OBJECTIVES: Recent studies suggest decline of lung function in COPD occurs in the earlier course of disease than previously thought, which suggest need for implementation of aggressive testing to avoid delay in diagnosis and respective initiation of treatments. This study aimed to assess the difference in health outcomes, specifically acute exacerbation and severe acute exacerbation between the patients diagnosed at varying severities of COPD. METHODS: This prospective cohort study used the National Health Insurance Service-National Sample Cohort(NSC) to enroll newly diagnosed COPD patients with varying disease severities of mild, moderate and severe COPD between 2006 and 2007, then the patients were followed up until the events of acute exacerbation and severe acute exacerbation or until 31st December 2013. RESULTS: Total of 1,280 patients (685 patients diagnosed as mild COPD, 383 patients diagnosed as moderate COPD, 212 patients diagnosed as severe COPD) was enrolled to the study. When compared to patients diagnosed as mild COPD, the risk of acute exacerbation was higher for patients diagnosed as moderate COPD (unadjusted HR: 1.13, 95% CI: 0.70-1.82; adjusted HR: 1.07, 95% CI: 0.72-1.59) and more dramatically with patients diagnosed as severe COPD (unadjusted HR: 2.45, 95% CI: 1.54-3.88; adjusted HR: 2.12, 95% CI: 1.43-3.14). The risk of severe acute exacerbation was also higher for patients diagnosed as moderate COPD (unadjusted HR: 1.45, 95% CI: 0.99-2.13; adjusted HR: 1.36, 95% CI: 0.94-1.96) and for the patients diagnosed as severe COPD (unadjusted HR: 2.94, 95% CI: 2.02-4.29; adjusted HR: 2.56, 95% CI: 1.77-3.71) as compared to mild COPD patients. CONCLUSIONS: The risk of acute exacerbation and severe exacerbation was increased in patients diagnosed as moderate COPD and more dramatically with patients diagnosed as severe COPD when compared to patients with mild COPD at diagnosis, which may contribute as an evidence to enhancing importance of early diagnosis in COPD.

PRS11: RISK FACTORS OF ASTHMA AND THEIR ROLE IN TRIGGERING THE ASTHMATIC ATTACK

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OBJECTIVES: There is an increasing interest in understanding what the asthma risk factors are, and their frequency in triggering asthma attacks in Pakistan. So the main aim is to evaluate the frequency of risk factors triggering the asthmatic attack. METHODS: Retrospective study was done. Hospital and community based cross-sectional study was conducted from February 2015 to June 2015 in Bahawalpur. Total 341 patients were approached using systemic sampling method while only 209 patients participated in the study. Questionnaire consisted of 3 parts including, demographic information, triggering risk factors, and use of precautionary measures. Summarization of data was accomplished by descriptive statistics. Complete analysis was done using SPSS version 16.0. RESULTS: Out of 209, 109 (52.1%) were males and 100 (47.9%) were females with the overall average mean age ± SD of 22.29 ± 13.49
years. Dust factor being the leading cause that triggers the asthmatic attack in 195 (93.3%) patients followed by pollution 168 (80.3%), seasonal factors 135 (64.6%), smoking 104 (49.7%), cold air 71 (34%), occupational chemicals 39 (18.6%), pet animals 34 (16.3%), stress 20 (9.5%), cockroaches 17 (8.1%) and the least affecting factor was medicine use affecting 6 (2.9%). Furthermore, only 46 (22%) patients used precautionary measures and confirmed its effectiveness in preventing the asthmatic attack when they were exposed to the risk factors. Out of 192 who were prescribed with the inhaler only 59.4% patient can use inhaler effectively and 88.5% keep it with them while traveling to prevent the worsening of asthmatic attack. CONCLUSIONS: Asthma is not a fatal disease but can prove fatal by negligence. Avoidance of risk factor is the primary care in asthma. The use of the precautionary measures was proved to be of great importance in preventing asthma. The use of inhalers was also prescribed but many patients were unable to use them correctly leading to their therapeutic failure.

**RESPIRATORY-RELATED DISORDERS - Cost Studies**

**PRS12: BUDGET IMPACT OF A NEW, FIRST-IN-CLASS TRIPLE FIXED DOSE COMBINATION THERAPY FOR COPD PATIENTS**

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**OBJECTIVES:** The 2017 GOLD Report recommends triple therapy with an inhaled corticosteroid, a long acting beta2 agonist, and a long acting muscarinic antagonist for symptomatic chronic obstructive pulmonary disease (COPD) patients who continue to experience exacerbations. Multiple inhalers are currently required to administer triple therapies; posologies or device type may differ, potentially reducing adherence. A first-in-class triple fixed dose combination (FDC) containing beclomethasone dipropionate, formoterol fumarate and glycopyrronium in an extra fine formulation and a pMDI inhaler with dose counter, is indicated as maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. This study estimates the budget impact of the new FDC therapy in the UK. **METHODS:** A budget impact model was developed, using national population statistics and COPD epidemiology data to identify triple therapy eligible patients. Patients were assigned to different COPD therapies, for the “world with” and “without” triple FDC, and a five-year forecast was developed based on current and prospective potential market shares. For each therapy the associated drug acquisition cost, and rate and cost of severe (requiring hospitalization) or moderate exacerbations was applied. **RESULTS:** The analysis demonstrated that the introduction of triple FDC would produce savings in each of the five years. Over this time period, depending on the level of uptake of the triple FDC (10%, 20% and 30% uptake at 5 years assessed), the net cumulative budget impact is estimated to be a saving ranging from approximately £31 to £95 million. Savings arise from displacing more expensive open triple therapies and from reducing the exacerbation rate and related costly hospitalizations. **CONCLUSIONS:** The new COPD triple FDC therapy is predicted to have a positive budget impact, delivering savings through both reduced drug acquisition costs and reduced morbidity.

**PRS13: BUDGET IMPACT ANALYSIS OF SAME AND MIXED BUDESONIDE AND FORMOTEROL INHALERS IN THE TREATMENT OF ASTHMA IN RUSSIAN FEDERATION**

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**OBJECTIVES:** To assess the economic benefits of a change in therapy with separate inhalers of budesonide and formoterol via same devices to therapy with mixed devices of budesonide and formoterol. **METHODS:** Information search was conducted in the public domain. Pharmacoeconomic analysis method – budget impact was performed. The study had a time horizon of a one year. We compared costs for patients prescribed the same inhaler for budesonide and formoterol (budesonide via Easyhaler, formoterol via Easyhaler) versus mixed inhalers: budesonide via Easyhaler and formoterol via Turbuhaler, Aerolizer or Modulit (Atimos). Cost consist of cost of basic pharmacotherapy, compensation costs for treatment of exacerbations (hospital visits and courses of oral corticosteroids), compensation costs for treatment of lower respiratory tract infection. **RESULTS:** The total direct cost per patient with asthma amounted to EUR 2,046 to same devices group and EUR 2,577 on average to mixed devices group. Prescription of the same devices to 1000 patients resulted in additional budget expenditures of EUR 511,213 per year, compared with mixed inhalers. **CONCLUSIONS:** Using of same separate inhalers of budesonide and formoterol is associated with potential economic savings when compared to therapy regimens involving mixed devices in Russian Federation.

**PRS14: BUDGET-IMPACT OF SELEXIPAG FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) IN GREECE**
**PRS15: THE COST OF TIOTROPIUM 5MCG + OLODATEROL 5MCG IN THE MANAGEMENT OF COPD IN GREECE**

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**OBJECTIVES:** To estimate the annual cost of COPD management in Greece with and without the use of tiotropium 5mcg + olodaterol 5 mcg ( Spiolto® Respimat®). **METHODS:** A cost minimization model was developed in Excel 2010® , which estimated the annual per patient cost of COPD management by treatment. Only direct medical costs were included in the analysis. The model took into consideration three cost categories: pharmaceutical costs, cost of exacerbations and other disease management costs (including hospitalization, patient follow-up and lab and imaging tests). Resource use data were obtained from Greek published studies, as well as the international literature when necessary. Drug acquisition costs were estimated based on the Price Bulletins issued by the Ministry of Health. All unit costs were taken from officially published sources. The cost base year was 2016 and the perspective adopted was that of the National Organization of Health Care Services Provision (EOPYY). **RESULTS:** The estimated annual per patient cost to EOPYY for the management of COPD ranged between €1,443.1 and €1,642.4. Thirty-three percent of total costs was attributed to pharmaceutical treatment, 31% was associated with the management of exacerbations, and the remaining 36% was associated with patient monitoring and follow-up costs. The annual per patient cost of Spiolto® Respimat® was estimated at €1,568.9, which was lower than the respective cost of other new generation drugs, such as Ultibro® Breezhaler® (€1,614.4), Anoro® Ellipta® (€1,614.4) and Duaklir® Genuair® (€1,642.4). In addition, the annual cost of Spiolto® appeared to be comparable with the cost of older COPD drugs, since although it increased pharmaceutical costs, it reduced other cost components, such as exacerbation costs. **CONCLUSIONS:** The introduction of tiotropium 5mcg + olodaterol 5 mcg in the management of COPD in Greece is anticipated to have a manageable budget impact to EOPYY.

**PRS16: EVALUATING THE ANNUAL COST PER RESPONSE RATE OF PIRFENIDONE AND NINTEDANIB FOR THE TREATMENT OF PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS**

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**OBJECTIVES:** The current clinical practice for the management of patients with Idiopathic Pulmonary Fibrosis (IPF) includes two alternative therapeutic options, pirfenidone and nintedanib. The analysis aimed at evaluating their efficiency within the Greek healthcare system by comparing their annual cost per response rate from a payer’s perspective. **METHODS:** In assessing the efficiency of the two therapeutic options, the cost per response rate was estimated to reflect the annual drug cost for achieving a rate of decline not more than 10 percentage points in the % predicted FVC, an endpoint consistent with a slowing of disease progression and clinical stabilization. Clinical data for
the IPF patient populations of mild-to-moderate physiological impairment were derived from pirfenidone’s ASCEND & CAPACITY 1 & 2 trials (weighted average) and nintedanib’s INPULSIS 1 & 2 trials. For each therapeutic option, respective costing data of drug acquisition were obtained from official government sources (values in €, 2017). **Results:** The analysis estimated that the annual costs to achieve clinical stabilization was €27,856 and €31,802 with pirfenidone and nintedanib, respectively. The difference in the annual cost per response rate between the two alternatives was in favor of pirfenidone with generated savings of €3,947 (€31,802 vs €27,856). For the treated IPF patient population, results indicate that the savings realized from treating patients with pirfenidone instead of nintedanib could be invested in covering the annual cost for 17% more IPF patients receiving therapy with pirfenidone or for 14% more IPF patients reaching clinical stability. **Conclusions:** Within the Greek healthcare environment of scarce resources and significant budget constraints, the annual cost per response rate indicates that pirfenidone constitutes a cost-saving therapeutic alternative to nintedanib for the treatment of patients with mild-to-moderate IPF and yields sufficient savings to treat and stabilize disease progression for more patients compared to its competitor.

**PRS17: SYSTEMATIC REVIEW ON ECONOMIC IMPACT OF AIR POLLUTION ON HEALTH**

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**Objectives:** The impact of the exposures to air pollution can be seen from both health and economical perspective. This review study synthesizes available literatures that related to the financial implications of air pollution on human’s health. **Methods:** The databases used to find the relevance articles were PubMed, Scopus and Web of Science. Online databases were searched until April 2017. Searching strategies were done using Mesh terms and identified keywords for each databases. The articles were limited to English language and journal articles only. Articles on indoor air pollution or from review papers, proceedings and reports were excluded from this review. From initial search of 2095 articles, 268 duplicate articles were removed. After reviewing titles and abstracts, 36 articles fulfilled our inclusion and exclusion criteria to be included in this review. **Results:** Effects of air pollution on health cause significant increased in healthcare utilization. For every increased in particulate matter 10-2.5, there were 0.3% to 3.7% increased in hospital admissions and outpatient visits due to air pollution related illnesses. The effects were more prominent in short-term, high level of particulate matter exposures. The financial implications of haze on health were measured using cost of illness (COI) and willingness to pay (WTP) approaches. It was calculated from either provider’s perspective, patient’s perspective or combination of both. The financial implication of haze on health measured using WTP was higher because it included preventing, averting, mitigating and utility loss due to illness. The ratio of monetary values of economic impact of air pollution on health calculated using WTP to COI were ranging from 1.5:1 to 9:1. **Conclusions:** The monetary burden due to the economic loss and increase in healthcare expenditure was very significant. We need to allocate appropriate resources to reduce air pollution level and to meet the healthcare demand associated with it.

**PRS18: A COST-OF-ILLNESS ANALYSIS FOR COMMUNITY ACQUIRED PNEUMONIA IN GREECE**

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**Objectives:** Community acquired pneumonia (CAP) is accompanied by a high clinical and economic burden, especially when patients’ condition requires hospitalization. The purpose of the present analysis was to estimate the mean direct outpatient and inpatient cost of CAP episodes in Greece. **Methods:** Data were collected from the Emergency Department of the Sotiria Chest Diseases Hospital. For CAP outpatients, data on diagnostic tests, number of physician visits and medication were collected, while for inpatients, data included diagnostic tests, medication, length of hospital stay, additional tests during hospitalization and discharge instructions. Moreover, it was recorded whether patients of both groups returned for reassessment and if so, whether additional tests and medication were provided. Cost calculations were performed from a third payer perspective (direct costs only) and refer to 2016. **Results:** Overall, 249 patients were included in the analysis, 149 inpatients and 100 outpatients, with a mean age of 55.1 years (SD=18.764). Mean length of hospital stay was calculated at 11.35 days (SD=9.71). For outpatients, mean direct cost was estimated at 110.64€ (SD=58.23) per patient, while for inpatients at 7,406.56€ (SD=12,124.93) per patient. The main driver of the inpatient cost was hospitalisation (94.97%), followed by medication during hospitalisation (3.30%) and diagnostic tests (0.87%). For outpatients, prescribed medication represented the highest proportion of total cost (38.84%), followed by diagnostic tests (33.51%) and physician visits (17.54%). **Conclusions:** CAP imposes a high economic burden on the Greek healthcare system, mainly due to the cost of hospitalisation. Further investigation is required to identify the reasons of the high hospitalisation rates and duration observed in Greece, in order to improve patient management models and reduce, when possible, inpatient care, while maintaining optimum clinical outcomes.
**PRS19: ECONOMIC EVALUATION OF MULTI-DRUG RESISTANT TUBERCULOSIS IN GHANA: PATIENT LEVEL DIRECT COST ANALYSIS 2013 - 2016**

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**OBJECTIVES:** In Ghana, Direct cost of Multi-Drug Resistant (MDR) TB treatment is mainly covered by public sector through Global Fund financing mechanism. This includes economic support of patients to reduce out-of-pocket payment, improve treatment uptake and adherence. In spite of this, MDR-TB patients experience several economic barriers to access healthcare. This study evaluated the direct cost of illness to the patients and determine the adequacy of economic support to inform policy in the Greater Accra Region. **METHODS:** We conducted a census of all MDR-TB patients diagnosed in Greater Region, Ghana from January 2013- December 2016. Reviewed MDR-TB laboratory and treatment registers and identified all MDR-TB client diagnosed during the period. All clients who were alive at time of study and had not been lost to follow up participated in the study. We interviewed participants using digitized structured questionnaire on TBcare mobile app. Data abstracted include demographic, occupation, monthly income, cost of transportation, feeding, consultation, diagnosis, hospitalization, food supplement, medication or treatment and accommodation (if client lost it due to illness). We also abstracted data of direct financial support received from Global fund through Health facility. Data was managed in EPI info 7 to determine per capita direct cost and estimated total direct cost saving to patients. **RESULTS:** Cumulative incidence MDR-TB was 1.4/100,000 with 14.5 percent Case fatality and 16.4 percent lost to follow up. Age ranged 18-58 years with mean 38.6±10.2 and 77.8 percent males. Monthly Income ranged 0.00-1162.80 USD with mean 168.10 USD Direct cost of illness ranged 300.50 – 16,130.20 USD with per capita direct cost of illness 2,202.60 USD which constitutes 109.2 percent of client's annual income. Total Direct cost saving to patients 121,144.50 USD **CONCLUSIONS:** In spite of Global fund economic support, direct cost of illness to MDR-TB patients in the region is still high, constituting 109% of annual income.

**PRS20: IDIOPATHIC PULMONARY FIBROSIS: A COST OF ILLNESS ANALYSIS IN GREECE**

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**OBJECTIVES:** Idiopathic pulmonary fibrosis (IPF) is the most common and severe type of interstitial lung diseases. Low 5-year survival rate, significant deterioration of physical activity and low health-related quality of life are some of its consequences, while the management of the disease is considered costly. Purpose of the present analysis is the estimation of the IPF cost in Greece. **METHODS:** The analysis was based on self-administered questionnaires, which included questions concerning current prescribed medication (substance and dosage), frequency of visits to the treating physicians, laboratory tests and hospitalizations. Questionnaires were collected anonymously by the treating physicians upon patient informed consent. Cost calculations were performed from a third payer perspective (direct costs only) and refer to year 2016. **RESULTS:** Overall, 123 IPF patients were included in the analysis, with a mean age of 71.23 years (SD=7.104). Mean annual direct cost of IPF was estimated at 22,574.20€ (SD=9,606.17€) per patient, primarily driven by the cost of medications (97.80%) and followed by hospitalizations (1.52%), laboratory tests (0.35%) and physician visits (0.33%). Also, 45.0% of the patients stated that they partially participated to their medical expenses concerning IPF, while 2.7% paid the overall expenses on their own. **CONCLUSIONS:** The management of IPF imposes a high economic burden compared to other chronic conditions on both the health system and the patients in Greece. The cost of IPF highlights the necessity to improve the disease management in order to avoid unnecessary expenditures and the insurance coverage in order to secure equal patient access in both the health care services and in outcomes.

**PRS21: ESTIMATING THE EXCESS COSTS OF COMMUNITY-ACQUIRED PNEUMONIA IN ELDERLY PEOPLE IN JAPAN**

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**OBJECTIVES:** In Japan, there are approximately 1.9 million new CAP cases every year, with approximately 70% of cases involving patients who are >65 years old. The purpose of the current study was to estimate the excess costs of CAP in elderly people in Japan. **METHODS:** This study included patients who were ≥65 years old, received any treatment every year from August 1, 2012 to July 31, 2015 obtained from an administrative database maintained by
respectively. The bulk of the hospitalisation costs (82%) was assigned to COPD (HC.1 x HP.1) amounting to 159.2 million (or 4.9% of HC.5.1.1) and 123.0 million (or 1.0% of HC.1 x HP.1), euro. The main cost drivers were prescribed pharmaceuticals, medical devices, and inpatient medical care. Hospital DRG data were used to assign monetary value to the relevant disease categories (J40-J47). Due to missing ICD-coding of the Austrian data of outpatient care, rehabilitation, ambulance and emergency services, we approximated the relevant disease categories via official statistics of DESTATIS. Direct non-medical costs included invalidity pensions, sick leave and informal care allowances. Indirect costs refer to economic productivity losses caused by sick leave, early retirement and premature mortality of the workforce. RESULTS: We estimated direct medical costs of CRD in the year 2014 at 431.1 million euro. The main cost drivers were prescribed pharmaceuticals (SHA-category HC.5.1.1) and in-patient hospitalisations (HC.1 x HP.1) amounting to 159.2 million (or 4.9% of HC.5.1.1) and 123.0 million (or 1.0% of HC.1 x HP.1), respectively. The bulk of the hospitalisation costs (82%) was assigned to COPD, more than half (56%) to the age-
group 65-84 and to males (55%). Direct non-medical costs attributable to CRD totalled 25.2 million. The annual
economic costs were 186.5 million or 0.06% of GDP. In total, we calculated the economic burden of CRD amounting
to 642.7 million euro or 0.19% of GDP in 2014. CONCLUSIONS: The financial burden of CRD in Austria is
substantial. Because COPD is the major cost driver and causally linked to smoking, these social costs are largely
preventable.

PRS24: ESTIMATING THE LIFETIME TOTAL ECONOMIC COSTS OF RESPIRATORY DISEASE IN BEEF AND DAIRY CALVES IN THE UK
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BACKGROUND: Penetration of calf respiratory disease vaccination in the UK is low (estimated 25% of dairy calves
and 35% of beef calves). Market research indicates that an important barrier to vaccination is a limited understanding
of costs of calf respiratory disease across the lifetime of the animals. OBJECTIVES: To estimate the lifetime total
economic cost of calf respiratory disease in beef and dairy cattle. METHODS: Separate analyses were conducted for
dairy heifer (DH), dairy-bred beef (DBB) and beef suckler (BS) calves. Analyses considered costs at the individual
animal level from the perspective of the producer. Effects on expenditure (additional resources) and losses (decrease
in production) were derived from the published literature. Contemporary (2015) valuations were applied using data
mainly from Agriculture and Horticulture Development Board (AHDB). RESULTS: The total cost included the
immediate costs of calf respiratory diseases and the subsequent impact on productivity across the animal’s life course.
In DH calves this included a 2-week delay to first calving, 4 and 8% reduction in first and second lactation milk yields
respectively, and a lifetime reduction of 109 days in milk due to reduced longevity in the herd. In DBB and BS calves
costs were compared to target to finish at 22 (DBB) or 16 (BS) months of age and included 72 and 202g reduction in
daily liveweight gain for moderate and severe/chronic respiratory disease respectively, and impaired carcass quality.
The costs of impaired lifetime productivity exceed the immediate costs of calf respiratory disease. The estimated total
economic lifetime cost of respiratory disease was: £772 (DH); £131 (DBB moderate) £327 (DBB severe); £128 (BS
moderate); £263 (BS severe). CONCLUSIONS: Calf respiratory disease leads to significant immediate and
subsequent lifetime productivity economic costs. These cost estimates have potential to inform partial budget models
to assess the incremental net benefit of vaccine interventions.

PRS25: EVIDENCE MAP OF COSTS STUDIES IN CYSTIC FIBROSIS SINCE 2000
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OBJECTIVES: To create an evidence map of studies reporting the direct and indirect costs associated with cystic
fibrosis, and the geographical settings in which these studies were conducted. METHODS: We searched the
We analysed the abstracts identified by the search to determine the different types of costs reported across the range
of geographical locations and interventions. We presented the findings as an evidence map. RESULTS: We found a
total of 60 abstracts. Of these, 58 reported direct costs from 11 countries and seven reported indirect costs from five
countries. The most common setting was the United States, with 15 abstracts, followed by the UK (13), Australia (7),
Canada (6), Germany and France (3 each), the Netherlands (2) and Brazil, Denmark and New Zealand (1 each).
Nine studies were reviews of the international literature. Fourteen studies reported costs of healthcare in general.
Specific interventions studied included prenatal or neonatal screening (18 abstracts), antibiotics for respiratory
infections (usually Pseudomonas, 11 abstracts), rhDNase and lung transplants and associated treatments (4
abstracts each). Twenty five abstracts were economic models and 24 were cost studies. CONCLUSIONS: As with
many diseases, there is a relative lack of published data on indirect costs of cystic fibrosis, and two-thirds of studies
reporting cost data were from just four jurisdictions: Australia, Canada, the UK and the USA.

PRS26: EARLY MODELLING OF THE COST-EFFECTIVENESS OF STRATIFIED MEDICINE IN COPD
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OBJECTIVES: To develop a health economic model that included a great diversity of COPD patient and disease
characteristics and multiple intermediate outcomes, which can be used to inform stratified medicine in
COPD. METHODS: Relevant patient characteristics and outcomes were included in the model after three literature
reviews on: 1) multidimensional prognostic COPD indices, 2) COPD phenotypes, and 3) treatment effects in
subgroups. Based on this a draft conceptual model was constructed and discussed with a panel of seven COPD
experts. A patient-level simulation model was developed using the baseline patient population of five large COPD
direct cost (confidence interval 95%) was €7,393 (6,509 to 8,546) per hospital stay of 10.9 days/patient. Mean sick leave due to severe asthma (mean: 1.9 exacerbations/patient), of whom 22 patients required hospitalization, with a mean of 1.7 exacerbations/patient. A scenario analysis in which lung function decline was decreased by 20% in the overall population led to an increase in life expectancy of 0.60 years and a gain in QALYs of 0.41. CONCLUSIONS: The developed model can be used to calculate outcomes and evaluate treatment options for a wide variety of subgroups. It can also provide valuable information to guide research and development of new treatment options in an early stage by showing the possible impact of new treatments on a range of outcomes.

PRS27: EVALUATING THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATION OF BACTERIAL PNEUMONIA IN THE US DEPARTMENT OF DEFENSE POPULATION

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OBJECTIVES: Among military personnel, bacterial pneumonia (BP) is the most common respiratory infection for hospital admissions, associated with a significant economic burden in the United States. We examined the economic burden and health care utilization (HRU) of BP in the US Department of Defense (DoD) population. METHODS: Patients diagnosed with BP were identified (International Classification of Diseases [ICD], 9th Revision, Clinical Modification diagnosis code 482.9: ICD-10: J15.9) using DoD data from 01OCT2011-30SEP2016. The first diagnosis date was designated as the index date. A comparison cohort was created for non-BP patients with the same age, gender, race, and index year—as well as similar baseline Charlson Comorbidity Index scores—as the disease cohort. The index date was chosen randomly for the comparison cohort to minimize selection bias. Patients in both cohorts were required to have continuous medical and pharmacy benefits 1 year pre- and post-index date. Study outcomes, including HRU and costs, were compared between the disease and comparison cohorts based on the matched sample. RESULTS: Eligible patients (N=6,342) with and without BP were identified. After 1:1 propensity score matching, 4,655 patients were identified in each cohort with well-balanced baseline characteristics. Patients with BP were more likely to report a greater mean number of inpatient (0.5 vs 0.1 visit, p<0.001), emergency room (ER; 1.3 vs 0.5 visits, p<0.001), ambulatory (23.2 vs 12.3 visits, p<0.001), and pharmacy (14.0 vs 9.0 visits; p<0.001) visits. Higher all-cause health care costs were observed among BP patients, including mean inpatient ($7,736 vs $1,582; p<0.001), ER ($816 vs $310; p<0.001), ambulatory ($6,994 vs $3,403; p<0.001), pharmacy ($2,146 vs $881; p<0.001), and total costs ($17,692 vs $6,176; p<0.001). CONCLUSIONS: During a 12-month period, DoD patients diagnosed with BP reported higher HRU and costs than their matched controls.

PRS28: ECONOMIC IMPACT OF SEVERE ASTHMA IN SPAIN: OBSERVATIONAL LONGITUDINAL MULTICENTER STUDY

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OBJECTIVES: Severe asthma is responsible for a considerable amount of the burden associated with asthma. This study aimed to estimate the economic impact of severe asthma from the Spanish societal perspective through the annual estimation of the associated direct and indirect costs. METHODS: Observational, longitudinal, retrospective, multi-centre study carried out in 20 Spanish secondary settings (Pulmonary and Allergy Services) among a representative sample of patients aged ≥18, diagnosed with severe asthma according to ERS/ATS consensus and who have not experienced an exacerbation in the previous 2 months. Asthma-related healthcare resource utilization (routine and emergency visits, hospitalizations, tests, pharmacologic treatment) as well as asthma-related days off work were collected over a retrospective 12-month period from medical records review (inclusion period: June to November 2016). Total costs were calculated by multiplying the natural resource units used within 1 year by the corresponding unit cost (€ 2017). RESULTS: 303 patients were included, mean age was 54.3 years and 66.7% were women. There were 5.7 physician visits per patient (3.3 in secondary care) The most common pharmacologic treatment was fixed dose combination of β2-adrenergic antagonists/inhaled glucocorticoids (96.7%), followed by leukotriene receptor antagonists (57.1%) and biologic treatment (omalizumab) (39.3%). 139 patients (45.9%) had at least one exacerbation (mean: 1.9 exacerbation/patient), of whom 22 patients required hospitalization, with a mean hospital stay of 10.9 days/patient. Mean sick leave due to severe asthma was 9.15 days per patient. Mean annual direct cost (confidence interval 95%) was €7,393 (6,509-8,514) per patient. 62.4% of the cost was due to omalizumab
treatment. The cost per exacerbation was €1,195/patient. When indirect costs were added (€856/patient (476-1,573)), the total annual mean cost rose to €8,250/patient (7,193-9,733). **CONCLUSIONS:** The economic impact of severe asthma in Spain amounts to 8,250€/patient from the societal perspective.

**PRS29: DISEASE-RELATED COST BURDEN IN PATIENTS UNDERGOING SINUS SURGERY FOR CHRONIC RHINO SINUSITIS: A CLAIMS-BASED ANALYSIS**

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**OBJECTIVES:** We sought to quantify the cost burden and healthcare utilization in chronic rhinosinusitis (CRS) patients, with and without nasal polyposis (CRSwNP and CRSsNP), who require treatment with endoscopic sinus surgery (ESS). The additive contributions of nasal polyposis (NP) and revision surgery to 1-year costs were also evaluated. **METHODS:** Data from 2012-2015 were extracted from the Blue Health Intelligence database. Adult patients (age 18-64) having ESS (ethmoidectomy CPT 31254 or 31255) for CRS, with index visits of <1 week and medical and pharmacy enrollment for ≥1 year pre- and post-index surgery were included. Related healthcare utilization was defined as any visit with a primary diagnosis of CRS, acute sinusitis, or NP, or any prescription from a therapeutic category commonly used to treat CRS or related comorbidities. The primary outcomes included one-year revision rates and one-year medical and pharmacy expenditures. **RESULTS:** A total of 23,542 patients met all inclusion criteria (mean age 44; 50% male), and 9,665 (41.1%) also had NP. The revision ESS rate within 1 year was 2.1%, and these occurred twice as often in CRSwNP compared to CRSsNP (3.1% vs. 1.4%). Mean one-year cost of treatment, including the index ESS, was $8,668 for CRSsNP and $10,757 for CRSwNP in patients not requiring revision ESS. For those requiring revision ESS within the first year, mean one-year expenditures increased by $11,186 to $19,853 for CRSsNP and by $13,395 to $24,153 for CRSwNP. **CONCLUSIONS:** In a large commercially insured US population, the disease-related expenditures for patients having ESS for CRS are substantial, as are the additive impacts of NP and revision surgery. CRSwNP doubled the risk of revision surgery in the first year after ESS compared to CRSsNP and cost 24% more, even in the absence of a second procedure.

**PRS30: PREVALENCE AND TREATMENT COST OF NON-COMMUNICABLE DISEASES RELATED TO SMOKING IN INDONESIA**

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**OBJECTIVES:** This study aimed to estimates the current incidence and treatment cost of non-communicable diseases attributed to tobacco among Indonesian population in 2015. **METHODS:** An epidemiological study was performed. Using national universal coverage database in 2015 we calculated the incidence and treatment cost of 19 diseases. Proportion of smoking attribution toward diseases and treatment cost due to smoking were calculated using smoking attributable fraction (SAF) formula, using the prevalence of smoking and relative risk of each disease. **RESULTS:** The study revealed that the incidence of smoking related diseases accounted for 991,331 about 21.6% of total incidence of chronic diseases in Indonesia. The highest rank of diseases prevalence was hypertension, chronic obstructive pulmonary diseases (COPD) and ischemic heart disease. The treatment cost of smoking in Indonesia was conservatively estimated to be at least US$ 2,177 million, approximately 2.5% of the 2015 gross domestic product. A majority of the cost was largely concentrated in the male population (US$2,164 million). Treatment costs of hypertension, COPD, and ischemic heart disease had the highest cost burden. **CONCLUSIONS:** This study finding provides scientific evidence about economic burden of smoking, particularly the healthcare expenditure covered by government. Tobacco control efforts need to be prioritized in to prevent higher losses of the nation. This study’s evidence is important for informing national public health policy to advocate the health promotion and prevention program.

**PRS31: COST-BENEFIT ANALYSIS OF A SMOKING CESSION PROGRAM FUNDED BY THE SPANISH NATIONAL SYSTEM IN PRE-OPERATIVE PATIENTS**

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**OBJECTIVES:** Despite measures to stop smoking leading to a drop in its prevalence, morbidity-mortality due to tobacco use is still high. Patients smoking at the time of surgery are at elevated risk of postoperative complications. Thus, decreasing smoking prevalence is a primary objective for healthcare professionals and authorities yet. The aim was to analyze the efficiency of a smoking-cessation program in pre-operative patients funded by the National Health System (NHS) in Spain. **METHODS:** A cost-benefit analysis was performed from the NHS perspective in year 2016 in
a smoking annual any-type surgery cohort ready to quit smoking. This cohort was identified from the year-2014 national annual hospital discharge report and characterized using published inputs from national health survey. Included costs corresponded to the implementation of the smoking-cessation program, and were medical counselling/follow up and quitting smoking drugs (varenicline, bupropion and nicotine-replacement-therapy), which are not funded currently. Benefits were considered healthcare costs avoided due to postoperative complications averted as a consequence of smoking cessation, at least, 8-weeks before surgery. Net cost-benefit, return-of-investment (ROI) and benefit per averted smoker were computed. RESULTS: Assuming a composite effectiveness of 21%, the funded program would produce 8,368 extra quitters and would achieve a total net cost-benefit of €3.1 million per year of implementation. Given the annual total cost of the program (€12.6 million of which €4.4 correspond to drugs), the ROI was 24% annually (€1.24 of benefit per €1 of investment). The average cost per additional averted smoker was €1,511 with a net healthcare benefit of €366 per patient. Univariate sensitivity analyses were robust and sensitive to the incremental use of varenicline (better cost-benefit). CONCLUSIONS: From the NHS perspective in Spain, the benefit of funding smoking-cessation in pre-operative patients, in terms of healthcare costs savings are far greater than the costs, with a wealthy return-of-investment.

PRS32: REAL-WORLD COST EFFECTIVENESS COMPARISON OF SYMBICORT TURBUHALER AND DUORESP SPIROMAX IN UK PATIENTS WITH ASTHMA OR CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To compare economic outcomes between patients with asthma or chronic obstructive pulmonary disease (COPD) receiving continuous maintenance inhaled corticosteroid/long-acting beta agonist (ICS/LABA) treatment with Symbicort and those switching from Symbicort to DuoResp. METHODS: This was a historical cohort study using anonymised data from two UK primary care databases, the Optimum Patient Care Research Database and the Clinical Practice Research Datalink. Included patients had ≥2 years of continuous data (1-year baseline pre- and 1-year outcome post-index date). Patients switching to DuoResp were matched (1:3) with those continuing on Symbicort. Mean asthma/COPD-related healthcare costs (medication, primary care and hospital visits) were calculated in 2014 £ and compared between groups, adjusting for confounders. Risk domain control of disease (RDC), a composite measure defining absence of exacerbations, adjusted for rhinitis, was used to assess disease control. Cost-effectiveness was assessed based on total treatment costs and the absolute proportion of patients achieving RDC. RESULTS: Patients who switched to DuoResp had lower baseline respiratory-related costs than the Symbicort group when ICS costs were included (p=0.036). In the outcome year, switching to DuoResp was associated with significantly lower mean costs per patient in total respiratory medication (~£80; p<0.001), primary care consultations (~£13; p<0.001) and total respiratory-related costs including ICS (~£92; p<0.001). The adjusted proportion of patients achieving RDC was 58% for DuoResp versus 54% for Symbicort. Adjusted mean cost was £492 (95% CI: £461, £523) for DuoResp users and £597 (£575, £620) for Symbicort users, for a difference of ~£105 (~£132, ~£78) after adjusting for all baseline costs. Bootstrap sensitivity analysis found DuoResp to be less costly and more effective than Symbicort with 93.7% consistency. CONCLUSIONS: Compared with patients with asthma or COPD continuing Symbicort treatment, those switching to DuoResp demonstrated a favourable cost-effectiveness ratio in the UK primary care setting.

PRS33: COST-EFFECTIVENESS ANALYSIS OF TACROLIMUS AS PRIMARY IMMUNOSUPPRESSION FOR LUNG TRANSPLANT RECIPIENTS IN THE CZECH REPUBLIC

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OBJECTIVES: To assess the cost-effectiveness of tacrolimus as primary immunosuppressive therapy after lung transplantation in comparison with cyclosporine A (CsA) in the Czech Republic. METHODS: A developed 20-year Markov cohort model with one-year cycle length projects outcomes (Quality-Adjusted Life-Years, QALYs; Life-Years Gained, LYGs) and costs of care in lung transplant recipients, including primary prophylaxis of graft rejection, from healthcare payers’ perspective. Model health states are defined by occurrence of acute and/or chronic complication (e.g. rejection, infection) and death. Transition probabilities between health states and corresponding utilities were taken from published literature. Costs associated with organ transplantation, post-transplantation care (including immunosuppressant agents) and managing complications were based on KOLs’ statement and reimbursement lists. Costs and outcomes were discounted by 3%. One-way sensitivity analysis (OWSA) accompanied with scenario analysis (SA) were conducted. Probability sensitivity analysis (PSA; 10,000 iterations) was performed with Czech Willingness-To-Pay (WTP) threshold of €45,000/QALY gained. RESULTS: Tacrolimus compared with CsA demonstrates an incremental cost-effectiveness ratio of €317,103/QALY gained over a 20-year time horizon. Both...
calcineurin inhibitors bring in total 10.924 LYGs and 6.890 QALYs, however, complications associated with tacrolimus- and CsA-based therapy decrease QALYs by 0.359 and 0.573 (i.e. incremental QALYs: 0.214), respectively. Total costs of tacrolimus- and CsA-based therapy are €160,219 and €153,434 (i.e. incremental costs: €6,784), of which only 24.9% and 20.6% are costs of immunosuppressive drugs, respectively. PSA showed that probability of primary tacrolimus-based therapy being cost-effective is 83.7% at WTP threshold. Average probabilistic result is very close to base-case deterministic result. OWSA and SA also confirmed the robustness of the base-case setting of analysis. CONCLUSIONS: Tacrolimus is a cost-effective immunosuppressive therapy in lung transplant recipients, protecting them from chronic lung graft dysfunction, which manifests as bronchiolitis obliterans syndrome. To our knowledge, this is the first cost-effectiveness analysis of tacrolimus as primary immunosuppression after lung transplantation.

PRS34: COST-EFFECTIVENESS OF ROFLUMILAST AS ADD-ON TO TRIPLE INHALED THERAPY VERSUS TRIPLE INHALED THERAPY IN PATIENTS WITH SEVERE AND VERY SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE ASSOCIATED WITH CHRONIC BRONCHITIS IN THE NETHERLANDS

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OBJECTIVES: To assess the cost-effectiveness of roflumilast (ROF) added to ICS+LABA+LAMA versus ICS+LABA+LAMA alone in Dutch patients with severe (FEV1<50% predicted) chronic obstructive pulmonary disease (COPD), chronic bronchitis and ≥2 moderate or severe COPD exacerbations in the past year. Data used were derived from the REACT phase 3b/4 clinical trial (NCT01329029). METHODS: An Excel-based cohort state transition (Markov) model estimated total costs and outcomes over 40 years from a Dutch societal perspective. The model has three GOLD-based states: severe COPD, very severe COPD, and death. All patients enter in the severe state and there is an irreversible transition from severe to very severe COPD. Background rates of moderate and severe (requiring hospitalizations) exacerbations were estimated with negative binomial regressions adjusting for disease severity and treatment in the trial sub-population treated with ICS+LABA+LAMA. Published health-related quality of life weights were applied to health states and exacerbations to generate quality-adjusted life years (QALYs). List prices for drugs were used. RESULTS: ROF reduced the annual rate of exacerbations (moderate or severe) compared with ICS+LABA+LAMA alone (rate ratio [RR]: 0.87, p=0.0840). The reduction of the severe exacerbation rate (RR: 0.74; p=0.0213) was greater than that of moderate exacerbations (RR: 0.94; p=0.5195). In Dutch patients with severe COPD, chronic bronchitis and ≥2 moderate or severe COPD exacerbations in the past year, approximate incremental gains for ROF were 0.20 QALYs at €2,846 per patient (probabilistic cost per QALY: €14,135/QALY), with a 99% probability of being cost-effective at a €80,000/QALY threshold. ROF remained cost-effective under several different sensitivity analyses, and had a favourable cost-effectiveness when evaluated in patients with very severe COPD. CONCLUSIONS: ROF as add-on to ICS+LABA+LAMA is cost-effective for patients with severe or very severe COPD and frequent exacerbations in the Netherlands.

PRS35: COST-EFFECTIVENESS OF SELEXIPAG FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) IN GREECE

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OBJECTIVES: To investigate the cost-effectiveness of the addition of oral selexipag versus continuous subcutaneous (SC) treprostinil in insufficiently controlled functional class (FC) III pulmonary arterial hypertension (PAH) patients already receiving an endothelin receptor agonist (ERA) and a phosphodiesterase type 5 inhibitor (PDE-5i), from a Greek payer perspective. METHODS: A patient-level micro-simulation model with three-month cycles and a lifetime horizon was used. Eligible patients enter the model and initiated selexipag or SC treprostinil in FC III. Patients can deteriorate (or improve during the first cycle only) between FC II, FC III, and FC IV and may die at any time. After a morbidity event, patients were assumed to progress to FC IV and initiate intravenous (IV) epoprostenol, representing the most common clinical practice in Greece. The probability of disease progression and death was based on morbidity and mortality events derived from GRIPHON trial (maximum 4.2 years). Utilities associated with patient’s FC and treatment’s administration mode (SC, IV) were taken from the literature. A payer perspective was adopted (€, 2017). An annual discount rate of 3.5% was applied for costs and health benefits. RESULTS: Selexipag versus SC treprostinil was found to be a dominant strategy (less costly and more effective). Selexipag was associated with 0.78 incremental QALYs compared with SC treprostinil (3.64 vs 2.87) and cost-savings of €747,896 (€446,737 vs €1,194,633) over a patient’s lifetime. Cost-savings were mainly attributable to drug and consumable costs. Results were most sensitive to changes in morbidity and mortality risks of selexipag, disutility due to treprostinil administration method and discount rates. At the defined willingness-to-pay threshold of
PRS36: ASSESSMENT AND SIMULATION OF COSTS AND QOL FOR SUBLINGUAL IMMUNOTHERAPY IN PAEDIATRIC ASTHMA VS PLACEBO: PRELIMINARY DATA

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OBJECTIVES: Specific immunotherapy (SIT), either subcutaneous (SCIT) or sublingual (SLIT), is an allergen-oriented immunomodulation. It consists in administrating increasing doses of the sensitizing allergen, to induce tolerance or "desensitization". Nonetheless, the usefulness of SLIT in paediatric asthma is still matter of debate due to sporadic studies, a non-rigorous methodology, the lack of a real assessment of costs associated. The aim of our study was to evaluate the efficacy of SLIT vs Placebo in term of QoL and the related costs in children with allergic asthma measured under the usual circumstances of health care practice. METHODS: A 24-month, multicentre, prospective, randomized, double-blind, placebo-controlled, parallel-group study evaluated the efficacy, safety, and tolerability, and cost-effectiveness of SLIT in combination with asthma SoC in children and adolescents in 8 Italian Centres. The NHS, the patient and the society perspectives have been considered. QoL has been assessed considering activity limitation; emotional problems and the global PACQLQ score. QALY has not been assessed since results from mapping disease specific and generic questionnaires were still not available. Simulation considered: a 1,000 patient cohort, assessed unit costs and a time discrete Markov model with a discount rate of 3.5%. Transition probabilities come from transition rates by assessing the exponential matrix of a Kolmogorov model of patient condition evolution. RESULTS: Total costs from the NHS, patient, and society perspectives of 1,000 patients are €1,201,534.12, €1,030.42, €1,880,004.15 respectively for the control group, and €1,316,556.09; €0.00; €1,399,226.49 for the study group. QoL shows a higher mean in the study than in the control group. Differences of emotional problem and PACQL scores assessed before and after randomization are not statistically different in the two groups. CONCLUSIONS: With comparable QoL, SLIT induces an increasing of direct costs but a reduction of societal costs because of a reduction in out-of-pocket expenses and indirect costs.

PRS37: COST EFFECTIVENESS OF NINTEDANIB VERSUS PIRFENIDONE TREATMENT IN IDIOPATHIC PULMONARY FIBROSIS IN TURKEY

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OBJECTIVES: To assess the cost effectiveness of nintedanib versus pirfenidone treatment in the treatment of patients with idiopathic pulmonary fibrosis (IPF) in Turkey. METHODS: Based on an economic evaluation of cost-effectiveness of nintedanib treatment for IPF by UK, the adaptation of this model performed in Turkey. A Markov model was mainly built on the basis of the INPULSISTM clinical data, in terms of lung function, acute exacerbations, overall survival and quality of life. In the model, patients were distributed to start in the various lung function health state according to their baseline disposition, then progress over time. Cohort is followed over lifetime and the outcomes are evaluated every 3 months. One-way and probabilistic sensitivity analyses were also conducted. Each health state was associated with a specific utility and a background treatment costs which were calculated according to expert opinion and unit costs determined by local Social Security Institution. Costs are expressed in Turkish Lira (TRY). RESULTS: In “broad” patient population model, Nintedanib provide a cost advantage of 1,079,338.25TL per QALY and 7,889,146.32TRY per life years gained (LYG) as compared to pirfenidone for the first year. For the following years, cost advantage of Nintedanib will be 921,977.09TL per QALY and 7,889,146.32TRY per LYG as compared to pirfenidone. In “restricted” patient population model, Nintedanib provide a cost advantage of 4,613.15TRY per QALY and 4,220.61TRY per life years gained (LYG) as compared to pirfenidone for the first year. For the following years, cost advantage of Nintedanib will be 13,517.60TRY per QALY and 12,367.37TRY per LYG. CONCLUSIONS: Base-case deterministic results indicate that Nintedanib treatment dominates Pirfenidone, with lower costs and more QALYs gained. Lower rate of exacerbations with Nintedanib is an important driver of these results.

PRS38: ECONOMIC EVALUATION OF SINGLE INHALER TRIPLE THERAPY FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) USING THE GALAXY MODEL

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RESULTS: Selexipag versus SC tretoprostilin was found to be a dominant strategy for the treatment of FC III PAH patients insufficiently controlled with ERA and PDE-5i in the Greek healthcare setting.

CONCLUSIONS: Selexipag versus SC tretoprostilin was found to be a dominant strategy for the treatment of FC III PAH patients insufficiently controlled with ERA and PDE-5i, in the Greek healthcare setting.
OBJECTIVES: FULFIL (NCT02345161) showed the clinical benefit of single inhaler, once-daily fluticasone furoate/umeclidinium/vilanterol (FF/UME/VI) 100μg/62.5μg/25μg versus twice-daily budesonide/formoterol (BUD/FOR) 400μg/12μg for patients with symptomatic COPD (Lipson, 2017). The cost-effectiveness analysis of FF/UME/VI versus BUD/FOR, based on FULFIL data, is reported here. METHODS: A treatment-specific adaptation of the GALAXY COPD model (Briggs, 2017) was developed to assess cost-effectiveness from the UK healthcare system perspective. The model input parameters included baseline characteristics and efficacy results from FULFIL and UK National Health Service reference cost data. Outputs included exacerbation rates, costs, life-years (LYs) gained and quality-adjusted life years (QALYs). Estimated incremental costs (ICER) per LY and per QALY gained were calculated. A discount rate of 3.5% for costs and benefits was used. Sensitivity analyses were performed on input parameters. RESULTS: The predicted cumulative number of exacerbations per patient over their lifetime was 8.26 with FF/UME/VI and 10.3 with BUD/FOR. The accumulated LYS (undiscounted) was 10.197 in patients who received FF/UME/VI and 9.43 with BUD/FOR; the accumulated QALYs were 5.36 and 4.89, respectively. The total accumulated costs over a lifetime were £20,080 with FF/UME/VI and £18,410 with BUD/FOR. Patients who received FF/UME/VI gained an additional 0.767 LYS and 0.478 QALYs compared with BUD/FOR, with an additional cost of £1,670. The ICER was £3,500 per QALY, compared with BUD/FOR. Using alternative time horizons, treatment with FF/UME/VI was associated with ICERs of £3,660 at 5 years and £3,300 at 10 years, per QALY, compared with BUD/FOR. Sensitivity analyses showed that variation in main parameters did not alter the results. CONCLUSIONS: Based on the economic analysis, treatment with FF/UME/VI was predicted to reduce the total cumulative number of exacerbations, including severe events, compared with BUD/FOR. LY, QALY and cost findings suggest that FF/UME/VI may be a cost-effective treatment option for COPD in the UK. Funding: GSK (HO-16-13835)

PR339: COST-EFFECTIVENESS ANALYSIS OF TWO LONG-ACTING MUSCARINIC ANTAGONISTS FOR COPD TREATMENT IN SPAIN: UMECLIDINIUM VS. TIOTROPIUM (HO-17-18472)

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OBJECTIVES: To estimate the incremental cost-effectiveness ratio (ICER) of the long-acting muscarinic antagonist umeclidinium compared with tiotropium, considered the standard of care for Chronic Obstructive Pulmonary Disease (COPD), from the Spanish National Health System (NHS) perspective. METHODS: The analysis was based on a head-to-head trial comparing changes from baseline in lung function (FEV1) between umeclidinium 62.5mcg and tiotropium 18mcg, on a 12-week-period (Feldman G. et al. Int J Chron Obstruct Pulmon Dis 2016). A previously published linked equations cohort model, based on ECLIPSE and TORCH studies, which estimates COPD progression, exacerbation rates, associated healthcare-costs, quality-adjusted-life-years (QALYs) and survival, was used (Miravitlles M. et al. Int J Chron Obstruct Pulmon Dis 2016). A 3-year time horizon was selected. COPD diagnosed patients with post-bronchodilator FEV1 of 30%-70% predicted and respiratory symptoms (mMRC dyspnoea scale ≥ 2) were included. Differential treatment effect was maintained until first year of analysis, based on a 52-weeks umeclidinium trial; subsequently no differences were assumed. Effectiveness was measured in QALYs, deriving utilities from a Spanish observational study. Direct-costs were obtained from local sources and treatments-costs from Spain retail prices for 2017 (£45.27 and £49.06 for umeclidinium and tiotropium respectively). Results were expressed as incremental costs per QALY gained (ICER), applying a 3% discount to costs and QALYs. Deterministic (DSA) and probabilistic sensitivity analyses (PSA) were performed. On DSA different discounts for tiotropium retail price were tested. RESULTS: At base-case umeclidinium was dominant over tiotropium, gaining 0.0135 QALYs with cost-savings of £192.20. DSA for tiotropium price showed that umeclidinium was cost-effective up to 36.3% tiotropium discount, as ICERs were below the accepted €30,000/QALY willingness-to-pay threshold in Spain. Varying main parameters in PSA did not have a significant impact on results. CONCLUSIONS: From the Spanish NHS perspective, umeclidinium is a dominant alternative to tiotropium, the standard of care for COPD.

PR340: COST-EFFECTIVENESS ANALYSIS OF ADDING NEW DRUG THIOZONIDE TO IV-TH DRUG REGIMENS FOR MULTIDRUG-RESISTANT TUBERCULOSIS

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OBJECTIVES: to build a model, including clinical characteristics of patients with multidrug-resistant tuberculosis (MDR-TB), and estimate healthcare costs and efficacy of therapy MDR-TB in Russian. METHODS: a cohort-based Markov cost-effectiveness model was developed to estimate the incremental cost-efficacy ratio (ICER) of adding new drug thiozonide (200 mg, 400 mg, 600 mg + IV-th drug regimen) to IV-th drug regimen (involving 8 months Gm Lfx Z Cs/Td PAS Pto/Eto + 12-18 month Lfx Z PAS Cs/Td (Pto/Eto) for the treatment of MDR-TB. As clinical research
currently ongoing and there is no efficacy data on thiozonide, for the early economic evaluation the assumption was made that thiazonide will be not less efficacy than bedaquilline (assumption based on their similar chemical molecule). Outcome measures were quality-adjusted life years (QALY) and disability-adjusted Life Year (DALY). The model used a 3-year time horizon and 3 month cycle length. Willingness to pay threshold (WTP) for Russian health care system was estimated at €26,383 (1648924 RUB), exchange rate mean in 2017 - €1 = 62.5 RUB. RESULTS: applying the base case settings resulted in 1.15 incremental QALYs, -4.75 incremental DALYs, and incremental costs of €1,654.74, €3,309.5 and €4,964.2 (103421, 206841, 310262 RUB) for thiozonide 200/400/600 mg dosages regimen respectively compared with the fourth treatment regimen alone. Incremental cost-effectiveness ratio (ICER) evaluated at €1,438.9, €2,877.8 and €4,964.2 (89931, 179862, 269793 RUB) per QALY gained and €362.1, €724.2, €1,086.3 (22630, 45261, 67891 RUB) per DALY for 200/400/600 mg dosages regimen or thiozonide respectively. According to non-official WTP threshold of €26,383 (1648924 RUB) adding thiozonide to IV drug regimens therapy of MDR-TB will be cost-effective versus IV-th drug regimens alone. CONCLUSIONS: using the model the user can enter their own data (sample size, efficacy, relapse and mortality rate) for the early economic evaluation of the new drug for multidrug-resistant tuberculosis treatment.

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**PRS41: COMPARISON OF BUDESONIDE INHALERS FOR TREATMENT OF ASTHMA IN ADULTS AND ADOLESCENTS IN RUSSIAN FEDERATION: COST – EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** To compare the cost-effectiveness of two budesonide dry powder inhalers, which included Easyhaler and Turbuhaler devices in adult and adolescent patients in Russian Federation. The patients were represented by persons older than 12 years of age with asthmatic disease, who had no experiences with inhaler usage (inhaler naive). METHODS: Information search was conducted in the public domain. Pharmacoeconomic analysis methods: cost – effectiveness analysis was performed. The study had a time horizon of 1 year. The evaluation of therapy effectiveness was based on quality-adjusted life years (QALY) criteria. The QALY was calculated of relationship between quality of life and compliance. Utility data were received from published literature. The direct cost of the various medications per patient was calculated. Cost analysis was conducted on the cost of basic pharmacotherapy, compensation costs for treatment of exacerbations, compensation costs for side effects and adverse events. Exacerbation defined as any of the following: hospital visits, primary care physician visits and visits to healthcare professional. RESULTS: Results showed that budesonide via Easyhaler had a total direct cost per adult/adolescent patient with asthma amounted to EUR 985 per year (versus EUR 1,113 to the Turbuhaler group) and cost saving prepared by of EUR 161 per QALY versus budesonide via Turbuhaler. CONCLUSIONS: Treatment of asthma in adult/adolescent patients of budesonide via Easyhaler was a dominant by compare to budesonide via Turbuhaler in Russian Federation.

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**PRS42: COST–UTILITY ANALYSIS OF TWO BUDESONIDE INHALERS FOR TREATMENT OF ASTHMA IN CHILDREN IN RUSSIAN FEDERATION**

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**OBJECTIVES:** To compare the cost-utility of two budesonide dry powder inhalers in children in Russian Federation. Inhaler devices included Easyhaler and Turbuhaler. The patients were represented by inhaler naive persons 6-12 years old with asthmatic disease. METHODS: Information search was conducted in the public domain. Pharmacoeconomic analysis methods: cost – utility analysis was performed. The study had a time horizon of 1 year. The quality-adjusted life years (QALY) indicator was used as an outcome measure. The QALY was calculated of relationship between quality of life and compliance. Utility data were received from published literature. The direct cost of the various medications per patient was calculated. Cost analysis was conducted on the cost of basic pharmacotherapy, compensation costs for treatment of exacerbations, compensation costs for side effects and adverse events. Exacerbation defined as any of the following: hospital visits, primary care physician visits and visits to healthcare professional. RESULTS: Results showed that budesonide via Easyhaler had a total direct cost per patient per year with asthma amounted to EUR 1139 (versus EUR 1411 to the Turbuhaler group) and cost saving prepared by of EUR 161 per QALY versus budesonide via Turbuhaler. CONCLUSIONS: Comparison of two budesonide dry powder inhalers in children showed that treatment of asthma with budesonide via Easyhaler was a dominant by contrast to budesonide via Turbuhaler in Russian Federation.

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**PRS43: A COST MINIMIZATION ANALYSIS OF AZELASTINE/FLUTICASONE COMBINATION NASAL SPRAY VERSUS AZELASTINE AND FLUTICASONE NASAL SPRAYS MONOTHERAPY IN MODERATE TO SEVERE ALLERGIC RHINITIS: AN EXPERIENCE FROM ISLAMIC REPUBLIC OF IRAN**

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OBJECTIVES: Allergic Rhinitis (AR) is a symptomatic disorder which is due to allergen exposure and IgE inflammatory pathway activation in respiratory tract. AR is categorized upon symptoms’ type and duration and its impact on patients’ health related quality of life into mild and moderate to severe. AR treatment is based on allergen avoidance, medical therapy and immune therapy. Medical therapy includes oral and intranasal antihistamines and intranasal corticosteroids. Intranasal corticosteroids are first-line treatment in moderate to severe AR. This study aimed to assess Azelastine/Fluticasone combination nasal spray cost-effectiveness and budget impact in comparison with Azelastine and Fluticasone nasal sprays monotherapy in mild to moderate AR patients in Islamic Republic of Iran (I.R.I.) health care system. METHODS: A systematic review (SR) was performed to find relevant randomized clinical trials of Fluticasone/Azelastine (50μg/125μg), Fluticasone (50μg) and Azelastine (125μg) nasal sprays which evaluate their clinical effectivenesses. According to performed SR results, clinical effectiveness of two arms of study were approximately equal. Hence, a cost minimization analysis was done. As micro costing, direct medical costs (drugs’ costs, GP office visits’ costs, specialists’ office visits’ costs and allergy-related tests’ costs), from official health tariffs book in I.R.I. were calculated from a payer perspective. Dollar currency rate was considered 32447.29 IRR/1$. Model time horizon was 14 day. Because of this short time horizon, discount rate was not applied. At last, a budget impact analysis was done according to AR incidence rate in I.R.I. RESULTS: Azelastine/Fluticasone combination nasal spray can save 2.05$ per patient for each course of treatment in AR patients in I.R.I. In addition, budget analysis results showed that it can minimize overall cost around 63755.5$ at the end of fifth year in AR patients I.R.I. CONCLUSIONS: This study showed that Azelastine/Fluticasone combination nasal spray is a cost saving alternative in I.R.I. health care system.

PR54: THE COST EFFECTIVENESS OF OMALIZUMAB FOR THE TREATMENT OF SEVERE ALLERGIC ASHTMA IN KOREA

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OBJECTIVES: Severe Allergic Asthma is a major cause of morbidity and mortality around the world, associated with a heavy societal burden in Korea. The aim of this study was to evaluate the cost-effectiveness of Omalizumab compared with standard therapy in the treatment of severe allergic asthma patients over 12 years old from health-care perspective in Korea. METHODS: A Markov model was developed to evaluate the cost-effectiveness of Omalizumab added to standard therapy comparing with standard therapy. 1-month cycle model with 5 states (stable, clinically non-severe exacerbation, clinically sever exacerbation, death due to severe exacerbation, and all-cause death) was to project costs and QALYs over 30 years. Effectiveness and utility data were mainly derived from INNOVATE trial. Death rate due to exacerbation is based on Korean-specific data. Direct medical cost based on health states were obtained from 3 hospitals in Korea. Annual discount rate was 5%. One-way sensitivity analysis was performed to confirm the robustness of the model. Exchange rate used was 1,123 KRW per USD (2017 June). RESULTS: Total expected cost and QALYs of Omalizumab added to standard therapy versus standard therapy alone was USD 50,899. 8.04 QALYs gained respectively for 30 years. Incremental cost per QALYs gained was 23,589 dollar per QALY gained. The model appeared to be most sensitive to changes in the death rate due to exacerbation. One-way sensitivity analysis showed that ICER of add-on therapy group with Omalizumab compared with standard of therapy was from 17,839 to 29,870 dollar per QALY gained. CONCLUSIONS: Considering Omalizumab is an orphan drug, this option is likely to be cost-effective option for adults with severe allergic asthma compared with standard therapy alone in Korea.

PR545: ASSESSING THE COST EFFECTIVENESS OF A NEW, FIRST-IN-CLASS TRIPLE FIXED DOSE COMBINATION THERAPY FOR COPD PATIENTS

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OBJECTIVES: The 2017 GOLD Report recommends triple therapy with an inhaled corticosteroid (ICS), a long acting beta2 agonist (LABA), and a long acting muscarinic antagonist (LAMA) for symptomatic and chronic obstructive pulmonary disease (COPD) patients who continue to experience exacerbations. Triple therapy is currently administered by using multiple inhalers, often with different posologies, which may reduce adherence leading to sub-optimal treatment. A first-in-class triple fixed dose combination (FDC) containing beclomethasone dipropionate (BDP), formoterol fumarate (FF) and glycopyrronium, in an extra fine formulation and a pMDI inhaler with dose counter, is indicated as maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. This study assesses the cost effectiveness of the triple FDC compared with other treatment options available. METHODS: A five
state Markov state-transition cohort model was built based on GOLD 2017 classification of airflow limitation (mild, moderate, severe, and very severe) and death. The probability of a severe or moderate exacerbation was applied to each state. Transition probabilities and treatment specific utilities were derived from pivotal trials, and the lung function (FEV1) decline modelled beyond the trials. Trial comparators models include ICS/LABA (BDP/FF), LAMA alone (tiotropium) and open triple therapy (BDP/FF + tiotropium). UK costs and figures were used as default case. **RESULTS:** Triple FDC therapy is dominant over open triple therapy, as it is similarly effective in most scenarios and has a lower drug acquisition cost. It provides more Quality Adjusted Life Years (QALYs) than either LAMA alone or ICS/LABA (largest QALY gains of 0.4 and 0.2 respectively) at an additional cost per patient of less than £1,000. Cost per QALY gained is well below NICE thresholds. **CONCLUSIONS:** The new triple FDC therapy for COPD is cost effective as compared to open triple therapy, LAMA alone or ICS/LABA.

**RESPIRATORY-RELATED DISORDERS - Patient-Reported Outcomes & Patient Preference Studies**

**PRS46: THERAPY ADHERENCE IN ASTHMA – ASSESSMENT OF POTENTIAL ADHERENCE BARRIERS**

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**OBJECTIVES:** Medication-related non-adherence (NA) is a well-known challenge in the real-world treatment of patients. However, causes of NA are still not well understood. The aim of this study was to determine causes of NA (adherence barriers) of German asthma patients based on the Asthma-Adherence-Barriers-Questionnaire (Asthma-ABQ), which has already been validated in other chronic diseases. **METHODS:** Randomly selected German GPs/pulmonologists consecutively enrolled asthma patients from 01/2015-01/2016. Patients completed the Asthma-ABQ during a telephone-interview. The questionnaire consists of 16 items formulated as statements. Each item needs to be answered on a 4-point-Likert-scale ranging from “strongly agree” to “strongly disagree”. A higher score indicated a higher influence of a certain barrier on patient’s perceptions. A barrier was assumed to exist at a score >2. **RESULTS:** 542 asthma patients (mean age: 53.0 years, female: 74.9%) were included. On average 3.2 (range:0-9) different barriers were identified per patient. In 6.3% of the patients none of the assessed barriers existed. The presence of more than one barrier/two barriers was detected in 81.5%/61.8% of the patients. The most frequently reported barriers (present in 39.9%-53.7% of the patients) were items indicating the perceived need of a medication (because patients felt healthy or they believed that medicines in principle are harmful). 28.2% of the patients were concerned about side effects, 26.8% would stop/reduce their medication if they noticed side effects. Also, unintentional factors like forgetfulness (27.7%) and depression (31.2%) seemed to be considerable issues. **CONCLUSIONS:** Assessing not only the degree of NA but also its potential associations is an important aspect for the development of successful adherence-promoting interventions, since some barriers are perceived as more burdensome than others. Also, patients can experience multiple barriers, which may imply that a personalized or multi-factorial approach may be useful in the prevention of NA. This study was funded by GSK (HO-14-14930).

**PRS47: NON ADHERENCE TO INHALATIONAL MEDICATIONS AND ASSOCIATED FACTORS AMONG PATIENTS WITH ASTHMA IN A REFERRAL HOSPITAL IN ETHIOPIA, USING VALIDATED TOOL TAI**

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**OBJECTIVES:** The main objective of the present study was to assess self-reported non adherence level and to identify the potential factors associated with nonadherence. **METHODS:** An institution based cross-sectional study was conducted in university of Gondar referral hospital. The data was collected using a validated tool called Test of Adherence to Inhalers (TAI). **RESULTS:** Among the total of study participants, higher proportions of patients were female (57.3%). Large number of the respondents (59.1%) were Unable to read and write. 18.3% of inhalational user asthmatic patients were not adherent to inhalational medications. According to this study only 49.4% of the respondents were adherent to inhalations and 32.3% of them were intermediate adherent to inhalational anti asthmatics medications. Lack of education about the Proper use of inhalational anti-asthmatics medications, poly pharmacy and co-morbidities were statistically significant factors associated with non-adherence. **CONCLUSIONS:** The rate of non-adherence to inhalational anti asthmatics is high. Therefore, promoting optimal medication adherences through education, proper patient consultation is essential to optimize the benefits of treatment. Measurement of the degree of non-adherence to inhaled treatment in each individual patient is important in early interventional practice.

**PRS48: QUALITY OF LIFE OF ASTHMA PATIENTS IN GREECE: WHAT CAN WE DO TO IMPROVE IT?**

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OBJECTIVES: The objective of this study was to assess asthma-related Quality of Life of patients suffering from asthma and the impact of poorly controlled asthma in asthma-related QoL. METHODS: The sample derived from a population of asthmatic patients who sought for help at the emergency department of a public respiratory hospital with severe asthma attacks and the study was conducted from 01/12/2014-31/07/2015. Patients (n=100) were equally divided in intervention and control group. An informative intervention (leaflet) was provided to the intervention group about the beneficial effect of compliance in medical advice and followup. Data on socio-demographic characteristics, symptoms of asthma and use of medication were collected. Patients in both groups completed the mini Asthma Quality of Life Questionnaire (mini AQLQ) to assess asthma-related QoL twice, during their visit at the Emergency Department and 30 days after the visit by phone. RESULTS: The study sample consisted of 32 males and 68 females (mean age=48.1 years, SD=18). Patients who attended follow-up (n=61) demonstrated significantly higher mean scores in physical symptoms, social and occupational activity domains and higher mean overall score in the mini AQLQ compared to patients who failed to attend (p=0.001, p=0.021 and p=0.002, respectively). Intervention group patients had statistically significant higher scores in four domains of the mini AQLQ (physical symptoms, emotional function, environmental stimuli and social and occupational activity limitation) and in the overall QoL score in comparison to control group patients (p<0.001). CONCLUSIONS: Educational initiatives to improve compliance to medical advice and asthma-related Quality of Life can be substantially beneficial towards social and health improvement as the inadequately controlled asthma affects not only the daily life of the patients and their physical and mental health, but it is also associated with low work performance and a poor overall quality of life.

PR50: DIFFERENCES IN DISTRIBUTIONAL PROPERTIES AND RESPONSIVENESS BETWEEN A GENERIC (EQ-5D) AND DISEASE-SPECIFIC (ASUI) UTILITY INSTRUMENT IN PATIENTS WITH SEVERE EOSINOPHILIC ASTHMA

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OBJECTIVES: EQ-5D is a generic instrument for deriving Health-State Utility Values (HSUVs) and is preferred for conducting cost-utility analyses by reimbursement agencies. The Asthma Symptoms Utility Index (ASUI) is a disease-specific instrument which can also be used to create HSUVs. This study compares distributional properties and responsiveness of EQ-5D-5L and ASUI in patients with severe eosinophilic asthma in the MUSCA study. METHODS: MUSCA (GSK/ClinicalTrials.gov identifier 200862/NCT02281318) was a 24-week randomised,
double-blind, placebo-controlled trial of mepolizumab in severe eosinophilic asthma. EQ-5D-5L and ASUI were administered at baseline and weeks 4, 12, and 24. In this post-hoc analysis, we examined the relationship of EQ-5D and ASUI with demographic and clinical characteristics, as well as study outcomes at baseline and end of study. RESULTS: 549 and 488 patients completed the EQ-5D-5L and ASUI questionnaires at baseline, respectively, of which 527 and 470 had data available at end of study. At baseline, mean EQ-5D-5L index was considerably higher than ASUI (0.80 vs. 0.67). The proportion of patients reporting perfect health (ceiling effect) was considerably higher for EQ-5D-5L compared to ASUI (baseline: 16% vs. 5%; week 24: 28% vs. 17%). The mean change from baseline was higher for ASUI compared to EQ-5D-5L (0.10 vs 0.05). When exploring within person change over time, ASUI consistently demonstrated higher effect sizes than EQ-5D-5L both in patients improving and worsening according to other study outcomes including self-assessed response to treatment, exacerbations, lung function, asthma control, and activity limitation. CONCLUSIONS: More favourable distributional properties and responsiveness to change in disease status were observed for a disease-specific utility instrument (ASUI) when compared to EQ-5D-5L, a generic utility instrument. Generic instruments may not adequately or sufficiently capture and reflect important changes in quality of life associated with severe asthma.

PRS51: EXPLORING THE BURDEN OF ILLNESS AND IMPACT OF SQ-STANDARDISED GRASS ALLERGY IMMUNOTHERAPY TABLET TREATMENT (AIT) ON QUALITY OF LIFE (QOL) IN PATIENTS WITH ALLERGIC RHINITIS (AR) IN GERMANY AND THE NETHERLANDS

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OBJECTIVES: The purpose of this study was to understand the impact of AR and subsequent SQ-standardised grass AIT on adults’ and children’s QoL METHODS: 3 allergists were interviewed to explore their experience of treating AR. Clinicians treating AR in the Netherlands and Germany recruited adults and children who had received at least 3 years of SQ-standardised grass AIT. Telephone interviews were conducted with patients to explore experience of AR and AIT. Interview transcripts were analysed using grounded theory methods. Saturation analysis was conducted for impact-related concepts. RESULTS: 15 adults (aged 19-61) and 18 children (aged 11-17) were interviewed. Clinicians and patients reported that before SQ-standardised grass AIT, the most common AR symptoms were nose- and eye-related. Together with coping strategies, these had considerable negative impacts on patients’ QoL. Symptoms decreased gradually, with all patients reporting considerable improvement by the last year of treatment. 53% of adults and 89% of children reported improvement in the first year; clinicians reported symptom improvement for the majority of patients in the first year of treatment. Gradual symptom reduction during treatment led to positive impacts on social, work/school, and physical functioning and less need for impactful coping strategies. Many patients (60% of adults; 39% of children) experienced oral side effects in the first months of AIT, though these resolved with time. After treatment, efficacy on symptom reduction and/or disappearance and subsequently on daily life was sustained for 100% of adults and 92% of children. Saturation of concepts was achieved. CONCLUSIONS: SQ-standardised grass AIT considerably improved AR symptoms and therefore impact on daily life for the majority of patients during and after treatment. Despite small sample sizes and long recall periods, the consistency of reports between doctors, children and adults and achieving saturation suggests the robustness of the study data and efficacy of SQ-standardised grass AIT.

PRS52: A REVIEW OF THE QUALITY OF LIFE AND EDUCATIONAL BURDEN OF ALLERGIC RHINITIS ON ADOLESCENTS

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OBJECTIVES: Allergic rhinitis (AR) is a common chronic condition that can have a considerable impact on people’s lives. The aim of this literature review was to report the burden of AR on adolescents. METHODS: A literature search of electronic databases (MEDLINE, EMBASE, NHS EED, HTA) was undertaken to identify studies (from 2002 onwards) quantifying symptoms, quality of life (QOL), daily activity, emotional, and educational burden of AR in adolescents (10-18 years). Results were assessed by two reviewers. RESULTS: Of 2136 de-duplicated references, 22 remained after initial abstract review and followed by full-text review. One study included parent-reported rather than adolescent-reported data. Studies reported different outcomes, including symptoms (n=5), QOL (n=9), daily activity (n=5), emotional (n=2) and educational (n=7) burden. Nasal congestion and rhinorrhea were the most bothersome symptoms. In five comparative QOL studies, AR was associated with reduced QOL versus controls. In another study, non-responders to treatment had significantly worse QOL than responders. With respect to symptoms, poor QOL was particularly associated with nasal congestion, nasal pruritus, and ocular symptoms. One study reported items that had most impact on patient’s QOL. A negative impact of AR on daily activities was consistently reported across studies. With respect to emotional function, there was evidence of AR adolescents being unhappy,
irritable, tired, frustrated, angry and upset. One comparative study showed higher levels of anxiety and depression versus controls. AR negatively impacted education in adolescents, with studies reporting school absenteeism and reduced productivity. In studies that quantified the impact of AR on examination grades, grades were reduced. One study, however, reported increased school performance in those with AR. **CONCLUSIONS:** Although AR can be perceived as a trivial disease, its symptoms can have a detrimental impact on QOL, emotions, education, and daily activities in adolescents. Improved management could potentially reduce this burden.

**PRS53: SOCIAL BURDEN OF COPD**

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**OBJECTIVES:** To evaluate the social and economic burden of COPD in Bulgaria generated from the disability adjusted life years (DALY). **METHODS:** An observational study among 426 Bulgarian COPD patients was conducted for the period 2014-2015. DALYs were estimated per the World Health Organization methodology. In our sample no patients died during the duration of the study, this is why a value of 0 was assumed for years of life lost (YLL). Disability weight (DW) for COPD value was obtained from the study of Haagsma et al. The average life expectancy was assumed to be 88 years, as per WHO methodology. Monetarized value was obtained through the multiplication of DALY by the GDP/capita. **RESULTS:** The DALYs in the group of patients with mild severity are lowest due to the low disutility index and number of patients in this sample group (n=30). On average a patient with mild COPD spends 0.62 years of his life in disability due to the disease, while those with moderate and severe spend 6.00 and 9.00 years respectively. Assuming annual working income is lost by patients for the DALY period, costs of lost productivity is obtained by multiplying the average DALYs by the GDP per capita, thus expressing the resources "lost" per patient throughout his life. This amounted to the following indirect costs experienced by patients: 3,596.52€; 34,204.01€; 51,332.20€ respectively. **CONCLUSIONS:** This is the first Bulgarian study evaluating the economic and social burden of COPD and first one that applies the DALYs for COPD in Bulgaria. To the best of our knowledge, it is also the first one that monetizes the values for DALYs. We demonstrated a significant societal burden of COPD in Bulgaria, which is in correlation with severity of the disease.

**PRS54: THE TWO-YEAR THERAPY WITH OMALIZUMAB IN CHILDREN WITH SEVERE PERSISTENT UNCONTROLLED ASTHMA: DYNAMICS OF QUALITY OF LIFE**


**OBJECTIVES:** Omalizumab is one of the most frequently used recombinant, humanized, monoclonal antibody treatment in children with bronchial asthma (BA). Dynamics of quality of life (QoL) is the important aspect to assess the response to treatment in children with uncontrolled severe persistent BA. To determine the cut-off of the significant quality of life improvement in the first 2 years of therapy with Omalizumab, according to the pediatric patient registry with severe persistent uncontrolled BA **METHODS:** Data of 34 children (average age 12.2 years) with severe uncontrolled persistent BA, who got the treatment with Omalizumab from January 2015 to June 2017, were analyzed. The quality of life of all children was assessed with the questionnaire PAQLQ(S): before the therapy with Omalizumab, in 16 weeks, in 6 months, in 9 months and then every 6 months. The maximum treatment time period for Omalizumab was 2 years. **RESULTS:** Positive dynamics of QoL was observed in all children. After 16 weeks of therapy the total score of QoL (TsQoL) was improved by 18% (p=0.000); after 6 months - by 23.82% (p=0.000); after 9 months – by 25.44% (p=0.000); after 1 year – by 26.42% (p=0.000); after 1.5 year – by 25.92% (p=0.000); after 2 years – 27.54% (p=0.000). All children had a positive dynamics of BA during the therapy with Omalizumab: the number of exacerbations and the requirement of quick-relief medications have been reduced, asthma control has been improved; there was no severe exacerbation requiring emergency admissions; the basic therapy volume was reduced by half after 6 months of the therapy with Omalizumab in 2 children. **CONCLUSIONS:** Our results indicate that the minimum duration of the treatment with Omalizumab should be at least 1 year in children with severe persistent asthma. Results require further analysis.

**PRS55: ASSESSMENT OF THE EFFICACY OF THE TWO-YEAR TREATMENT WITH OMALIZUMAB, ACCORDING TO THE PEDIATRIC REGISTRY OF THE CHILDREN WITH SEVERE PERSISTENT UNCONTROLLED ASTHMA**

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**OBJECTIVES:** The efficacy of the two-year treatment with Omalizumab (MONARCH) was assessed according to the pediatric registry with severe persistent uncontrolled BA. **METHODS:** The registry included 34 children with severe persistent uncontrolled BA aged 12.2 years. The total score of QoL (TsQoL) was improved by 18% (p=0.000); after 6 months - by 23.82% (p=0.000); after 9 months – by 25.44% (p=0.000); after 1 year – by 26.42% (p=0.000); after 1.5 year – by 25.92% (p=0.000); after 2 years – 27.54% (p=0.000). All children had a positive dynamics of BA during the therapy with Omalizumab: the number of exacerbations and the requirement of quick-relief medications have been reduced, asthma control has been improved; there was no severe exacerbation requiring emergency admissions; the basic therapy volume was reduced by half after 6 months of the therapy with Omalizumab in 2 children. **CONCLUSIONS:** Our results indicate that the minimum duration of the treatment with Omalizumab should be at least 1 year in children with severe persistent asthma. Results require further analysis.
OBJECTIVES: The goal of asthma management is to achieve the disease control. Asthma questionnaires provide additional useful information about the disease in children with severe persistent uncontrolled asthma (SPUA). To analyze the efficacy of the 2 years therapy with Omalizumab and the impact on the quality of life (QoL) of children with SPUA, according to the pediatric patient registry. METHODS: Data of 34 children (average age 12.2 years) with SPUA were analyzed. All children received the treatment with Omalizumab from January 2015 till June 2017. Such criteria as "symptoms", "activity limitation" and "emotions" of all the children were assessed by the questionnaire PAQLQ(S): before the therapy with Omalizumab, after 16 weeks, after 1 year and after 2 years. RESULTS: Before Omalizumab therapy all the children had low scores on each questionnaire’s PAQLQ(S) domains, low scores of ACT-test - 13 points (Me 14 [9; 17]), and high doses of daily basic therapy – 654.422 µg/day (Me 500 [500;1000]). After the start of the therapy with Omalizumab the domain "activity limitation" improved progressively in 16 weeks, 1 year and 2 years – 17.89%, 27.34%, 27.92% (p=0.000), respectively; "symptoms" - by 18.89%, 27.46%, of 27.08%(p=0.000); and "emotional function" - by 18%, 26.36%, 28.39% (p=0.000). During the therapy with Omalizumab: the number of exacerbations and the requirement of quick-relief medications have been reduced (in 16 weeks at 76.7%, p=0.000), asthma control has been improved (in 16 weeks the ACT-test results were improved by 23.96%, p=0.000); there was no severe exacerbation requiring emergency admissions. The basic therapy volume was reduced by half two years after the start of the therapy with Omalizumab in 5 children. CONCLUSIONS: The analysis of the questionnaire PAQLQ(S) reflects the dynamics of asthma. Our results confirmed that the QoL assessment is a reliable and important instrument for obtaining information about the disease development.

PR556: QUALITY OF LIFE ASSESSMENT IN ILD – A COMPARISON OF EQ-5D WITH THE DISEASE-SPECIFIC K-BILD

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OBJECTIVES: The King’s Brief Interstitial Lung Disease questionnaire (K-BILD), a disease-specific quality of life questionnaire (QoL) for individuals with interstitial lung disease (ILD) has not been applied in a German setting yet. Thus, a comparison of K-BILD with the well-established EQ-5D-5L could show its usability in clinical settings. METHODS: We calculated mean of EQ-5D-index and visual analog scale (VAS) and K-BILD alongside with their correlation in total score and in different domains for 239 patients with different ILD entities from the longitudinal observational HILDA study. Additionally potential predictors (age, sex, ILD entity, FVC percentage of predicted value (FVC%), DLCO percentage of predicted value, and either sum of comorbidities (model1) or distinct comorbidities (model2)) for QoL were investigated with linear regression models. RESULTS: Means were as follows EQ-5D-index 0.79 (SD 0.18), VAS 60.4 (SD 19.3) and K-BILD 53.4 (SD 11.5). EQ-5D and K-BILD showed moderate positive correlations (EQ-5D-index vs. K-BILD 0.61; VAS vs. K-BILD 0.57). The "breathlessness and activities" K-BILD domain highly correlated with the "usual activities" (-0.70) and "mobility" domain (-0.66) of EQ-5D index. Other domains showed moderate correlations. In model1 higher FVC% was associated with higher QoL (EQ-5D index 0.0028 p=0.0001; VAS 0.26 p=0.0006; K-BILD 0.16 p=0.0007) whereas comorbidity burden decreased QoL (EQ-5D index -0.032 p=0.0015; VAS: -3.14 p=0.0034; K-BILD -2.13 p=0.001). In model2 FVC% showed similar results (0.0023 p=0.0005; 0.0023 p=0.0021; 0.16 p=0.0009). Heart Insufficiency and Diabetes Mellitus influenced EQ-5D-index (0.13 p=0.0354; -0.0087 p=0.008) and Depression decreased K-BILD (-0.46 p=0.023). Other factors had no significant influence. CONCLUSIONS: K-BILD and EQ-5D score reveal similar QoL trends and are sensible to the same disease-related factors. K-BILD reacts more sensitively to ILD-specific aspects of QoL rendering it a valuable complementary measure to EQ-5D-5L which is usually recommended for health care decision making.

RESPIRATORY-RELATED DISORDERS - Health Care Use & Policy Studies

PR557: RELEVANCE OF SURGICAL INTERVENTIONS FOR TREATMENT OF OBSTRUCTIVE SLEEP APNEA IN GERMANY

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OBJECTIVES: Obstructive Sleep Apnea (OSA) is a common disease in developed countries which can lead to significant comorbidities if left untreated. First-line treatment for OSA is nightly application of positive airway pressure (CPAP) to ensure airway patency. Though highly effective, its efficacy is reduced low due to side effects and low degree of convenience, which impacts therapy adherence. Different surgical procedures have been introduced over the past and are performed regularly in patients with CPAP failure. Aim of this study is to evaluate recent application of OSA surgery in Germany and its relevance for treating the condition. METHODS: Procedural data on OSA surgery
was obtained from the official German Hospital Statistics, which is routinely collected for all treatments performed in hospitals and is publically available from InEK institute. All cases that were coded with principal diagnosis of OSA (G47.31) in 2015 were included in the analysis. RESULTS: A total of 7,729 surgical interventions for OSA were performed in Germany in 2015, while a total of 60,846 CPAP treatments were initiated. The majority of the surgical procedures were nasal surgery (39.9%) followed by tonsil surgery (17.6%) and Uvulopalatoplasty (13.6%). Other procedures include Glossectomy (1.9%) and Hypoglossal Nerve Stimulation (0.7%). CONCLUSIONS: Surgical interventions amount to approximately 11% of the total OSA treatments in the in-patient sector. According to recent clinical data, 10-20% of patients refuse or fail CPAP initially and 30-50% do not adhere sufficiently over long term. Given the high prevalence of OSA and the significant rate of failure for CPAP as first-line therapy, a higher relevance of surgeries as second-line treatment was expected. Reasons for the rather low number are not clear, but could include use of other non-surgical therapies that are not documented in available data or a low acceptance of surgery. Further research is required to obtain better understanding of these reasons.

PRRS58: EVALUATION OF THE “SOPHIA ASTHME” SUPPORT PROGRAMME FOR ASTHMATIC ADULT PATIENTS

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OBJECTIVES: SOPHIA is a program developed by the French Health Insurance. The program includes a free access information website, provision of leaflets, and regular phone calls from an asthma nurse, in order to promote self-management and adherence to asthma treatments. The objective of this study was to evaluate the effect of the program on medication and health care use in adult asthma patients at one year. METHODS: A controlled before-after study was conducted within the SNIIRAM (claims database of the French Health Insurance). Subjects 18 to 44 years old in 2014, receiving at least 2 asthma medications deliveries in 2013, and covered by the general scheme of Health insurance were included. The program was implemented in 2015 in 18 French departments. Each eligible subject from pilot departments (i.e. the eligibles) was matched with an eligible subject from a department without the program (i.e. a control) on a propensity score. The primary endpoint was the ratio controller/total asthma medications. RESULTS: A total of 99,578 pairs were analyzed. No impact of the program was observed on the primary endpoint (OR=0.997). The program was associated with an increased total number of anti-asthma drug packs dispensed (slope=0.36, p<0.0001). A non-significant decrease in the number of days of sick leave (slope = -0.09) and in the percentage of subjects with sick leave (OR=0.96) was observed. In terms of asthma-related costs (reimbursed), the program was associated with increased asthma medication expenditure (+€15, p=0.02) and a decrease (not statistically significant) of sick leave expenditures. CONCLUSIONS: In this very early evaluation, the program did not show a clear impact on the majority of endpoints. This could be explained by the small proportion of participants to the program (10%) within the eligible population and the large inclusion criteria. Analysis of a more specific asthmatic population revealed more favorable impact of the program.

PRRS59: OUTCOME MEASURES USED TO ASSESS INTERVENTIONS FOR ASTHMA CONTROL: A SYSTEMATIC REVIEW

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OBJECTIVES: A variety of outcome measures have been used to assess asthma control. As a result, comparisons across studies are difficult. We sought to give an overview of the outcome measures that have been used to assess
asthma interventions. METHODS: Articles from peer-reviewed journals, published from January 2008 to May 2015, were identified by searching MEDLINE. Articles were included if: 1) they were published in English or French, 2) they reported an intervention aiming at improving asthma control in adults, and 3) the study design was: randomized or non-randomized controlled trial, before-after study, time series analysis or observational. Studies were analyzed to identify and classify the outcomes according to the National Institute of Health (NIH) and the Agency for Health Care Research and Quality (AHRQ) recommendations published in 2012. RESULTS: The literature search identified 739 citations on abstract and title, of which 377 were reviewed in detail. A total of 109 articles met the inclusion criteria including 9 systematic reviews and/or meta-analysis. The most common domains of asthma clinical research outcomes measures identified in the 100 original studies were: use of hospital care (n=100), lung function (n=73), asthma medications (n=66), composite scores of asthma control (n=44) and quality of life questionnaires (n=33). Various types of outcomes were identified within each domain. The most common outcome within each aforementioned respective domain was: asthma hospitalization (49/100 [49%]), peak expiratory flow rate monitoring (47/73 [64%]), any type of asthma medication (rescue or control) (10/66 [15%]), asthma control questionnaire (ACQ) (n=27/44 [61%]) and asthma quality of life questionnaire (AQLQ) (n=17/33 [51%]). Asthma exacerbations lacked of standardized definition and were reported only in 30 studies. CONCLUSIONS: There are a multitude of outcomes used for the assessment of asthma interventions. Future research in the field should consider NIH recommendations in order to standardize asthma outcomes assessments.

PRS60: SYSTEMATIC LITERATURE REVIEW OF THE IMPACT OF ASTHMA SUPPORT PROGRAMS DEDICATED TO ADULT PATIENTS

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OBJECTIVES: To evaluate the impact of asthma support programs dedicated to improve asthma control. METHODS: A systematic literature review was conducted by epidemiologists, pharmacists and asthma physicians, following PRISMA recommendations. The search was performed in Medline, Embase, CINAHL, specialized websites, and the Trip database from January 2005 to April 2015. Articles were included if they reported the evaluation of an asthma program dedicated to asthmatic adults patients, and fulfilled the COCHRANE EPOC design selection criteria. The selection was performed by two independent reviewers. The quality of studies was evaluated using the COCHRANE EPOC Risk of bias tool. A data synthesis was performed. RESULTS: Of 1,058 studies identified by the literature search, 46 met the eligibility criteria (39 original studies and 7 systematic reviews). Studies were mainly experimental (34) or quasi-experimental (10) studies, and were mainly conducted in Europe (19) or North America (15). The majority of studies included patients participating to the program during 1 year. Twenty five studies included 100 to 1,000 patients each, 15 studies less than 100 patients and 4 studies more than 10,000 patients (using electronic healthcare databases). Programs consisted in one or several among the following types: patient education (16), information and counseling (14) - mainly inhalation device training in the framework of an action plan -, remote monitoring (7) or medication management (5). The intervention was performed by physicians (17), nurses (16) or pharmacists (7). Despite some inconclusive or negative results, patient education programs seem to improve asthma control and quality of life, increase controllers use and decrease relivers and health care use. Results concerning exacerbations and compliance were heterogeneous. The sole delivery of information and counseling had poor impact. CONCLUSIONS: The studies were heterogeneous in terms of programs and outcomes, thus difficult to analyze and synthetize. Patient education programs seem to have some impact.

PRS61: ARE LABA/LAMA/ICS FDCS A TRIPLE THREAT FOR COPD COMPETITORS IN THE COST-CONSTRAINED EU5?

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OBJECTIVES: Long-acting beta2 agonist (LABA)/long-acting muscarinic antagonists (LAMA)/inhaled corticosteroid (ICS) fixed-dose combination (FDC) therapies are poised to enter the EU5 (France, Germany, Italy, Spain, UK) chronic obstructive pulmonary disorder (COPD) markets, where they will compete with multiple inhaled brands and increasing generic LABA/ICS FDC and LAMA options. This research explored the EU5 market access landscape that emerging LABA/LAMA/ICS FDCs will face. METHODS: Across the EU5, 255 pulmonologists were surveyed regarding their current and expected prescribing for COPD, while 16 payers who influence reimbursement nationally or regionally were interviewed. RESULTS: Interviewed payers will preferentially reserve LABA/LAMA/ICS FDCs for GOLD grade III or higher patients, especially in France and Spain, where improvements in specific subpopulations are increasingly required from clinical trials. Furthermore, German and, to some extent, UK payers believe ICS safety concerns may impede triple FDC uptake while promoting that of LABA/LAMA FDCs. However, these payers, and their Italian counterparts identify improved clinical outcomes or compliance data due to dosing schedule and/or device as a potential reimbursement lever for triple FDCs, although these attributes alone will not secure price premiums given open-combination generic options. In fact, payers in the highly cost-sensitive Italian, Spanish, and UK markets suggest undercutting open combinations on price could promote triple FDC uptake. Likely reimbursement restrictions are only somewhat reflected by surveyed EU5 pulmonologists anticipated prescribing of triple FDCs by year-end 2019. In Germany, 22% of respondents expect to prescribe LABA/LAMA/ICS FDCs first-line for severe/very severe COPD versus 29-55% elsewhere, with overall patient share of 11-29% anticipated for the triple FDCs at this time-point. CONCLUSIONS: Cost will be key to optimal market access for emerging LABA/LAMA/ICS FDCs. Generic alternatives will significantly influence reimbursement decisions and prescribing patterns. Ultimately, manufacturers must be aware of payer priorities and preferences, and be savvy in pricing negotiations in order to optimize return on investment.

PRS62: POTENTIAL SAVINGS ACHIEVED THROUGH SWITCHING COPD PATIENTS FROM ICS-CONTAINING REGIMENS TO LAMA-LABA: A DUTCH PERSPECTIVE

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OBJECTIVES: The updated 2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Strategy positions a combination of a LAMA (long-acting muscarinic antagonist) and a LABA (long-acting beta2-agonist), as a mainstay treatment for the majority of symptomatic Chronic Obstructive Pulmonary Disease (COPD) patients. The use of -inhaled corticosteroid (ICS) in combination with LABA is reserved for GOLD C patients as an alternative to the combination of LABA and LAMA. The triple therapy (LAMA-LABA-ICS) is reserved for GOLD D patients on LAMA-LABA therapy with further exacerbations. Despite these recommendations, there is considerable use of ICS outside of the GOLD strategy in the Netherlands. METHODS: We elaborated a model that calculates the 5-year impact of the switches between different maintenance therapy options on the Health Care Resource Use (HCRU) in COPD patients. Changes in HCRU were generated based on differences in the risk profile of maintenance COPD therapies for COPD exacerbation, pneumonia and diabetes events. Costs applied were based upon Dutch data. RESULTS: As an illustration switching all ICS patients without ICS recommendation (LABA-ICS and LAMA-LABA-ICS) to LAMA-LABA could avoid 120,466 COPD exacerbations, 34,878 pneumonias and 11,319 diabetes complications in the Netherlands over a 5-year timeframe. This would represent total savings of €263 Million for the Dutch Healthcare System, about 10% of current expenses on COPD care. This equals to €60 euros for drug acquisition, €49 due to less pneumonia, €46 due to less exacerbations, €15 due to less diabetes complications). CONCLUSIONS: The 2017 GOLD guidelines recommend the first-line use of LAMA-LABA, in the treatment of the majority of symptomatic COPD patients. This analysis shows that savings can be achieved in the Netherlands when patients are switched from ICS-containing regimen to LAMA-LABA, mainly due to less ICS-related diabetes and pneumonia events, and less COPD exacerbations.

PRS63: SINK OR SWIM: HOW CAN ASTHMA BIOLOGICS SUCCESSFULLY SAIL THE ROUGH WATERS OF EU5 MARKET ACCESS?

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OBJECTIVES: Emerging biologics targeting severe, refractory asthma must compete to convince the cost-constrained EU5 (France, Germany, Italy, Spain, the UK) that they are worthy of investment. This research explored the evolving reimbursement and prescribing landscape for asthma biologics as they seek to secure optimal market
access. **METHODS:** Across the EU5, 16 payers who influence reimbursement nationally or regionally were interviewed, and 255 pulmonologists were surveyed. **RESULTS:** All interviewed payers demand unequivocal proof of added benefit from new agents for favorable reimbursement terms. Those in Germany highlight the G-BA’s determination of no added benefit for mepolizumab (GiaxoSmithKline’s Nucala) to exemplify the penalty for using an inadequate comparator regimen and flawed trial design when superiority in head-to-head studies is required. The importance of clinically relevant end-points is also stressed across countries, with rate of exacerbation for severe asthma rather than surrogates such as FEV1 specifically mentioned. Likewise, 57% (Italy) to 78% (UK) of surveyed pulmonologists select reducing exacerbations as a top-five prescribing driver for asthma biologics. In all countries, clinical performance trumps treatment cost among surveyed physicians’ prescribing drivers overall; however, interviewed payers everywhere also seek substantial price discounts or managed entry agreements at national and subnational levels in exchange for optimal reimbursement and positioning. These payers stress that, despite different mechanisms of action and use of different biomarkers, asthma biologics will ultimately compete for the same small, largely overlapping population of severe, refractory asthma. The opportunity to ease payers’ cost concerns with positive pharmacoeconomic data is also pinpointed. **CONCLUSIONS:** Emerging asthma biologics face the modern day EU5 market access reality of frugal payers increasingly reliant on health technology assessment and pharmacoeconomic results as a lever to stringent reimbursement negotiations, and increasingly seeking cost-cutting opportunities. Realistic prices, meaningful discounts/entry agreements, well-designed clinical trials, and persuasive pharmacoeconomic data will help float the asthma biologics’ market access boat.

**PRS64:** **COST AND TREATMENT OF ASTHMA AND COPD IN THE REAL PRACTICE: A REGIONAL SEGMENTATION**

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**OBJECTIVES:** Italian recommendations for the management of Asthma and Chronic Obstructive Pulmonary Disease (COPD) are respectively GINA and GOLD international Guidelines, with some local documents available for COPD. The aim of this research was to investigate the variability concerning the pharmaco-utilization of respiratory treatments among Italian Regions. **METHODS:** A desk research was conducted to gather international and local guidelines. The research integrated hospitals and territory data supplied by QuintilesIMS (i.e. LRx and Monitor Spesa Databases) and Ministry of Health data (epidemiologic data at local and regional levels), in order to achieve a comprehensive overview of the current drug utilization scenario. The analysis included 13 different molecules, both branded and generics, belonging to the following respiratory drug classes: long-acting antimuscarinics (LAMA), long-acting beta2 antagonists (LABA)/LAMA and inhaled-corticosteroids (ICS)/LABA. The analysis included 90% of all prescriptions delivered in 2016, within all the 21 Italian Regions. **RESULTS:** Prevalence and incidence in the use of respiratory drugs included in the analysis showed a positive correlation; no difference among Regions in North, Centre and South of Italy were observed. Nonetheless, the research highlighted intra-regional variability in terms of treatment cost per-capita and per-patient. In addition, costs per-patient varied significantly among Regions, with a statistical reduction in Southern vs Northern ones (p<0.05). Southern Regions showed a higher generic dispensing ratio (GDR) compared to Northern Regions, both considering prevalent and naive patients. **CONCLUSIONS:** The research highlighted a great tendency to prescribe generic drugs in Southern Regions, especially in naive patients. Indeed, the per-patient cost of drugs was lower in Southern Regions, and this finding can be explained with the presence of a financial plan, agreed with the Government to settle regional debts (i.e. Repayment plan). On the contrary, in Northern Regions drug prescriptions are reduced in terms of volumes, but not in terms of values, probably due to the lower GDR.

**PRS65:** **ANALYSIS OF CONSUMPTION OF ANTI-TB MEDICINES IN UKRAINE DURING 2012-2016**

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**OBJECTIVES:** According to the statistics of the Ministry of Health in Ukraine in 2016 about 700 thousand people were ill with tuberculosis, 600 thousand of them were on the dispensary record, including 142 thousand with an open form of tuberculosis. Currently, an important task for the treatment of patients with tuberculosis in Ukraine is to provide them with anti-TB drugs, as needed. **METHODS:** ATC/DDD-method developed by WHO. **RESULTS:** During 2012-2016 in the pharmaceutical market of Ukraine the number of INNs of anti-tuberculosis drugs decreased from 11 to 6, and TNs from 25 to 19. It was established that in 2012, 28.84 DIDs of anti-tuberculosis drugs were consumed; in 2013 - 30.92 DIDs; in 2014 - 9.00 DIDs; in 2015 - 5.90 DIDs; in 2016 - 22.36 DIDs. The Ukrainian protocol for TB treatment indicated three schemes: I - 4 drugs for 2 months, II - 2 drugs for 4 months and III - 5 drugs for 2 months. In terms of 700000 patients with TB, the prescribed treatment regimens for the years are as follows: in 2012 - all patients received I and II regimens, 441714 patients received also III treatment regimen; in 2013 patients received I-II treatment regimens during the year, and 586890 patients also received the III scheme; in 2014 only 578755
patients received one of the treatment regimens I or II; in 2015 there was also little used of drugs, I or II schemes for only 384196 patients, and in 2016 the volume of drug use increased and they were again enough to fully support all patients during the I-II treatment regimens, and 38671 patients also got the III scheme. **CONCLUSIONS:** Thus, the treatment of patients with tuberculosis in Ukraine takes place at state funds, and starting from 2016 we observe the sufficient provision of TB patients with medicines.

**PRS66: PRIMARY DATA COLLECTION VERSUS USE OF RETROSPECTIVE CLAIMS DATA: METHODOLOGY LESSONS LEARNED FROM A LINKED DATABASE STUDY IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)**

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**OBJECTIVES:** Primary data collection either by a retrospective medical chart review, as part of a prospective observational study or use of retrospective claims data, are common methods in non-interventional health care research. By using a linked dataset, the aim of this study was to assess strengths and limitations of primary data (PD) and claims data (CD) with data obtained from a population of German COPD patients. **METHODS:** Prospectively collected PD from 536 patients (04/2013-11/2014) were linked to CD from a German sickness fund (AOK Nordost) on a patient level, covering the same observation period. Characteristics of both datasets were assessed by (1) an analysis of value differences in (1a) patient characteristics, (1b) documented exacerbations and (1c) prescriptions of bronchodilators (ATC codes: R03*), and (2) a comparison of patient characteristics between both datasets. **RESULTS:** 536 patients were included in this post-hoc analysis (mean age 67.98 years: 36.38% female). The percentage of comorbid patients reported in PD was lower than in CD (e.g., depression 6.7% vs. 29.3%, \(p<0.001\)). Based on PD, 20.9% experienced at least one exacerbation versus 29.1% based on CD. Mean number of COPD prescriptions per patient year was 3.7 prescriptions (PD) versus 10.3 (CD), for 440 patients with drug treatment data available in both datasets. In terms of generalizability, we observed that patients in the complete claims dataset (74,916 patients) were three years older and to a higher percentage female than PD patients. Moreover, they were less comorbid and less frequently visiting physicians than PD patients. **CONCLUSIONS:** Even if the same patient population and follow-up period is observed, substantial differences on values of key variables between PD and CD exist. Data linkage may provide a more complete and precise overview and could thereby provide an opportunity to improve external and internal validity.

**PRS67: OBSERVED REDUCTION OF HEALTHCARE UTILIZATION AFTER Omalizumab INITIATION AMONG PATIENTS WITH PERSISTENT ASTHMA FOLLOWED IN CANADIAN CLINICAL SETTINGS.**

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**OBJECTIVES:** The primary objective was to evaluate the health care utilization (HCU) following omalizumab (OMA) initiation as assessed by the reduction in number of hospitalizations, emergency room (ER) visits, and oral corticosteroid (OCS) use in patients covered in Ontario. The number of night awakenings was an exploratory endpoint. **METHODS:** This study is a retrospective, pre-post cohort, observational study. The data was collected from the patient support program. Individuals were enrolled to the Ontario Trillium Drug Program and had access to OMA through Exceptional Access Program (EAP). Individuals were identified and their OMA EAP claims for the relevant period. The primary objective was to evaluate the health care utilization (HCU) following omalizumab (OMA) initiation as assessed by the reduction in number of hospitalizations, emergency room (ER) visits, and oral corticosteroid (OCS) use in patients covered in Ontario. The number of night awakenings was an exploratory endpoint. **METHODS:** This study is a retrospective, pre-post cohort, observational study. The data was collected from the patient support program. Individuals were enrolled to the Ontario Trillium Drug Program and had access to OMA through Exceptional Access Program (EAP). Individuals were identified and their OMA EAP claims for the relevant period. The data extract included patients with an enrollment form receipt date greater than July 17th 2013 or a reactivation form receipt date greater than July 17th 2013. The end date of data collection was May 5th, 2016 **RESULTS:** 148 patients (mean age 57.6; female 62.2%) formed the study population. Omalizumab was associated with a 74.4% reduction in the number of hospitalization (pre vs post-omalizumab’s 12 month treatment period: 0.7 vs 0.2 \(p<0.001\)). 89.9% of patients did not have any asthma related hospitalization. There was a reduction of 87.5% in ER visits (7.3 vs. 0.9 \(p<0.001\)), 66.2% of patients did not have any emergency visit. A 74.7% reduction of the number of high dose OCS by (4.23 vs. 1.07 \(p<0.001\)), 52.7% of patients did not need to take any courses of high dose OCS. The mean number of night awakenings / per week decreased from 6.1 (8.03) to 1.3 (2.79) following 12 month treatment with omalizumab. **CONCLUSIONS:** There was an observed reduction in the number of hospitalizations, ER visits, and high-dose OCS courses post-omalizumab use in patients with severe uncontrolled asthma in a Canadian real-world setting. The results are consistent with outcomes observed in previous large real-world trials such as the Experience registry.

**PRS68: IMPACT OF GLOBAL BUDGET ON PERSONAL MEDICAL EXPENSE FOR INPATIENT WITH RESPIRATORY DISEASE: AN INTERRUPTED TIME SERIES ANALYSIS**
OBJECTIVES: Soaring medical expense has been a global issue for a decade, and China is confronted with an even greater burden. Increasing medical expense brings great economic burden for patients. From 2009, Global budget payment system (GBPS) was introduced in Shanghai for public hospitals instead of fee-for-service (FFS) payment system to curtail medical expense, and fully implement from 2011. The aim of this paper is analysis to evaluate impact of GBPS in medical expense per capita of inpatients of respiratory disease in Shanghai. METHODS: Daily number of hospitalizations and medical expense of respiratory disease of residents participated in Urban Employee’s Basic Medical Insurance (UEBMI) in Shanghai from April 1, 2009 to March 31, 2012 was collected by Shanghai Health Insurance Bureau (SHIB). An interrupted time-series analysis (ITS) was used to evaluate the impact of GBPS pilot extended from 2010 and fully implement from 2011 compared to baseline in medical expense. RESULTS: A Segmented autoregressive integrated moving average (ARIMA) was used to evaluate model medical expense per capita. Our study showed GBPS could retard the monthly increasing speed of medical expense per capita. The monthly increment of total medical expense, medical insurance coverage service expense and self-paying service expense per capita were decreased by CNY 0.08 thousand, 0.07 thousand and 0.01 thousand in 2010 and CNY 0.07 thousand, 0.05 thousand and 0.02 thousand in 2011. But the instant effect of CBPS showed no significant association. CONCLUSIONS: This study demonstrated the effect of controlling personal medical expense of GBPS, both in medical insurance coverage service expense per capita and self-paying service expense per capita. Study also provided supports that GBPS could slow down the monthly increasing speed of medical expense per capita.

PRS69: BUDGET IMPACT ANALYSIS OF TREATMENT WITH ULTIBRO BREEZHALER® VERSUS SERETIDE DISKUS® 50/500 MG FOR MODERATE TO VERY SEVERE COPD PATIENTS

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OBJECTIVES: To assess the budget impact of COPD management with Ultibro Breezhaler® (UB) vs. Seretide Diskus® 50/500 µg (SD) in France over the next 6 years based on the results of the FLAME study. METHODS: A budget impact model was developed to estimate healthcare savings of a broader use of UB vs. SD in the treatment of patients with moderate to very severe COPD (25% ≤ post bronchodilator FEV1 < 60%), who had at least one exacerbation in the previous year and an mMRC≥2. Pneumonia (severe and non-severe) and exacerbations (moderate and severe) rates from the 52-weeks-duration FLAME study were used. The model used management costs (€, 2016) of COPD (treatments, management of exacerbations and pneumonia). For each stay, a DRG cost (€, 2014) was calculated. No discount rate was applied. RESULTS: The mean cost of treatment combined with the impact of exacerbations and the management of adverse events decreased by 137€ per patient per year (1405€ with SD vs. 1268€ with UB). Based on French guidelines (SPLF, 2016), we estimated that 250 000 patients needed a 2nd line of treatment for the prevention of exacerbations among 2.5 millions of COPD patients in France. A linear growth of UB market shares for these patients from 8% (actual) to 50%, for instance, would allow to save 70M€ (cumulated) for French NHS over the next 6 years. Currently, French NHS spends 3.5 billions euros every year for the management of COPD in France. CONCLUSIONS: From the French NHS perspective, replacing SD by UB in the COPD treatment strategy of patients with moderate to very severe COPD who had at least an exacerbation in the previous year with an mMRC≥2 could generate substantial savings.

PRS70: SMOKING CESSATION INTERVENTIONS BASED ON SOCIAL MARKETING PRINCIPLES: A REVIEW

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OBJECTIVES: Addiction is one of the social issues and problems which causes endangering the health of individuals of a society. One of the approaches which nowadays have mostly attracted attentions is to use the social marketing principles for Smoking Cessation. The aim of this study is to investigate the studies conducted on the smoking cessation interventions which have used social marketing principles. METHODS: This study had a systematic search which conducted in March 2015. Key words such as quit smoking, stop smoking, smoking cessation, and social marketing were searched in Pubmed, Scopus, and Web of Science database. Totally, 120 articles were extracted. After investigating and eliminating duplicate articles, 16 articles remained for being reviewed. Two reviewers screened the selected studies independently and differences were resolved by discussion. RESULTS: The results indicated in terms of social marketing principles, only three articles followed all social marketing principles. One article had all these principles, but in the section of marketing mix, price and place were not mentioned. Six articles had considered five principles in conducting their own studies. In general, the principle of competition was more neglected in most of articles and in case of marketing mix, including price, product, place, and promotion, in some of the articles, only
some of the components of marketing mix were used. **CONCLUSIONS:** The approach of social marketing can have important role in improving the smokers’ or even non-smokers’ awareness and being effective in changing their attitudes. Particularly social marketing studies which had used online methods or mass media such as TV had more success because public access to them was simpler. One of the important deficits seen in most of studies on smoking cessation was the lack of complete observance of all social marketing stages, and the factor of competition and marketing mixes had received less attention.

**PRS71: PHARMACOECONOMIC EFFECTIVENESS OF THE INCLUSION OF GLYCOPYRONIUM BROMIDE INTO THE PROGRAM OF REIMBURSEMENT OF ESSENTIAL DRUGS FOR PATIENTS WITH COPD**

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**OBJECTIVES:** The aim of this study was to evaluate pharmacoeconomic advisability of the inclusion of the Glycopyronium bromide into the program of reimbursement of essential drugs (PRED) for the therapy of patients with chronic obstructive pulmonary disease (COPD) **METHODS:** Two regimens of baseline therapy of COPD with long-acting muscarinic receptors antagonists were compared: with Tiotropium bromide, and with Glycopyronium bromide. The impact on the PRED budget (time horizon was set to 3 years), and cost-effectiveness of these medical technologies were analyzed. The program of reimbursement of essential drug only includes the costs of pharmacotherapy; therefore, only direct medical costs were taken into account in the analysis of budget impact. A surrogate endpoint was chosen as the medical efficiency criterion in the cost-effectiveness analysis, i.e. the frequency of COPD exacerbations during the therapy with long-acting muscarinic receptors antagonists. The data on the frequency of exacerbations were taken from a Russian epidemiological study **RESULTS:** The substitution of the original Tiotropium bromide with Glycopyronium bromide reduced the market value of baseline COPD therapy by 43.33% or by almost 8 802 RUB per patient per year. The sensitivity analysis showed that price fluctuations led to 15% changes of these results. Compare to generic Tiotropium bromide, the use of Glycopyronium bromide reduced the costs by 12.23% (2 486 RUB per patient per year). The range of changes of this results depending on price fluctuations was 10%. **CONCLUSIONS:** It is advisable from the pharmacoeconomic perspective to substitute Tiotropium bromide with Glycopyronium bromide in PRED

**PRS72: THE EFFECT OF SMOKING CESSATION INTERVENTIONS IN PATIENTS WITH COPD: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** The prevalence of chronic obstructive pulmonary disease (COPD) is expected to rise in not only developed countries, but also developing countries. Smoking is the largest risk factor for COPD and smoking cessation is the most effective way to prevent or slow the progression of the disease. In 2012, 14.6% of Korean adults aged 40 and over were COPD patients. But smoking rate for Korean male adults was 39.3% in 2015, which is the highest level among OECD countries. In this study, we reviewed literatures to investigate the benefits of smoking cessation in COPD patients. **METHODS:** A systematic literature search was performed based on PICO-SD. The main searching terms were COPD, emphysema, bronchitis, pulmonary disease, and smoking cessation in PubMed, EMBASE, Cochrane CENTRAL, KoreaMed, and RISS. The participants were current smokers with COPD. We included smoking cessation counselling/education, drugs (varenicline, bupropion), and nicotine replacement treatment as interventions but excluded if it was only part of a disease management program. The comparison were no treatment or usual care or placebo. The outcomes were quit rate, FEV1 decline rate, quality of life, exacerbations, and mortality. We included randomized/non-randomized controlled trials (RCT/nRCT), and cohort studies written in English or Korean. Four review authors independently extracted the data and resolved any disagreements by consensus. **RESULTS:** We identified 4551 records and completed a PRISMA flowchart. Based on title and abstract, we excluded 4312 records and assessed 239 full-text articles. Finally, 20 studies were selected; 18 RCTs, 1 nRCT, 1 cohort study. We found consistent evidences that such interventions were very supportive to help COPD patients quit smoking. Also, abstinent patients from smoking showed better health outcomes than those relapsing and/or consistent smokers in terms of FEV1 decline rate, exacerbations, and all-cause mortality. **CONCLUSIONS:** Smoking cessation is effective in reducing prevalent symptoms and improving health status in COPD patients.

**PRS73: PATIENT INPUT INTO VALUE ASSESSMENT OF RESPIRATORY MEDICINES: LESSONS LEARNED FROM VALUE FRAMEWORKS IN OTHER DISEASE AREAS**

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Objective: Frameworks designed to objectively assess the value of drugs are continually being developed and updated. The objective of this research was to review existing value frameworks across therapeutic areas, identify the extent to which patient perspectives were incorporated, and derive findings that could assist in the development of a value framework for respiratory disease. Methods: A literature review of value frameworks was undertaken using PubMed and Google Scholar with “value framework” search words. Frameworks were subsequently assessed focusing on five domains: (1) geographic and clinical scope, and current status of the framework, (2) ownership and stated purpose, (3) framework innate characteristics, (4) implementation characteristics (referring to the way the value framework has been used since release), and (5) the degree of patient involvement. Results: A total of 12 value frameworks were identified for further analysis. These focused on oncology (n=4), orphan diseases (n=3), no specific disease (n=3), cardiology (n=1) and medical devices (n=1). Five key findings were identified. First, engagement with patients, manufacturers, and drug developers was repeatedly mentioned (5/12). However, patient involvement such as setting up and implementing value frameworks was rare, and approaches to capturing and quantifying patient needs were not observed. Second, several frameworks used weightings to emphasize aspects of value (6/12). Third, simple scoring and visual techniques were employed to aid framework uptake and understanding (3/12). Fourth, prioritization was utilized to aid stakeholder decision-making (4/12). Finally, less tangible aspects of value were gaining traction (e.g., value of hope, real option value, scientific spill over) (6/12). Conclusions: Our analysis of 12 published value frameworks indicates patient burden of illness, needs, and priorities are rarely collected. In respiratory disease, for which patients play a crucial role in managing their conditions, a value framework needs to directly incorporate the patient perspective (clinical, economic, and humanistic burdens) and ensure it is weighted appropriately. Supported by AstraZeneca

PR574: POPULATION HEALTH IMPACT OF OMALIZUMAB OVER 15 YEARS OF EXPERIENCE IN MODERATE TO SEVERE ALLERGIC ASTHMA

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OBJECTIVES: Asthma affects 334 million persons worldwide. 15 million days are lost due to disability from asthma every year. Omalizumab was first registered in Australia (in 2002 for moderate and 2005 for severe allergic asthma). Until 31st Dec 2016 the estimated exposure worldwide in adult patients was 516,481 patients-years. This analysis estimates the contribution of omalizumab to the reduction in worldwide asthma burden over 15 years. METHODS: Reduction of asthma burden was estimated in asthma related deaths; exacerbations leading to hospitalization or Emergency Department (ED) visits and improvement in quality adjusted life years (QALYs). Cumulative asthma deaths avoided were calculated by applying exacerbation related mortality on exacerbations leading to: (i) hospitalization (ii) hospitalization or ED visit. Annualized exacerbation rates and the QALY gain were based on Brown et al. 2007. Proportions of clinically significant severe exacerbations and of ED visits/hospitalizations by exacerbation type were based on the European registration trial (INNOVATE). Proportion of patients by age was based on a large observational study in 14 countries (eXpeRience) and age specific mortality risks were retrieved from Roberts et al. 2013. RESULTS: Over 15 years omalizumab reduced number of exacerbations leading to: (i) ED visits by 38,580 (2,572 per year) and (ii) hospitalizations by 74,024 (4,935 per year). Overall avoided asthma deaths with type of exacerbation ranged from 527 to 802. At least 37,187 QALYs were gained. Limitations: only deaths avoided in secondary care were included; no inclusion of pediatric population exposed; generalization of mortality risks across different geographies. CONCLUSIONS: On average each patient responding to omalizumab gained 1 year and 1 month of full health. Omalizumab reduced asthma deaths by 58% in secondary care. Continuous effort is necessary from all stakeholders to link access to effective treatments to appropriate disease management. Data for asthma mortality risk outside secondary care is warranted.

PR575: RECRUITING METASTATIC PATIENTS INTO NON-SMALL CELL LUNG CANCER STUDIES (NSCLC): LESSONS LEARNED FROM A NON-INTERVENTIONAL STUDY OF NSCLC PATIENTS WITH CENTRAL NERVOUS SYSTEM (CNS) METASTASES (METS) AND NON-CNS METS.

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OBJECTIVES: To describe challenges of recruiting CNS mets patients in a multi-center, prospective, observational study in France and Germany. METHODS: To be included, patients were required to be ≥18 years of age, have histologically or cytologically confirmed NSCLC, a documented diagnosis of metastasis between 2 and 8 months before study inclusion, performance status 0 to 2, available clinical chart at the study site since the diagnosis of
metastatic NSCLC, and be able to provide written informed consent. Patients participating in a clinical trial or not able to answer patient reported outcomes (PROs) were excluded. Patients were recruited into CNS mets and non-CNS mets cohorts (target n=86/cohort). Sites were not required to maintain a screening log for excluded patients. Recruitment challenges were ascertained during biweekly site contacts and two investigator teleconferences attended by a total of 7–12 sites. **RESULTS:** Currently, 31 sites are enrolled in the study. The non-CNS mets cohort recruitment was closed in February 2017. Recruitment for CNS mets cohort is continuing and was 64 patients on June 19th 2017. Twenty-four sites indicated inclusion/exclusion (I/E) criteria as major reasons for low recruitment, of these 46% said patient’s performance status was >2, an equal number of sites suggested patients refused participation, 25% said patients did not meet the diagnosis window and 17% said patients were too sick to complete PROs. Sites also highlighted resource constraint (19%) and observational study being low priority (13%) as barriers. **CONCLUSIONS:** Major reasons for poor recruitment were patients’ performance status, refusal to participate in the study and the diagnosis window. This study provides valuable information that can help design future CNS mets observational studies. Recommendations are to oversample sites that see CNS mets patients, and find a balance between suitable I/E criteria and the reality of recruiting to represent real world population.

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**PRS76: PREOPERATIVE SMOKING CESSATION: RECORDING OF SMOKING STATUS IN THE PORVOO HOSPITAL AREA IN FINLAND**

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**OBJECTIVES:** Smoking increases the risk of postoperative complications, length of hospital stays, and health care costs. Treatment guidelines recommend preoperative smoking cessation for all patients referred to an elective surgery. We characterized how often smoking status and smoking cessation interventions are documented in operation-related health care records in real-life clinical practice. **METHODS:** The data on smoking status, smoking cessation interventions, and operation-related complications were collected retrospectively from electronic health records generated at public primary health care units in the Porvoo Hospital Area and at the Porvoo hospital over a period of 7 months (06–12/2016). **RESULTS:** A total of 149 patients were included in the study (median age 65 years). Based on the preoperative assessment forms, 20.1% of patients (n=27/134) were current smokers. Altogether, four patients from primary health care units and six patients from the hospital had a record of smoking cessation intervention. Smokers had almost twice as many postoperative complications compared to non-smoking patients (14.3% vs. 7.5%). Smoking status was documented in 31.5% of primary health care referrals, and in 17.4% of hospital’s outpatient records. Smoking status was documented in 89.9% of preoperative assessment forms filled by the patient and a nurse. Based on the results, only one third of the smokers had their smoking status documented at their primary health care unit. **CONCLUSIONS:** According to the national treatment guidelines, smoking cessation intervention should be initiated at the primary health care unit in order to achieve smoking cessation, optimally 4–8 weeks before elective surgery. However, our report demonstrated that smoking status is recorded and smoking cessation intervention documented only for a minority of smokers. Preoperative smoking cessation requires early identification of smokers and documentation of smoking status in order to implement effective smoking cessation intervention at each step of the treatment pathway.
**PHP1: UNDERSTANDING STAKEHOLDER EXPECTATIONS FOR PATIENT ENGAGEMENT: A QUALITATIVE SURVEY**

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**OBJECTIVES:** Meaningful patient engagement (PE) in medicines development requires all stakeholders have a common purpose and vision, and a clear understanding of respective expectations. As phase one of a research project, a qualitative survey was undertaken to understand expectations from stakeholders. **METHODS:** The survey explored four key themes from the perspective of each stakeholder group: meaning, views, expectations and priorities for PE. Participants were grouped into 7 broad categories: policymakers/regulators; healthcare professionals (HCPs); research funders; payers/purchasers/HTA; patients/patient representatives; pharmaceutical/life sciences industry; academic researchers. **RESULTS:** 59 interviews were conducted: patients, n=10; HCPs, n=7; policy, n=8; payers, n=6; industry, n=13; researchers, n=8; research funders, n=7. Responses were received from a wide range of geographies (Europe, North America, Australia, Asia and Africa), PE experience and job seniority/role. There was generally alignment across the stakeholder groups on: meaning of PE; importance of promoting PE to a higher level than currently; need for a more structured process and guidance. The major area of no/little alignment was around stakeholder expectations of the role other stakeholders should play. Overall, policymakers/regulators were expected by others to take more responsibility to drive PE, create a framework and facilitate PE, provide guidelines of good practice and connect stakeholders, but this expectation was not recognised as strongly by the policymakers/regulators group themselves. HCPs were seen by others as the link between patients and other stakeholders but HCPs did not necessarily see themselves as having an active role in PE (in the context of medicines development) beyond recruiting for clinical trials. **CONCLUSIONS:** To our knowledge this is the first qualitative survey exploring stakeholders’ expectations from PE in medicines development. Despite broad stakeholder categories, clear themes emerged: a desire for effective PE but some discord in alignment, structure and clarity. A Stakeholder Expectations Matrix that summarises findings and provides an ‘action list’ for stakeholders will be presented.

**PHP2: UNDERSTANDING HTA AND PATIENT ENGAGEMENT: EFFECT OF INTEGRATING EXPERIENTIAL AND KNOWLEDGE LEARNING MODULES**

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**OBJECTIVES:** A new workshop format was developed with the goal to achieve a deeper understanding of the unique perspective of patients in the development or evaluation of new therapies and to increase the awareness of healthcare industry stakeholders for the importance and techniques of Patient Engagement (PE) in preparing for Health Technology Assessment (HTA). **METHODS:** A one-day pilot workshop, was held in Nov 2016 in Basel, Switzerland. Multidisciplinary participants (n=12) from the life sciences industry and 2 patient representatives attended. Interest in improving their understanding on knowledge component(s) was a criteria. Recruitment happened via networks of faculty members. HTA and PE content sessions were followed with experiential sessions using drawing exercises, which guided the participants through the experience of being diagnosed with a life threatening condition and, subsequently, the possibility to participate in a clinical trial. The workshop concluded with the participants prioritizing their personal expectations for innovation and HTA, starting as patients and subsequently as citizens. **RESULTS:** Overall, participants rated the pilot workshop as excellent or good for knowledge and experiential sessions. Integration of both learning modalities was described as innovative, useful, and enjoyable. Participation in the clinical trial session triggered cognitive responses among participants working in the life sciences industry, which limited their experiential learning. In response, patient perspectives were useful to consider perspectives beyond
those of industry employees, which prioritized advancement of science for societal good. Emotions describing the personal experiences included despair, shock, anger, guilt, hope, and the will to live. As citizens, they emphasized expectations such as finding solutions, remaining independent, enjoying life and “giving back”. CONCLUSIONS: PE and HTA were linked successfully in one workshop by integrating knowledge and emotional-experiential learning modules. Innovative learning structures can allow researchers, marketers, or other stakeholders from the life-science industry to gain knowledge and better understand the patient perspectives.

**PHP3: CONSUMER COMMENTS IN HEALTH TECHNOLOGY ASSESSMENT IN AUSTRALIA: HOW COMMON AND INFLUENTIAL ARE THEY?**

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OBJECTIVES: The Pharmaceutical Benefits Advisory Committee (PBAC) in Australia considers ‘consumer comments’ in its appraisals, acknowledging that patient perspectives and physician knowledge are important guiding factors for Health Technology Assessment (HTA) decisions. The objective of this study was to identify factors associated with the presence of consumer comments in Australian HTA and assess their impact on PBAC decisions. METHODS: Public summary documents published by PBAC between March 2015 and November 2016 were searched. Only appraisals on major submissions (for new medications or when substantial changes are made to current listings) were reviewed; appraisals informed by minor submissions and resubmissions were excluded. Information on consumer comments, indications and PBAC decisions were extracted. RESULTS: The search yielded 141 PBAC summary documents, out of which 59% included consumer comments from patients, healthcare professionals, and patient organisations. The inclusion of consumer comments increased by 28% between March–November 2015 and March–November 2016. When stratified by indication (excluding 7 submissions relating to vaccinations), consumer comments were 22% more prevalent in appraisals of oncology treatments (34/45) than non-oncology treatments (48/89) and 19% more in those of rare diseases (25/33) than non-rare diseases (57/101). When stratified by the type of subsidy listing, the proportion of appraisals that included consumer comments was similar (new listing: 57%; change of listing: 62%). Of the submissions that included consumer comments, 39% received a positive recommendation, which was lower than that seen in submissions that did not include consumer comments (57%). CONCLUSIONS: The inclusion of consumer comments was more prevalent in drug appraisals for cancer and rare diseases compared to other therapeutic areas. The presence of consumer comments appeared to be associated with lower chances of a positive PBAC decision. Additional analyses will be conducted to further explore the impact of consumer comments on PBAC decision-making.

**HEALTH CARE USE & POLICY STUDIES - Diagnosis Related Group**

**PHP4: THE ANALYSIS OF THE NUMBER OF SAME-DAY SURGERY CASES IN 2015 IN HUNGARIAN HOSPITALS**

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OBJECTIVES: Over the past few years one day surgery has become more specific in health care systems throughout the world. This study analyzed the available same-day surgical procedures in the Hungarian health care system in the year 2015. METHODS: Data were derived from the financial database of National Institute of Health Insurance Fund Administration and covering the year of 2015. We applied the usual performance indicators by comparing the actual number of same-day surgical interventions to the theoretical number of same-day surgical intervention which could have been performed by the hospitals among ideal circumstances. The number of cases was used to establish the rate of same-day surgical procedures. Hungarian hospitals were classified into the following groups: university clinical centers, county hospitals, city hospitals, specialized hospitals, Budapest’s hospitals, children’s hospitals and national health care institutes. RESULTS: 62.29% of the achievable same-day surgeries was accounted for by the publicly funded institutes in Hungary in 2015. We found that the rate of the above interventions was the highest in specialized hospitals (98.82%). The rate of the achievable same-day surgery’s case number was 60.03% in university clinical centers, which is lower than that in county hospitals (61.38%) and the city hospitals (66.90%), on the other hand, it is higher than the rate of Budapest’s hospitals (55.49%), children’s hospitals (50.66%), and national health care institutes (28.23%). CONCLUSIONS: Our results showed that in 2015 the specialized hospitals performed the most, while the national health care institutes performed the least case numbers regarding same-day surgeries in Hungary.

**PHP5: FUNDING NEW TECHNOLOGIES IN GERMAN INPATIENT CARE - DOES IT WORK?**
OBJECTIVES: Due to disincentives inherent in systems of diagnosis-related groups (DRGs), additional payments for newly approved technologies complement these prospective payment systems. In Germany, so called innovation payments are negotiated between individual hospitals and health insurances. Thus, hospitals may not have the same chance of being reimbursed for new, more expensive technologies. This study aims at investigating this temporary reimbursement mechanism. We examine factors that might be associated with agreeing innovation payments. METHODS: Based on a data set of the Scientific Institute of the AOK (including agreement data of the yearly budget negotiations between each German hospital and representatives of the health insurances) and data of the German Federal Statistical Office on state level, multilevel logistic regression was estimated to examine factors at hospital and state level. All German acute hospitals and innovation payments on all diagnoses are thus included in the study. Dependent variable was whether or not a hospital had successfully negotiated innovation payments in 2013 (n=1,358). RESULTS: In total, 32.9 per cent of the hospitals successfully negotiated innovation payments in 2013 (31.3 per cent of non-university hospitals, 91.9 per cent of university hospitals). The share of hospitals that successfully negotiated innovation payments varied considerably among the states. The chance of negotiating innovation payments increased for large and private for-profit hospitals and hospitals with university status. Additionally, hospitals located in areas with a low degree of competition – such as rural areas – had a lower chance of negotiating innovation payments. CONCLUSIONS: The study indicates that policy making generally compensates incentives of the DRG system by additional innovation payments. Patient safety is implicitly fostered by favouring university hospitals and large hospitals to use new technologies. However, the innovation payments may impede patient access in rural areas since hospitals in regions with low competition have a smaller chance to receive innovation payments.

HEALTH CARE USE & POLICY STUDIES - Disease Management

PHP6: MULTIPLE CHRONIC CONDITIONS IN OLDER PEOPLE AND THEIR EFFECTS ON HEALTH CARE UTILIZATION: A NETWORK ANALYSIS APPROACH USING SHARE DATA

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OBJECTIVES: The presence of multiple coexisting chronic diseases in individuals and the expected rise in chronic diseases are major public health challenges of modern societies. Individuals with multiple conditions are presumed to have greater health needs, more risk of complications, and more difficulty to manage treatment regimens. In our article we model the presence of multiple diseases in older people using network analysis and explore the influence of the presence of multiple diseases on health care utilization. METHODS: We use SHARE dataset of Wave 5, including data on 14 European countries and Israel for the people aged 65+. We model the presence of multiple coexisting diseases as a two-mode network analysis problem (the individuals are connected in a network through their diseases). This has special scientific relevance as network analysis has not been used so far to study this problem and very seldom before in the analysis using SHARE data. To appropriately model the presence of multiple chronic diseases we use modularity and blockmodelling techniques for two-mode networks. To verify the effects of multiple diseases on the rates of health care utilization we also use microeconometric models from causal inference (controlling for endogeneity). RESULTS: We show the presence of consistent clusters of diseases across the analyzed countries and confirm particular influence of the groups/clusters encompassing mental diseases (including dementia), arthritis (including osteoarthritis) and different types of ulcers, with slight variation by welfare regimes. In particular, there is a high influence of those clusters on the usage of drugs and hospitalizations. CONCLUSIONS: In the article, we develop a new method to study multiple diseases and their influence on health care utilization of older people, having wide application for health economic and medicine sciences in future. In conclusions, we also provide reflection of the research and policy relevance of the study.

PHP7: THE PRACTICAL APPLICATION OF A DIGITAL THERAPEUTIC EDUCATION PLATFORM FOR CARDIOVASCULAR REHABILITATION

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OBJECTIVES: - Describe the patient population of patients enrolled in the “AtoutCoeur” platform - Evaluate the patient education activity in the cardiac rehabilitation centre following AtoutCoeur’s launch - Evaluate AtoutCoeur’s performance in terms of helping patients to achieve objectives METHODS: The platform will be evaluated retrospectively based on real life data. To determine AtoutCoeur’s performance, the patients’ score for each of their objectives was considered. This score is determined based on an algorithm that takes into account their medical
PROFILE AND THEIR RISK FACTORS. RESULTS: Since AtoutCoeur platform’s launch in January 2017, 2755 patient education sessions were carried out which represents an average of 20.56 sessions for each of the 134 patients enrolled in the platform. The patient population was mostly masculine (75%) and between the ages of 41-60 (53%). 23% of patients suffered from hypertension and 22% suffered from a valve disease. In terms of risk factors, 17% of patients were at risk for dyslipidaemia and 16% were at risk for being sedentary or having hypertension. 20% of patients completed the SF12, HAD, and Ricci & Gagnon questionnaire. There was a significant evolution in terms of the scores for objectives when the first session after the shared diagnostic was compared to the 20th patient education session, notably concerning the “Healthy diet” objective (+234%) and the “Weight loss” objective (+213%). CONCLUSIONS: In the future more patients will be able to benefit from the platform. This platform can already be considered to be a great success based off the fact that 100% of patients enrolled in the cardiac rehabilitation centre at the Fondation Léopold Bellan are signed up for the platform. The platform’s activity levels were also relatively high in the first 6 months of the platform’s launch. Future evaluations will enable us to determine the evolution of questionnaire scores and patient quality of life.

PHP8: EVALUATION FRAMEWORK FOR DIGITAL MEDICINES IN EUROPE

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OBJECTIVES: The emergence of digital medicine (DM) like smart pills, implantable drug delivery or digital therapeutics as a potential tool for efficient and sustained patient monitoring has created a fast-growing product stream offering a new facet of personalised medicine. The drug/device combination brings the involvement of the biopharmaceutical industry much closer to digital wearable technologies enabling real-time monitoring of patient data with respect to drug adherence and behavioural indications. However, there is little knowledge about the evaluation of new digital medicines in Europe. The study objective is to determine the fundamental criteria with which payers will make reimbursement decisions for DM in the U.K., France and Germany. METHODS: A systematic literature review was conducted on open-access articles in ScienceDirect, Journal of Market Access and Health Policy and SpringerLink. Due to a small number of initial results, review was expanded to include non-academic grey literature. The review focussed on determining the key payer preferences for an evaluation framework. RESULTS: Currently, there is no established pathway for reimbursing DM in the three countries. In the UK, NICE will start assessing digital applications as part of NHS' Improving Access to Psychological Therapies programme. DM access is localised and restricted to pilot studies that indicate Trust-specific funding decisions. In France, accreditation from the government's Agency for Digital Health is required to work with patient data. In Germany, DM funding comes from the €300 million annual Innovation Fund. Currently, cost effectiveness (UK) and clinical outcomes (France and Germany) receive highest weightage in reimbursement decision-making for DM. CONCLUSIONS: The need for a robust evaluation system for DM is increasing as the number of innovative technologies brought to market rise. Currently, evidence requirements lean heavily on establishing DM on par with traditional drugs. But outcomes need to expand to include parameters like physician decision-making, self-management, data security and ethics.

PHP9: ARE PHARMACEUTICAL COMPANIES PRIORITIZING MULTI-INDICATION DRUGS?

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OBJECTIVES: To evaluate whether medicines were approved for more therapeutic indications in 2016 than they were in 2006. This would suggest a prioritization of multiple indications for one therapy from drug companies. METHODS: We reviewed European Medicines Agency (EMA) updates for human medicines from 2006 to 2016 in 54 disease conditions (n=753). We selected updates that related to changes in therapeutic indications (n=577). We then controlled for multiple updates of the same medicine by using only the latest update of a medicine (n=378). We evaluated the average number of relevant therapeutic updates in these years. We then counted the number of indications for each of these therapeutic areas, considering indications to be separate when they were in different disease areas. RESULTS: In 2006, there were 21 updates; in 2016, there were 49 updates; and the average across these years was 34.5 updates. We found that in 2006, the average number of therapeutic indications was 1.75, and in 2016 it was 2.0. Between these years, it varied from 1.3 to 1.72, with a very slight upward trend. CONCLUSIONS: Based on this data, pharmaceutical companies are not currently prioritizing multi-indication drugs more often than they did in the past. There is the possibility that the newer data, from the last three or four years, should be excluded from this evaluation. Many of these medicines were considered after their initial approval and they may not have had time to gain approval for secondary indications.

PHP10: RACIAL DISPARITIES IN TREATMENT OF PREGNANT WOMEN WITH DRUG USE, ABUSE AND DEPENDENCE
OBJECTIVES: Tobacco, alcohol, and other illicit drugs can cross the placenta increasing the risk of low birthweight, doubling the risk of stillbirth, producing congenital deformities and dependence in the newborn. The aim of this study is to determine racial disparities in receipt of treatment among pregnant women with drug use, abuse and dependence. METHODS: A cross-sectional study was conducted among pregnant women who self-reported being pregnant and who had ever used illicit substances within the past 12 months. Survey data was obtained from the National Survey on Drug Use and Health (NSDUH 2005-2014). A summary of pregnant drug users’ individual characteristics, drug use status and treatment utilization was prepared. Logistic regression was used to examine predictors of receiving drug treatment. Data management and analyses were conducted using SAS9.4. RESULTS: A total of 1,856 pregnant drug users were identified from 2005-2014. 19.23% pregnant drug users were dependent and 6% abused drugs respectively. About 81% of pregnant drug users reported using marijuana/hashish in the past 12 months, for an average of 111 days. Heroin was the drug for which majority of pregnant drug users (34.48%) sought treatment currently or during the past year. Pregnant drug users who were non-Hispanic African Americans (OR=0.3 [0.1,0.6] p<0.0016) and Hispanic (OR=0.5 [0.3,0.9] p=0.0423) were less likely to receive treatment compared to pregnant drug users who were non-Hispanic Caucasians. Pregnant drug users who abused drugs (OR=7.5 [3.6,15.8] p<0.0001) or were dependent on drugs (OR=11.9 [7.2,19.5] p<0.0001) were more likely to receive treatment. CONCLUSIONS: Study showed that non-Hispanic Caucasian pregnant women were more likely to receive treatment for substance use compared to non-Hispanic African American and Hispanic population. Appropriate medications, intense outpatient care, recovery and peer support should be provided to minority drug users as well as users who abuse or are dependent on drugs.

PHP11: RECENT TRENDS IN PROVIDER PERCEPTIONS AND USE OF VALUE FRAMEWORKS IN THE UNITED STATES (US)

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OBJECTIVES: The increasingly high cost of specialty and oncology drugs has resulted in the development of value assessment frameworks (VAF). It was the goal of this study to assess provider familiarity with VAFs and the manner in which VAFs are used to inform treatment decisions. METHODS: A blinded electronic survey was conducted with board-certified US oncologists in June 2017. Respondents were asked 11 questions about their knowledge, use, and perceptions of current oncology VAFs (ie, ASCO, NCCN, DrugAbacus, ESMO). RESULTS: Almost half (49%) of the 51 providers worked in private practice, 27% in a community hospital, and 20% in a teaching/academic setting. Respondents had the highest level of familiarity with NCCN Evidence Blocks (31% extremely familiar) and lowest with ESMO (61% not familiar) as rated on a 7-point Likert scale. Respondents reported utilizing the ASCO and NCCN VAFs with the highest frequency (73% and 80%, respectively) in the previous 6 months. Respondents identified that when utilizing the ASCO and NCCN VAFs, clinical assessment was the most important aspect, followed by overall patient specific parameters, and economic assessment. One-third (35%) of all respondents noted they were waiting for a revised VAF version to become available, while 21% stated that insufficient validation was the primary reason for not using current VAFs. Value rankings based on product cost and clinical benefit were rated as the most important information provided by VAFs, with a detailed health economic appraisal being the least important VAF objective. CONCLUSIONS: Involvement and use of VAFs across providers in the oncology environment is still not consistent in decision-making. Providers identified multiple limitations across VAFs, which result in sub-optimal adoption to inform care decisions. As VAFs evolve, ongoing research is needed to gauge changing provider and payer attitudes and application of VAFs in decision-making.

PHP12: ADULT RISK FACTORS OF NONCOMMUNICABLE DISEASE OUTCOMES

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OBJECTIVES: Global mortality for noncommunicable diseases (NCDs) remains high and is increasing. The impact of major NCDs on developed European countries is disquieting. A risk predictor analysis of NCD outcome indicators is key to fight increasing global mortality and aid global monitoring. With this motivation, this study aimed to address the risk factors of NCD outcomes. METHODS: Data from the World Health Organization (WHO) were used to assess NCD country profiles in 194 countries for the year 2014. The proportional mortality (percentage of total deaths) from NCDs was used as a predictor variable, and tobacco consumption, alcohol consumption per capita, raised blood pressure, and obesity variables were used as covariates. A random forest plot was used to examine NCD-related mortality risk factors while performing a Classification and Regression Tree (CART) algorithm. Classification
One of them (ChondroCelect) has been covered under §135 SGBV, one within the AMNOG process is not yet available. Further two products, listed on earlier vers

The objective of this study was to analyze the purchasing prices of the "additional list" drugs obtained by APHP in comparison to French hospitals formerly under overall allocation (ex-UOA). METHODS: We conduct a retrospective, cross-sectional comparative study over the period 2011-2015. The comparators selected are the ex-UOA hospitals. Annual data on consumption, local and national expenditure are extracted from the databases of the Hospital Information Technology Agency, respectively "ePMSI" and "Scansanté". Information on the level of "added medical benefit" (AMB), the status of medicines and their molecular nature are obtained from the Thériaque® database, the French public drug database and the French national generic’s register supplemented for therapeutically equivalent by the General Agency of Equipment and Health Products of Paris hospitals (AGEPS). Comparisons are made with the average national purchase prices, excluding AP-HP, and the average AP-HP purchase prices. The robustness of the APHP data is determined by comparison to the declarative data with the data contained in the internal database of AGEPS. Software R is used. RESULTS: Our study covers 1227 references of common unit of dispensing (CUD) (2011-2015). For the majority (46% - 55%) of CUDs, the purchase price declared by the APHP is equal to the average purchase price of the comparator. APHP obtains better purchase prices on a larger number of CUDs (28% -32%) than the comparator (20% -23%). The volume of consumption and the level of ASMR don’t have significant impact on distribution of the price differentials. By contrast, reimbursement price cap (RPC), molecular nature (monoclonal antibodies or human immunoglobulins) and the existence of competition have significant impact on distribution of price differentials. For the most CUDs, APHP’s declarative data are different with data contained in the internal database of AGEPS. CONCLUSIONS: In general, APHP obtains better purchase prices than ex-UOA hospitals for low-RPC medicines, human immunoglobulins and medicines subject to competition.

The EU Regulation No. 1394/2007 of the European Parliament and the Council on ATMP defines all medicinal products based on gene therapy, somatic-cell therapy or tissue engineering launched in Germany since 2007 as drugs. Therefore, ATMPs should fall under the AMNÖG process acc. to §35a SGBV – or be exempted from it. The objective of this study is to assess how ATMP products have been evaluated by the German Federal Joint committee (Gemeinsamer Bundesausschuss – G-BA) and what the consequences for the market access of the evaluated products were. METHODS: All ATMP products registered between 01.01.2009 and 22.06.2017 which have a centralized international (through EMA) or a national market authorization in Germany have been analyzed to understand (1) how many ATMP products went through a regular drug evaluation (AMNÖG)? (2) In how many cases has the G-BA decided to use a different way of assessment and what does the process of evaluation mean for the market access of those products in Germany? RESULTS: 15 ATMP products currently listed in Germany, either have a centralized marketing authorization for the EU (6 products) or a national authorization pursuant to the special provisions of Section 4b AMG (9 products). Of the 15 ATMP products two products (Glybera, Imlygic) covered within the AMNÖG process and two (MACI, Holoclar) under §135 and §137c SGBV, for the remaining 11 ATMPs a decision is not yet available. Further two products, listed on earlier version but withdrawn, no longer have a valid marketing authorization. One of them (ChondroCelect) has been covered under §135 SGBV, one within the AMNÖG process.
(Provenge). **CONCLUSIONS:** Though the EU regulation defines products based on gene therapy, somatic-cell therapy or tissue engineering as drugs, the market access process in Germany follows only in some cases the specific drug procedures for new drug products, the AMNOG process.

**PHP15: EARLY ACCESS TO MEDICINES PATHWAYS – RESULTS OF A GLOBAL SURVEY**


**OBJECTIVES:** Regulators and HTA bodies are increasingly promoting early access to medicines for the treatment of diseases with unmet clinical need. A variety of different early access pathways have emerged across settings. A global survey was undertaken to identify, map, and differentiate early access pathways. **METHODS:** Two survey tools were developed to map early access pathways across 25 countries. The first tool included 28 questions on different types of accelerated marketing authorisation, and was distributed to a selection of contacts from a number of regulatory bodies (n=12). The second tool included 15 questions on the use of medicines prior to marketing authorization (MA) and was distributed to HTA agencies from a number of countries (n=25). Both survey tools were available in English via Qualtrics from May 2017. **RESULTS:** Preliminary results from the survey (n=17) suggest that early access schemes can be grouped in four different pathways: a) MA with faster review time (n=3), b) MA with lower evidence thresholds (n=2), c) MA based on approval in other settings (n=2), and d) access to medicines prior to MA (n=14). Five regulatory bodies (EMA, FDA, MEDSAFE, PMDA, and HSA) reported some type of accelerated MA procedure. Fourteen countries (Austria, Norway, Sweden, Switzerland, Poland, Portugal, Belgium, Denmark, Germany, France, UK, Spain, Italy, USA, and Australia) grant access prior to MA. Two countries, Canada and Australia, also indicated additional methods of promoting faster access by commencing HTA in parallel with MA. **CONCLUSIONS:** Across all pathways, differences emerge in the eligibility criteria and conditions attached to early access. Except for verification review, all pathways require significant unmet clinical need or evidence of significant improvement over existing therapies.

**PHP16: FACTORS INFLUENCING INNOVATIVE DRUG REIMBURSEMENT IN POLAND**

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**OBJECTIVES:** In Poland, the Minister of Health (MoH) takes into account 13 criteria for reimbursement. Most of those criteria are related to HTA. The first criterion is Economic Commission Statement, and the second is a Recommendation of the President of Agency for Health Technology Assessment and Tariff System (AHTAPol). The aim of this study is to evaluate the relationship between recommendations of AHTAPol’s President (RAP) and MoH reimbursement decisions (MoHD). Additionally, we evaluated HTA consulting companies on the outcomes of their dossiers. **METHODS:** An analysis was performed for innovative drugs applications in the period of 2015-2016. The proportion of positive and negative decisions of RAP and MoH, and the association between RAP and MoHD using Cramér’s V coefficient was measured. An analysis was conducted of the reimbursement decisions for dossiers submitted per HTA company. In order to be included in the analysis, a company needed to have at least 10 applications evaluated in the specified time period. **RESULTS:** In the period analysed, 56% of applications received positive RPA and 49% received positive MoHD on reimbursement. 15% of applications, despite negative RAP, received positive MoHD. On the other hand, 23% of drugs with positive RAP were not reimbursed. Cramér’s V between RAP and MoHD amounted to 0.24 (value of 1 indicates full compliance). Dossiers prepared by INAR had the highest percentage (65%) of positive MoHD out of all submitted, and the highest number (20) of positive MoHD. Other companies were also analysed. Impact of Economic Commission Statements could not be analysed because of a lack of transparency. **CONCLUSIONS:** Analyses showed that there is a weak association between MoHD and RPA when measured by Cramér’s V. Results suggest that HTA company experience could have an impact on final MoHD, but further analysis should be taken.

**PHP17: HOW WELL DOES THE LEADING PHARMACEUTICAL REFORM MODEL WORK IN CHINA? – AN INTERRUPTED TIME SERIES ANALYSIS**

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**OBJECTIVES:** This present study aimed to explore the impact of the pharmaceutical reform of Sanming city, one of the most leading healthcare reform models in China on both drug and total health expenditures. **METHODS:** Interrupted time series analysis with two intervention points was used to examine the impact of the pharmaceutical reform in Sanming City, China. The first intervention point was the implementation of Zero Mark-up Drug Policy, whereas the second one was the launch of Centralized Procurement of Medicine Policy. Primary outcomes are monthly inpatient drug expenditure and monthly inpatient total health expenditure. Data
spanning from May 2012 to May 2014 are included. RESULTS: Both inpatient drug and total health expenditures exhibited rising trends before any policy was carried out. The launch of Zero Mark-up Drug Policy led to significant instant reductions in levels of inpatient drug expenditure (coefficient= -7,520.90, p<0.01) and total health expenditure (coefficient= -16,737, p<0.01). Moreover, the previous upward trends were changed into downward trends for inpatient drug expenditure (coefficient= -2,747.02, p=0.00) and total health expenditure (coefficient= -3,069.29, p=0.12). However, after the implementation of Centralized Procurement of Medicine Policy, we observed no significant instant level changes and also, the inpatient drug expenditure (coefficient=372.95, p=0.01) and total health expenditure (coefficient=788.76, p=0.06) resumed upward trends again meaning they returned to growing again. CONCLUSIONS: Although the pharmaceutical reform could control or reduced drug expenditure and total health expenditure in short term, the effect became weakened or even faded out in long term, indicating expenditures gradually resumed growing again and reached or even exceeded their baseline levels of pre-reform period. In all, the pharmaceutical reform as a whole failed to meet its goal of combating sharp growth of drug and total health expenditure.

**PHP18: TRENDS IN EMERGING NON-HTA DRUG VALUE ASSESSMENT FRAMEWORKS**

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**OBJECTIVES:** Despite the wide use of Health Technology Assessment (HTA) in some countries, common understanding of value definition and attributes that contribute to value in healthcare is lacking. In response to the debate on access to expensive drugs, various drug value frameworks (VFs) have emerged in recent years. This research aims at comprehensive identification of existing “non-HTA” VFs in the context of this current debate. **METHODS:** Comprehensive literature review of Medline and Japanese ICHUSHI database, websites of ESMO, EU Cancer Patient Coalition, OECD, ASCO, NCCN, and other scientific/governmental organisations was conducted with no time restrictions up to April, 2017 year to identify VFs others than used by HTA agencies. A descriptive analysis was performed to characterise VFs and trends in their development. **RESULTS:** 54 non-HTA VFs were identified. From 2011, a dynamic increase in new VFs was observed at 42% average annual rate with the highest nominal growth in 2015-2016 (24 new VFs). Most VFs originate from the United States (US) and Europe (70%) and are targeted at global (N=25), European (N=14), US (N=13) or other country’s stakeholders (N=2). VFs are to determine value of therapies in all indications (N=27) or in oncology only (N=16). VFs aimed at funding/clinical decision-making prevail (57%) followed by those informing R&D (19%). 90% of new VFs targeted at funding/clinical decision-making in 2015 were dedicated to oncology area. ESMO’s Magnitude of Clinical Benefit Scale, ASCO’s Conceptual Framework, DrugAbacus tool, NCCN Evidence Blocks and ICER value assessment Framework are amidst key recent VFs. **CONCLUSIONS:** VFs others than those used by HTA agencies are gaining importance but their current impact on decision-making is minor. More practicability and validity are expected to enhance their wider adoption. HTA agencies in Europe are showing increased interest in such VFs, which may end up more influential in Europe than in the US.

**PHP19: TIME RESTRICTED DECISIONS IN GERMAN BENEFIT ASSESSMENTS – A SUCCESS STORY?**

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**OBJECTIVES:** Manufacturers are committed to submit a dossier to the G-BA for an early benefit assessment of new drugs in Germany. The G-BA evaluates the dossier and decides about the added benefit of the drug versus the appropriate comparator. The decision on added benefit can be time restricted and reassessed after the deadline. The aim of this study is to give an overview of all time restricted and reassessed processes, to extract the reasons for a time restriction and to compare the decisions on added benefit of the initial assessment and the reassessment. **METHODS:** The G-BA decisions on added benefit and the rationale for all processes were retrieved up to March 15th, 2017 from the G-BA homepage. Extraction included active substance, indication, therapeutic area, G-BA decisions and rationales. **RESULTS:** 37 of all 238 decisions were time restricted. Of these, 15 had already been reassess. Orphan drugs, oncology drugs and drugs with conditional approval were especially prone to receive a time restriction. Common reasons for time restriction were missing data which needed to be generated for EMA or incomplete data on patient-relevant endpoints. The most common restriction period was 2.5 years. The added benefit in reassessments improved in 4 of 15 processes and deteriorated in another 4 of 15 processes. In 7 of 15 processes the added benefit did not change. A common reason for improvement was new data available, while for deterioration missing new data or new evident data which refuted the first decision was most common. **CONCLUSIONS:** A time restricted decision by G-BA frequently affects drugs with unsatisfactory data. Reassessment can improve added benefit if convincing new evidence is available.
PHP20: PRICING AND TIME-TO-MARKET FOR MONOCLONAL ANTIBODIES IN ITALY

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OBJECTIVES: Monoclonal antibodies (MABs) have been on the Italian market for nearly 20 years. We explored the different aspects of Market Access (MA) for MABs by disease area (DA) (autoimmune, oncology, rare, asthma, diagnostics, dyslipidemia, other), in order to highlight possible trends. METHODS: Information was retrieved from EMA and AIFA websites. Analysis was focused on type of pricing, average time to approval (TTA), presence of monitoring registries (MR) and managed entry agreements (MEA) for all MABs approved in Italy (1998 to April 2017). For pricing, we considered drugs with multiple formulations and defined three classes: linear (proportional price-dosage); semi-linear (non-proportional price-dosage); flat (equal price, regardless of dosage). Average TTA was analyzed by year, calculated as the difference between AIFA and EMA approval dates, divided by number of MABs approved in the year over the whole 20 years, last 10 and last 5 years. Presence/type of MR and MEAs were recorded and analyzed. RESULTS: 43 MABs were included, showing clear trend for linear pricing particularly in oncology (90%) and autoimmune diseases (60%). Average TTA was 409 days (1998-2017); 439 days (2008-2017) and 441 days (2013-2017), with wide variations; diagnostics 570, dyslipidemia 542, rare diseases 516, oncology 421 days. 21 (45%) of all MABs (75% in oncology) are currently subject to a total of 33 MR: 81% (17/21) for appropriateness of use, 55% (12/21) outcome-based, 21% (5/21) financial-based, as most MABs have >1 registry in place (eg. for different indications). Intersection of MR with MEAs yields a total of 47 agreements for 25 MABs, at increasing trend over years. CONCLUSIONS: Our analysis shows linear pricing is the most frequent approach for MABs in Italy. Financial MEAs and appropriateness-registries are widely applied, with several cases of multiple measures in place for the same MAB. Time to approval is still quite substantial, 1.2 years on average over the last 5 years.

PHP21: REAL WORLD EVIDENCE IN EUROPE - THE RESULTS OF AN EXPERT SURVEY

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OBJECTIVES: Interest in Real World Evidence (RWE), data not collected via traditional randomised controlled trials (RCT) used in different contexts, is increasing for market-access and reimbursement decision-makers. A global survey was undertaken to understand the use of RWE in these contexts. METHODS: The survey tool, 35 qualitative and quantitative open- and closed-ended questions, was developed iteratively with stakeholders (academia, health services, government bodies, patient organisations). The tool, available in English via Qualtrics from March 2017, included questions on the use of RWE for licensing and coverage recommendations, RWE ownership and the future of RWE. The survey was distributed to a selection of global contacts (n= 260). RESULTS: We analysed preliminary results for 46 returned surveys. Respondents were from 20 countries and a variety of roles (academia, HTA bodies, clinicians and patient organisations). Over two-thirds (69%, n=24) thought it unlikely RWE would support licensing and market authorisation-related decision-making, 91% (32) thought it more likely that RWE would have a role in national-level HTA periodic re-assessment. Less than 40% thought that RWE would ever play a similar role to RCT in drug evaluations, although 14 countries reported accepting lower levels of evidence for decision-making. Respondents from Spain, Russia, Cyprus, Bulgaria, Romania, France and the UK saw potential in the use of RWE in regulatory, reimbursement, and clinical based decision-making, economic evaluations and reassessment-re-review in the next 3-5 years. Those from Bosnia and Herzegovina, Belgium, Austria, Italy and Germany saw less potential. Barriers to RWE use included issues around lack of randomisation, lack of data availability and data quality. CONCLUSIONS: Whilst there are some differing opinions around the use of RWE for regulatory purposes, most respondents see it as a complement to RCT, rather than a replacement. The general opinion is that RWE will become more valuable over time if data quality and availability can be improved.

PHP22: MEASURING THE IMPACT OF THE FOOD AND DRUG ADMINISTRATION (FDA) UNAPPROVED DRUG INITIATIVE (UDI) ON DRUG PRICES AND EXPENDITURES
OBJECTIVES: The 2006 FDA-UDI was implemented to identify and remove unsafe/ineffective drugs from the market. Manufacturers of such drugs could conduct studies to prove safety and/or efficacy and file a New Drug Application, for which approval provided limited market exclusivity. To date, there has been very little research on the potential consequences of this policy on post-approval prices and quantities sold for these drugs. This objective of this study was to assess the impact on prices and quantities sold for drugs that have been approved within the FDA-UDI in the US.

METHODS: The DESI-II list prepared by the FDA Prescription Drug Wrap-Up program of 1984 was systematically searched to identify unapproved marketed drugs that were single-entity prescription drugs. For the drugs which obtained voluntary FDA approval within the FDA-UDI between 2006-2015, a retrospective longitudinal analysis was conducted based on the IMS Health National Sales Perspective database to analyze trends in total expenditures, units sold, and price/unit where all prices were adjusted to 2016 dollars. RESULTS: Eighteen previously-marketed unapproved drug products were identified and 17 were included in the analysis (Neostigmine was excluded due to a shortage unrelated to the policy). Compared to the baseline price measured at two years pre-approval, 11 showed increases in the price/unit two years post-approval ranging from 27% to 8820%, while a decline in price was observed for the remaining six drugs. In addition, 12 showed a decline in quantity two years post-approval (range 2%-93%) while increases were observed for remaining five drugs. Substantial variance was also seen in the changes in expenditures, and in the implied price elasticities. CONCLUSIONS: A marked increase was seen in post-approval prices along with decreases in quantities sold for most of the drugs approved in the FDA-UDI. However, the impact associated with the policy varied substantially across different drug products.

PHP23: PRICE COMPARISON OF NEW DRUGS IN JAPAN, EU AND US

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OBJECTIVES: Japan has the following pricing guidance: a premium is possible to be applied for an Orphan Designated drug if the premium has not been applied to its comparator. The objective of this study is to compare National Healthcare Insurance (NHI) prices of Orphan Designated drugs with Reference Countries’ prices (listed in US: Red Book; UK: MIMS; Germany: Rote Liste; France: Vidal) at the time of NHI price listing. METHODS: NHI price information was obtained from official websites of the Ministry of Health, Labor and Welfare (MHLW). We investigated if new drugs listed from April 2014 to December 2016 had reference countries’ prices and Orphan Designation, and selected NHI prices of new drugs which have at least one or more reference countries’ prices, in addition to Orphan Designation. We compared the selected NHI prices with “Foreign Average Price (FAP)”, the average of all existing reference countries’ prices the “EU Average Price (EUP)”, the average of all existing prices of UK, Germany and France and the “US Price (USP).” RESULTS: A total of 181 new drugs were listed on the NHI price list from April 2014 to December 2016. Out of 181 drugs, 120 drugs (66%) had at least one or more reference countries’ prices, of which 48 drugs (40%) received Orphan Designation. In addition, among the Orphan Designated drugs, 83%, 65% and 91% were priced lower than FAP, EUP and USP, respectively. For other drugs, 88%, 71% and 94% were priced lower than FAP, EUP and USP, respectively. CONCLUSIONS: In the past three years, NHI pricings for new drugs in Japan tended to be lower than Reference Countries’ prices, even of new drugs for unmet medical needs. Further guidance to value new drugs, especially Orphan Designated drugs, would be necessary for the pricing system in Japan.

PHP24: ATTITUDES TOWARDS GENERIC SUBSTITUTION IN GREECE

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OBJECTIVES: Generic substitution is a popular measure for cost containment in pharmaceutical markets. During the last period, it was among the main priorities of the pharmaceutical policy agenda in Greece, and a key element of the economic adjustment programme in health sector. In this context, this study aims to examine the determinants of patients’ attitudes towards generic substitution in Greece. METHODS: A cross-sectional survey was conducted on a representative national sample of 2012 adult individuals. The dependent variable is a binary variable regarding the extent to which respondents could accept generic substitution. The independent variables are: urbanity, social status, gender, age, marital status, education, source of information about pharmaceutical care, chronic conditions and knowledge about generics. The empirical analysis was conducted using a logistic regression model. RESULTS: Our findings suggest that 39.2% of the respondents were willing to accept generic substitution in the pharmacy, as they considered generic medication as an equal therapeutic alternative to branded pharmaceuticals. Male, high educated and those living in urban areas are more likely to have a positive attitude towards generic substitution. Moreover,
respondents who received information from their pharmacists are more likely to accept generic substitution, relative to those being informed by doctors. Chronic patients are less likely to accept generic substitution. In particular, the odds ratios are 0.79 and 0.70 for those having one and two or more conditions respectively. Social status, age, and marital status were not statistically significant determinants of the attitudes towards generic substitution. CONCLUSIONS: A significant share of the respondents is reluctant to accept generic substitution. In this context, some specific population groups may need further information about generic drugs and substitution, and the therapeutic equivalence between generics and branded drugs. The findings of this study are useful towards designing targeted interventions for specific population groups in Greece.

PHP25: EVALUATING PATIENTS’, PHYSICIANS’ AND PHARMACISTS’ PERCEPTION REGARDING GENERIC MEDICINES IN ETHIOPIA: FINDINGS AND IMPLICATIONS

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OBJECTIVES: Generic medicine prescribing has become a common practice in many countries. However, data regarding the perception of stakeholders (patients, prescribers and dispensers) regarding generic medicines in Ethiopia is scarce. The present survey aimed at investigating the perception of patients, physicians and community pharmacists regarding generic medicines in Ethiopia. METHODS: A quantitative cross-sectional survey was conducted between January 1 and February 1, 2017. The questionnaire was administered to patients, physicians and community pharmacists. Frequencies, percentages, Mann Whitney and Kruskal Wallis tests were performed using Statistical Package for the Social Sciences (SPSS) software version 21.0 for Windows (SPSS Inc., Chicago, IL). RESULTS: Majority of patients surveyed (83.1%) agreed that the costs of medicines in Ethiopia is too high and 61.4% of respondents believed that cost should be considered before a drug is prescribed. 75.2% of patients accept the pharmacist substituting their prescribed medications to a cheaper medicine. On the other hand, majority of physicians (70.6%) indicated a very low generic medicine prescription rate. About 91% of physicians and 87.2% of pharmacists agreed that they need a standard guideline to both prescribers and pharmacist on brand substitution process. Furthermore, 39.9% of the physicians and 87.2% of pharmacists agreed that drug advertisements by the manufacturers would influence their prescribing/dispensing practice. CONCLUSIONS: Our findings demonstrate that a significant proportion of patients, doctors and pharmacists hold negative perceptions of generic medicines. The insights obtained in the present study will be useful to healthcare organizations, policy makers and other stakeholders to design and implement a robust generic medicine policy and guideline, thereby promoting the rational and cost-effective use of medicine in the country. [BM1] Physicians

PHP26: OPEN TO THE PUBLIC? A COMPARATIVE ANALYSIS OF DATA PUBLISHED UNDER THE “EMA POLICY ON THE PUBLICATION OF CLINICAL DATA” AND DOSSIERS FOR EARLY BENEFIT ASSESSMENTS IN GERMANY

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OBJECTIVES: Evidence on new drugs is key to various parties in health care for clinical and health policy decisions. With the “EMA policy on the publication of clinical data” in 2015 public availability of such evidence has been highlighted. However, publication of clinical data is not a new issue and has been practiced before by HTA agencies like G-BA and IQWiG in Germany. The aim of this study is to determine the information provided in both, German dossiers/benefit assessments and the EMA database, comparing reporting quality. METHODS: All documents were retrieved from the G-BA homepage and the EMA database until March 15th 2017. The following sources for extraction had to be available: Dossier module 4 and benefit assessment (G-BA), any clinical data available on the EMA database. Extraction included 16 study methods and 8 results items (method used by Koehler et al. BMJ 2015; 350: h796). Reporting quality was rated as “completely reported”, “partly reported” or “not reported”. RESULTS: Overall only 2 drugs had both available, G-BA dossier/assessment and EMA clinical data (Elotuzumab and Carfilzomib). For these 2 drugs 15 clinical studies were assessed. Both sources reached high grades of completeness. G-BA dossiers/assessments (2 studies) were 100% completely reported for methods (32 out of 32 items) and 87.5% completely reported for results (14 out of 16 items). For EMA clinical data (13 studies), the rate was 86.1% for methods (179 out of 208 items) and 97.1% for results (101 out of 104 items). CONCLUSIONS: Regarding reporting quality, no major differences between G-BA dossiers/assessments and EMA clinical data was observed. Both publicly available sources provide sufficient information on new drugs. Nevertheless, each datasource has advantages and deficits. AMNOG documents are available in German language only and the EMA database currently only contains a very limited number of newly approved drugs.

PHP27: MEDICINE PRICES DISPARITY AMONG RETAIL PHARMACIES IN SELANGOR, MALAYSIA

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OBJECTIVES: Data on medicine prices at retail pharmacies is vital to various stakeholders in health care for clinical and health policy decisions. This study aimed to determine the price disparity among retail pharmacies in Selangor, Malaysia. METHODS: A cross-sectional study was conducted in 2017 between 30 March and 31 March. Data was collected using structured questionnaire from 462 pharmacies selected using a systematic sampling method. Data was analyzed using SPSS version 24. RESULTS: The average medicine price of antiinfectives was the highest in all the pharmacies (75.23 ± 41.13). The price of antiinfectives was highe...
OBJECTIVES: To date, there is no stipulated law to control medicine prices in Malaysia. This free pricing policy has led to disparity of prices between innovator and generic medicine among the private healthcare settings, namely general practitioner (GP) clinics (independent, chained) and retail pharmacies (RPs) (independent, chained). This study was carried out to evaluate the medicine (innovator, generic) prices variation among the RPs in Malaysia. METHODS: Simulated client method was adopted in this study to obtain the actual selling medicine prices in the RPs in the state of Selangor, Malaysia. A total of 142 RPs were selected, using simple random sampling technique. Five data collectors were recruited and trained as simulated clients to elicit the actual selling price for the 10 selected medicines (both innovator and lowest price generic) which are highly used in Malaysia. RESULTS: For innovator, only salbutamol 100 mcg inhaler (200 doses) (p=0.043) and gliclazide 80 mg tablet (p=0.043) were sold at a lower price at chain RPs when compared to independent RPs. As for lowest price generic products, only furosemide 40 mg tablet (p=0.002) and metoprolol 100 mg tablet (p=0.036) were found to be cheaper at the chained RPs than the independent RPs. Of note, simvastatin 20 mg tablet (Zocor®) was sold at a higher median (range) price at the chained RPs than the independent RPs [RM 2.63 (2.19-3.80) versus RM 2.32 (1.17-4.13), p=0.009]. CONCLUSIONS: It was interesting to find that the perception of cheaper price of medicines in chained pharmacies as compared to independent pharmacies is fallacious. The findings of this study will facilitate policy makers in drawing conclusion about the differences of medicine prices and will be useful in devising appropriate policy for medicine price control in Malaysia.

PHP28: PRICING PANTOPRAZOLE IN GREECE: A TALE OF DISTORTION

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OBJECTIVES: Generics in Greece are priced at 65% of the price of the reference off-patent while off patents are priced at the minimum between a decrease of 50% of their latest on - patent price, and the average of the three lowest prices of the same product among the EU countries. The purpose of this study is to assess the price level of generics pantoprazole in Greece. METHODS: Official pricing data were used to identify the three EU countries which set the outpatient market price for off-patent pantoprazole 40 mg in Greece in December 2016. The ex-factory prices for the originator and generics in each of the three EU countries were derived from the official price sources in each country. All prices were normalized to correspond to monthly treatment. RESULTS: Originator pantoprazole price derived from the prices of the same product in Ireland, Poland and Austria. Average ex-factory price for generic pantoprazole 40mg in Greece (2.05€) were lower than the respective ex-factory price in Ireland (3.08€: -33.31%), in Poland (2.61€: -21.35%), and in Austria (2.76€: -25.68%). CONCLUSIONS: Average ex-factory price for generic pantoprazole in Greece is up to 33.31% below the respective generic prices at the EU countries with the lowest price of the reference originator. With rebates and clawback considered, the average ex-factory price for generic pantoprazole in Greece is further reduced by 30% approximately in 2016. However, despite the excessively low net ex- factory price of generics (after rebates and clawback), current generic penetration (~25%) still remains far from the MoU target of 40% by volume for 2017. This suggests for the need of an effective and reasonable pricing regulation to ensure market viability for generics in parallel with demand side measures to foster generic use through appropriate incentives for physicians, pharmacists and patients.

PHP29: DEMAND AND SUPPLY SIDE REGULATION OF BIOSIMILAR MARKETS IN GERMANY, FRANCE AND ENGLAND AND ITS IMPLICATIONS FOR MARKET ACCESS OF BIOSIMILARS

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OBJECTIVES: As an advanced market for biosimilars, Europe will become even more important expecting patent expiries of top biologicals until 2020. As market chances of biosimilars will highly depend on reimbursement regulations and regulation instruments addressed at physicians, pharmacies and patients, this study analyzes regulation strategies of three major European countries. METHODS: Based on a literature search in electronic databases and a hand search on websites of relevant national regulation authorities, we systematically compared national regulations concerning biosimilar markets. RESULTS: Central pricing and reimbursement decisions in all three countries are generally assisted bei HTAs, but only in France and partly in England biosimilars undergo an own HTA. In England and France price is set by central agreements, in the case of France a discount of 30% from the price of the biological is expected. As Germany assesses biosimilars as equivalent to the corresponding biological,
the price is indirectly influenced by the reference price set for reimbursement in social health funds. Decentral tendering in the hospital sector is used in all three countries, whereas only Germany up to now used special non-exclusive tendering variants in some cases of biologicals and biosimilars. Concerning the substitutability of biologicals and biosimilars, only in France pharmacies may legitimately do so in treatment-naïve patients. In Germany, on the other hand, in some regions minimal quota for the use of biosimilars are set for outpatient physicians to control their economic efficiency. **CONCLUSIONS:** Market access for biosimilars depends on the sustainable chance to achieve market shares and prices to refinance market access costs which are considerably higher than in generic markets. This requires the possibility of access to patients and physicians, which is closely connected to regulations concerning substitutability and substitution incentives, but also to regulations concerning price competition. Further discussion is needed on the use of tenders in these markets.

**PHP30: PRICING REGULATION FOR GENERICS IN GREECE: THE CASE OF ATORVASTATIN.**

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**OBJECTIVES:** Recent pricing regulation in Greece provides that generics are priced at 65% of price of the reference off-patent while off-patents are priced at the minimum between a decrease of 50% of their latest on-patent price, and the average of the three lowest prices of the same product among the 27 EU member states. The purpose of this study is to assess the price level of generics atorvastatin in Greece. **METHODS:** Official pricing data were used to identify the three EU member states which set the outpatient market price for off-patent atorvastatin 20mg and 40mg in Greece in December 2016. The ex-factory prices for the originator and generics in each of the EU countries were derived from the official price source in each setting. All prices were normalized to correspond to monthly treatment. **RESULTS:** Average ex-factory price for generic atorvastatin 20mg in Greece (2.68€) were 40.18% lower than the price in Croatia (4.48€), 51.45% lower than Belgium (5.52€) and 52.73% lower than Luxemburg (5.67€). Average ex-factory price for generic atorvastatin 40mg in Greece (3.97€) were 6.99% higher than the price in Slovenia (3.71€), 13.97% lower than Bulgaria (4.61€) and 46.43% lower than Croatia (7.41€). **CONCLUSIONS:** Average ex-factory price for generic atorvastatin in Greece is up to 52.73% below the respective generic prices at the EU countries with the lowest price of the reference originator. With rebates and clawback considered the average generic atorvastatin ex-factory price in Greece is further reduced by 30% approximately (for 2016). However, despite the excessively low generic price levels, current penetration (~25%) lacks behind the MoU target of 40% by volume for 2017, suggesting the need of a reasonable pricing regulation allowing viability for generics in parallel with demand side measures to enhance the use of generics through appropriate incentives for physicians, pharmacists and patients.

**PHP31: THE RESEARCH AND SUGGESTIONS ON THE ACCESSIBILITY OF HIGH VALUE DRUGS IN CHINA**

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**OBJECTIVES:** China has formed a multi-level medical security system, in which the health insurance acts as the main body and social assistance as the support. However, the protection level of major diseases is still low and the range of protection is narrow. Drugs to orphan and major diseases are often of high price, and the existence of the problems that patients becoming poor due to diseases, and becoming poor again due to diseases is still troublesome. In this paper, we study the feasibility of establishing a multi-party co-payment system for patients with such diseases, and put forward opinions and suggestions on the accessibility of high-value drugs. **METHODS:** Four methods: search in document data basement, surveys (52), and interviews with experts and discussions with focus group. **RESULTS:** Major diseases have certain similarities and drugs to these diseases are of usually high price, families of patients who need long-term use of drug, can’t usually afford the annual cost of drugs. This study focuses on the analysis of charitable participation in high-value drug co-payment protection mechanism, linking up health insurance, medical assistance and social charity and so on. By collecting information on domestic and international research, interviews with experts and scholars as well as research questionnaire content, forming a co-payment security mechanism with health insurance fund as the main body; commercial insurance, medical assistance and social charity working together, which could reduce the burden on patients, so that patients can afford high value drugs. **CONCLUSIONS:** The research shows that more than 86.7% of the people are for the establishment of co-payment mode to protect the patients of major diseases. But experts also pointed out that in the current stage of China’s health insurance, the financing capacity is insufficient, the participation of commercial insurance is low. The implementing of high-value drugs co-payment mechanism requires the promotion in national level.

**PHP32: E-HEALTH FUNDING IN EUROPE**

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OBJECTIVES: e-Health technologies which optimise traditional devices and drugs (e-Connected) cross different regulatory frameworks. This study aimed to provide an overview of the funding pathways for e-Health technologies in Europe. METHODS: A literature review was conducted from government and health authority websites, PubMed, and grey literature to identify funding regulations, processes, and practices in EU-5. RESULTS: In Europe, there is no standard reimbursement pathway specific to e-Health in place. EU directives are in development and the overall framework is to be established by 2020. Differences in reimbursement approach reflect differences in healthcare system structures leading to differences on what will be funded (scope), who pays (payer), and on what basis will payment be made (payment method). UK and Germany offer possibilities to have integrated contracts where all technology components may be funded together. However, there are no guarantees that all technology components will be funded. It depends on specific agreements with the CCGs (UK) and health insurances (DE). In other situations, each technology component is identified as one reimbursement area and goes through different reimbursement paths. Currently, most do not have a standard funding path such as remote monitoring fee, electronic health records (EHR) integration and maintenance. UK is a frontrunner in the use of EHRs as a national infrastructure is already in place unlike the other countries. However, interoperability of e-Health solutions with EHRs must be assured by the manufacturer for each type of EHR. CONCLUSIONS: E-health programs remain small scale pilots without any perennial funding. A major obstacle preventing e-Health solutions to reach the mainstream of healthcare provision is related to the lack of innovative and adequate reimbursement models. EU regulatory frameworks are still catching up with the technology. The lag in the regulatory pathways may explain the lack in clear funding pathways in the EU.

PHP33: COMPARISON OF FOOD AND DRUG ADMINISTRATION, EUROPEAN MEDICINE AGENCY AND SWISSMEDIC NEW DRUG APPROVAL: AN ASSESSMENT OF THE INTERNATIONAL HARMONIZATION

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OBJECTIVES: This study aims at comparing new human pharmaceutical drug approvals between the Food and Drug Administration (FDA), the European Medicine Agency (EMA) and Swissmedic (SMC) for the period January 2007 - 2017 using a comprehensive comparative analysis. METHODS: This study include regulatory information, approval date, indication of new drug in the assessment period. Descriptive statistic analyses were performed for all variables. Significant level (p-value) was set at 0.05. T-test and x2-test were used to assess differences. All analyses were performed using Microsoft Excel 2016. Data are presented using proportions (%) and time lag between approval dates in months. RESULTS: From January 2007 to 2017, FDA, EMA and SMC approved 134 new drugs in common. Overall, 66.4% of the products were first approved by the FDA while 30.6% by the EMA and 3.0% by SMC. T-test indicates that the difference in approval dates between SMC and EMA was non-significant (p=0.636) while it was significant between SMC and FDA (p<0.0001) as well as between EMA and FDA (p<0.0001). The indications approved by the FDA, EMA and SMC for the same product were similar in content for 31 (23.1%) drugs while it was different for 103 (76.9%). Significant differences (p<0.0001) exist between FDA and SMC as well as FDA and EMA. But differences were not significant between EMA and SMC (p=0.146). CONCLUSIONS: Drugs tend to be first approved by the FDA. Significant differences exist in characteristics of new drug in the assessment period between FDA on one side and EMA and SMC on the other side. Despite international trend to harmonization, based on scientific data included in a marketing application, regulatory decisions are complex and depend in part on an environment of public health policy and law as well as demands through researchers and health professional in the patient interest.

PHP34: INNOVATIVE CONTRACTING: USE OF COMPLEX MANAGED ENTRY AGREEMENTS

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OBJECTIVES: Simple managed entry agreements (MEAs) (e.g. finance-based) for high-cost pharmaceuticals in cost-constrained markets have existed for decades. However, efforts to balance remuneration for innovation with limited healthcare funds has led to an increase in complex MEAs (e.g. risk-sharing agreements). This study examined the current prevalence of MEA types for twelve countries, and willingness within these countries to adopt complex MEAs going forward. METHODS: Using secondary research, prevalence and types of MEAs were analyzed in twelve countries across Europe, North America, Latin America and Australasia, while primary interviews with US and EUS payers focused on historical and current use of MEAs and on willingness to adopt complex MEAs. Trends based on geography, pharmaceutical market size and common factors, such as entrenched HTA usage, were isolated, and potential roadblocks and barriers for further global complex MEA adoption were analyzed. RESULTS: Of the twelve countries examined, Italy, Sweden, Australia, and the UK exhibit high prevalence of MEAs, and those countries also
had either a high prevalence of current complex MEA use or willingness to adopt complex MEAs in the future. Among Canada, the US, France and Poland, there is medium-level MEA prevalence, with still strong willingness to adopt complex MEA types. However, low prevalence of MEAs is shown in Brazil, South Korea, Germany, and Spain, with all four countries reluctant to adopt complex schemes. This geographic distribution shows that while Europe is the current leader in MEA use, global MEA prevalence and willingness to adopt complex MEAs are on the rise. The main barriers to MEA adoption include the administrative and cost burden of monitoring, and lack of necessary infrastructure. **CONCLUSIONS:** European and other countries and industry have been using MEAs to mutually beneficial effect for some time, and the prevalence is growing globally. The use of complex MEAs is increasing rapidly in Europe and beyond.

**PHP38:** PROVIDING A FRAMEWORK FOR ASSESSING ACCESS TO MEDICINE

**PHP37:** PROBABILISTIC SENSITIVITY ANALYSIS AND ITS ROLE IN ASSESSMENT OF PROFITABILITY IN POLAND

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**OBJECTIVES:** In August 2016, guidelines for conducting Health Technology Assessment in Poland were updated. Since then, the Agency for Health Technology Assessment and Tariff System (AOTMiT) has required manufacturers to conduct a probabilistic sensitivity analysis (PSA) or provide an adequate justification for lack of it. The objective of this review is to assess whether current decisions made by AOTMiT depend on the results of PSA. **METHODS:** Submissions from 1 August 2016 up to 26 May 2017 with AOTMiT assessment reports and recommendations of the President of AOTMiT were identified and analysed, if probabilities of cost-effectiveness were publically available. If several probabilities were provided, appropriate ranges were used and graphically presented. **RESULTS:** A total of 32 submissions were identified within the analysed timeframe. PSA was performed in 21 (65.5%) cases and justification for lack of PSA in pharmacoeconomic analysis was only presented in 3 out of 11 (27%) remaining cases. Finally, only 14 out of 21 submissions were taken into consideration, since probability of cost-effectiveness was undiscovered in the 7 remaining cases. The recommendation of the President of AOTMiT was positive in 5 and negative in 9 cases. To assess a relationship between the PSA outcomes and recommendation character, the results were plotted on a graph. **CONCLUSIONS:** It can be assumed that technologies with a probability of being cost-effective lower than 30% tended not to be recommended. However, this analysis should be treated with caution as it was limited by a small number of appraisals with PSA results available. There is a need for greater transparency of PSA outcomes to assess their role in the decision-making process in Poland. To assess a correlation between results of PSA and character of the recommendation of the AOTMiT President, more samples need to be reviewed and analysed.

**PHP35:** FACTORS RELATED TO OUTPATIENT ANTIBIOTIC DRUG CONSUMPTION IN TURKEY

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**OBJECTIVES:** Turkey is currently a European leader in antibiotic consumption. To fight against increasing consumption, it is necessary to understand factors related to antibiotic drug consumption. To fill this gap in the literature, this study intends to probe factors related to outpatient antibacterial drug consumption in Turkey. **METHODS:** Data from the National Antibacterial Drug Consumption Surveillance report and the Turkish Statistical Institute were assessed. The number of physicians; socio-economic development index (SEDI); endocrine, nutritional, and metabolic disease mortality; employment; education; and geographic region were used as factors related to outpatient antibacterial drug consumption. Euclidean distance measure and complete linkage methods were used to draw a heatmap. A hierarchical cluster analysis was performed to visualize factors related to outpatient antibacterial drug consumption. Additionally, 81 provinces of Turkey were used as a decision-making unit in the analysis. Sensitivity analysis of province group differences in terms of study variables were examined using independent sample “t” and Chi-square (“X2”) tests. **RESULTS:** Study results revealed a close link between education and outpatient antibiotic drug consumption in Turkey. In addition, 81 provinces were categorized into two groups representing rural and urban regions of Turkey. The differences in province group sensitivity results – according to the number of physicians (t=2.522, p<0.05); SEDI (t=4.986, p<0.05); endocrine, nutritional and metabolic diseases, mortality (t=3.317, p<0.05); employment (t=1.684, p<0.05); antibacterial drug consumption (t=6.470, p<0.05); and education (t=3.544, p<0.05) – were statistically significant. **CONCLUSIONS:** The study results highlight the need to raise awareness in Turkey regarding appropriate consumption of antibacterial drugs. Antibiotic awareness campaigns, consideration of increasing cost, communication among stakeholders, and strong sustainable use policies are essential to combat increasing antimicrobial resistance in Turkey.
OBJECTIVES: One of the main goals of all health systems is to improve access to safe and effective medicines. Assessment is a very important phase of national medicine programs of access improvement. The goals of this study are to collect and compile suitable indicators and provide a comprehensive framework for assessing access to medicine. METHODS: A literature review with systematic search was conducted using Pub Med/ Medline, Scopus and Google Scholar databases in order to investigate the published materials on access medicines framework or indicators. The results of systematic search were completed with comprehensive government documents search. All the articles and documents were reviewed with two researchers and related indicators were extracted. Then the collected data were cleaned of duplicate entries or unnecessary concepts in focused group discussion consisting of academics and IRFDA (Iran food and drug administration) experts. Then a Delphi questionnaire was sent to the 17 experts from academia, Social Security Insurance, IRFDA, Ministry of Health and Iran Pharmacist Association. The Delphi technique has finalized with an expert panel. RESULTS: According to the results of systematic search, 126 indicators have been found. After primary cleaning, 77 indicators were sent to the 17 experts in a Delphi form. Delphi finalized in expert panel and 67 indicators were approved in 5 categories including physical availability and geographical accessibility (19 indicators), affordability (23 indicators), human resources (4 indicators), quality and safety (5 indicators), information and rational use (16 indicators). CONCLUSIONS: Full access to medicine has been composed of different aspects of access from providing national medicine list until rational use which have been categorized in five categories in this study. All the categories have several indicators to assessment and further local surveys are necessary to describing the access status in each country.

PHP39: PHARMACEUTICAL ASSISTANCE PUBLIC FUNDING IN A BRAZILIAN CITY AND ITS IMPLICATIONS FOR THE UNIVERSAL ACCESS TO ESSENTIAL MEDICINES

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OBJECTIVES: To ensure the constitutional right to health, a national health system was created in Brazil, in 1988, appointing municipalities as the main executors of health actions and services. The universal access to basic essential medicines is cities’ responsibility, while the federal government and the states dispense high-end drugs. However, an alternative way to get access to public funded medicines is being consolidated: a phenomenon called “Judicialization of Health”. It happens when an individual judicially claims healthcare provision. In 2015, the Health Ministry’s expenditure on drugs judicialization was USD 281,704,610.00 – 8% of the federal pharmaceutical assistance budget. Since municipalities have smaller funds, this research aims to analyze judicialization’s budget impact in a small Brazilian city and its implications for the universal access to essential medicines. METHODS: “Ouro Branco” was chosen due to its small populational size (estimated at 38,601 residents in 2016) and the availability of detailed expenditure records within the City Hall’s website. All the medicines purchase expenses using municipal resources were analyzed for 2015 and 2016. The amount disbursed in both the universal pharmaceutical assistance policy and the drugs judicialization was calculated for each year and for the whole period. RESULTS: Ouro Branco invested USD 28,486.17 in its universal policy for the 2015-2016 period (around USD 19,000 less than established by regulation) while USD 27,991.68 were destined to judicialization. In 2015, the judicialization expenses equated to 40% of the universal policy investment. In 2016, this ratio rose to 173%. Records show that, in 2016, all judicialization expenditure benefited only five citizens. CONCLUSIONS: Once all government levels answer to all price drugs judicialization, this phenomenon damages mostly small cities’ budgets and consequently their universal pharmaceutical assistance policy. Despite judicialization is based on the “right to health” argument, it harms the right’s universality when it reallocates public funds to benefit a few individuals.

PHP40: ACCELERATED UPTAKE OF INNOVATIVE HEALTH TECHNOLOGIES: A LITERATURE REVIEW


OBJECTIVES: The Accelerated Access Review made recommendations to speed up access of patients to innovative technologies (medicines, devices and diagnostics), but evidence on how best to achieve this is not readily available. We conducted a literature review of measures to accelerate uptake of health technologies after regulatory approval. This encompasses identification of markets in which pace of adoption has been reported as an issue, initiatives/mechanisms implemented to overcome delays or to accelerate uptake, and their outcome. METHODS: A systematic search of Embase, Medline, Cochrane and the grey literature published in English in 2011-2016. Combinations of search terms such as ‘health care’, ‘innovation’, ‘uptake’, ‘scheme’ and ‘reimbursement’ were used.
Identification of relevant articles and data extraction was performed by two independent reviewers with differences resolved by consensus. The evidence was synthesised using a narrative approach. **RESULTS:** Thirty-two articles met the inclusion criteria. A wide range of themes emerged, including horizon scanning; price negotiation; health technology assessment consideration of ‘innovation’; managed entry agreements (such as conditional approval and financial risk-share); health service financial flows; and leadership around promotion of evidence-based medicine. The most prevalent theme was conditional access. Many papers described the issues and conceptual solutions, rather than reporting implementation of measures and their outcome. **CONCLUSIONS:** The evidence base on accelerating innovation uptake is limited, from studies with varied designs and quality, and often specific to individual market and policy contexts. Nevertheless, a wide range of factors limiting uptake of innovative technologies is evident, and numerous potential solutions have been proposed. This suggests that multi-factorial interventions that are market and policy specific with pilot testing are required.

**PHP41: CAN EARLY ACCESS SUPPORT CONTINUED ACCESS? THE RELATIONSHIP BETWEEN EAMS AND NICE**

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**OBJECTIVES:** The Early Access to Medicines Scheme (EAMS) launched in April 2014 with the aim of providing patients with severe, life-threatening diseases without adequate treatment options to access to medicines prior to their marketing authorization. Thus, for products with an EAMS designation, there will be real world evidence (RWE) with the product prior to health technology assessment (HTA) decision-making by the National Institute for Health and Care Excellence (NICE). This research aimed to assess if, and how, EAMS data is being utilised in the NICE appraisal process. **METHODS:** All EAMS designations as of 26/06/2017 were identified from the MHRA website. For products with final NICE guidance, the full manufacturer submission, as well as all publically available NICE documentation was reviewed. **RESULTS:** 16 product:indication pairings with an EAMS designation were identified, of which 6 have received final NICE guidance. 6/6 were recommended and 6/6 included references to EAMS. 6/6 used the EAMS designation to support the product’s innovation status. The number of patients who received access to the assessed drug through EAMS was referenced in 3/6 submissions, and the number of sites with product access via EAMS was referenced in 1/6 submissions. No submissions referenced any RWE outcomes data collected during the EAMS period. References to EAMS not originating from manufacturers included: a patient advocacy group providing a “patient voice” of someone who had received a therapy under EAMS scheme, and public commentary from an NHS professional who reported experience of using a drug as part of the EAMS scheme. **CONCLUSIONS:** Our research shows that experience of products under EAMS has primarily been used to support patient and physician advocacy during the appraisal process. Currently, no RWE outcomes data has been collected while a product was available through the EAMS scheme has utilised to support NICE submissions.

**PHP42: THE INFLUENCE OF PHARMACEUTICAL REFORM IN KOREA A DECADE AGO: WHAT WE WALKED**

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**OBJECTIVES:** Korea had reformed the pharmaceutical listing/pricing system in 2007 according to the governmental DERP (drug expenditure rationalization plan) policy. It has brought innovative changes on the National Health Insurance (NHI) drug reimbursement including the transition into the Positive List System. The aim of this study was to look back the outcome of 10-years’ of it. **METHODS:** Total 15 literatures were selected and data from governmental published reports and internal data of HIRA were included. Impacts of the reform was categorized into 1) pharmaceutical benefit decision, 2) access to affordable drugs, 3) national drug expenditure corresponding the intermediate measures as quality, access, and efficiency to assess health-system performance (Marc Roberts et al. 2008). **RESULTS:** It has institutionalized evidence–based decision-making for medicines; acceptable only if clinically effective and cost-effective. Benefit decision is supported by the Committee equipped with advisory and sub-committees. Appraisal results are disclosed to the public from 2008 transparently. Although the concern on high-cost new drug entry is not only of Korea, the acceptance rate of new medicine (HIRA) is 60.7%~82.7% in 2011~2015 and lower than the UK but greater than Australia or Canada. For severe and rare disease treatments, equitable access was contributed by (i) the risk-sharing scheme for 9 products since 2013 (ii) more flexible ICER level comparing to common drugs (iii) economic evaluation exemption (2015). To streamline access, it reduced statutory period twice. The reform contributes to stabilize pharmaceutical expenditure; as a share of total healthcare expenditure has stopped increasing and maintained the level of <30% (2007~2011). There is no evidence it may strengthen or weaken industrial market or R&D. **CONCLUSIONS:** The reform has led to the improvement of the quality of drug
benefit decision, reinforcement of the access to the appropriate medicine, rationalization of the national drug expenditure and more efficient allocation of resources.

**PHP43: EXPENDITURE ON NON-PHARMACEUTICAL PRODUCTS IN IRELAND DURING A PERIOD OF HEALTHCARE COST CONTAINMENT**

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**OBJECTIVES:** Total expenditure on reimbursed pharmaceuticals in Ireland has fallen since the impact of the economic recession in 2008. However, data used to represent these figures typically contain both pharmaceutical and non-pharmaceutical products. The objective of this analysis is to delineate spending across these two different sectors over the past 14 years in Ireland and assess their relative trends. **METHODS:** Nationwide Primary Care Reimbursement Service (PCRS) data was used for 12 years between 2002 and 2015. The total expenditure across schemes that contain both pharmaceutical and non-pharmaceutical schemes was calculated, and non-pharmaceutical expenditure items were identified and subtracted to produce a total pharmaceutical and non-pharmaceutical expenditure estimates and calculate their relative proportions. **RESULTS:** For non-high-tech medicine, total expenditure decreased from €1.66bn in 2012 to €1.4bn in 2015 (15.7% decreases). For non-pharmaceutical items reimbursed under PCRS, the decrease in expenditure during this period was 0.68m (<0.5% decrease). In 2015, total expenditure on non-pharmaceutical products reimbursed under PCRS was €173m. **CONCLUSIONS:** Since the impact of the economic recession, the total cost of medicines reimbursed in Ireland has decreased. The decrease in expenditure, at a time of increasing demand, was supported by the introduction of mandatory rebates for innovative pharmaceutical medicines. This analysis shows that for non-pharmaceutical items, expenditure reductions over this period were not proportional.

**PHP44: POTENTIAL FUNDING SOURCES FOR BREAKTHROUGH THERAPIES**

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**OBJECTIVES:** Chronic diseases constitute a worldwide public health issue with important clinical unmet needs. Novel breakthrough therapies such as advanced therapy medicinal products (ATMPs) are in development to fulfill those unmet needs. ATMPs are expected to have high upfront costs. A key remaining question is the funding options of these new high cost therapies giving the large target population, and therefore the large budget needed. The aim of this study was to identify new funding sources for novel breakthrough therapies. **METHODS:** A systematic review was conducted in Ovid Medline and Embase to identify innovative funding sources for novel therapies. Studies published between January 2000 and January 2017, written in English or French were included. **RESULTS:** Four funding sources were mainly proposed in the literature: pooled funding, international transaction taxes, front-loading and debt reduction. Pooled funding is a combination of funding from multiple groups or multiple payers (in the case of the United States) to pay for a specific therapy. Another suggested solution is collecting funds through placing taxes and levies on specific transactions (e.g. plane tickets). Funds could also be provided through frontloading mechanism; some donors offer aids and resources to fund novel therapies like the International Finance Facility for Immunization that provided stable funding to achieve immunization goals. Furthermore, an international cooperation by debt reduction can constitute another solution, where a country creditor agrees to write off debt for a country debtor if the latter commits counterpart funding to an account that had been approved for a breakthrough therapy. **CONCLUSIONS:** The suggested methods may be a potential source of additional funds for novel advanced therapies. Those methods have already been used for communicable diseases. A worldwide cooperation is needed to adapt these methods for non-communicable diseases in order to ensure the patient access to innovative therapies while maintaining the health care system sustainability.

**PHP45: NEW DRUGS APPROVAL IN ITALY: ANALYSIS OF THE APPLIED NEGOTIATION CONDITIONS 2015-2017**

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**OBJECTIVES:** This study aims to track and analyse, using Official Journal publications, the negotiation conditions (Managed Entry Agreements [MEAs], monitoring registries, discounts) of novel drugs reimbursed in Italy. **METHODS:** Publicly available Official Journal (OJ) of 47 new active principles approved through European centralised procedure were screened since May 2015 to April 2017. These 47 drugs have completed the P&R process and have been reimbursed. Categorization by drug type and by therapeutic area. For each drug analysed, the kind of MEAs negotiated, the application of confidential discounts and monitoring registries have been tracked. **RESULTS:** Based on these criteria, 47 new drugs were reimbursed in Italy. The 31.6% of these drugs were
assessed as innovative, the 15.8% were orphan and the 10.5% hybrid. The 26.3% were oncological drugs and the 10.5% haematological. 40% (19) of the total sample had a MEA as approval condition agreed between the Marketing Authorisation Holder and AIFA. 3 drugs (15.8%) had 2 MEAs simultaneously applied (1 payment-by-results + budget cap and 2 price-volume + budget cap). One drug had a MEA applied but not disclosed in the OJ. Analysing the 22 MEAs tracked, the 82% were non-outcome based and the 14% were outcome-based. The only outcome-based MEA applied was the payment-by-results, while non-outcome-based MEAs were cost-sharing (6%), budget cap (39%) and price-volume agreements (56%). The 38% of the 47 screened drugs had monitoring registries and 32 (68%) out of these drugs had a confidential discount (13 also had a MEA). **CONCLUSIONS:** A broader use of non-outcome based (financial) MEAs emerged, highlighting the attention showed by AIFA to economic issues. Price-volume agreements appears as the mostly applied MEA, with a monitoring registry as measure to track appropriateness. Publicly available analyses of these tools would be of great help in understanding the real value of their application.


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**OBJECTIVES:** This study aims to track the Italian P&R timing step by step, to verify the trends in approval timings of reimbursed drugs assessed by AIFA from dossier submission (Start) to decision publication on the Official Journal (OJ). **METHODS:** Publicly available agendas and reports of all monthly decisional meetings of the Technical Scientific Committee (CTS) and the Price and Reimbursement Committee (CPR) were screened since January 2015, focusing on new active principles approved through European centralised procedure. Analysed drugs, divided into categories, include the ones with P&R process completed and have been reimbursed. These drugs are part of a monthly updated database (currently 145 drugs) aiming to track the process over the time. For each analysed drug standard checkpoints were identified to measure timings of each single approval steps. **RESULTS:** Up to May 2017, 47 reimbursed drugs have been categorized in: innovative (7), orphan (10), innovative and orphan (2), oncological (9) and other approved drugs (28). The analysis shows an average time between Start and OJ publication of 332 days (min 43 max 959), of which 143 due to CTS-CPR assessment. Other checkpoints reveals an average total administrative delay of 190 days (56% of total time). Timing is significantly reduced in all steps for innovative drugs (247 days) while results longer for oncological drugs (383 days), particularly the CTS assessment. Orphan drugs have shorter opening procedures, but longer assessments. The remaining 28 drugs have longer openings and faster CTS assessments. **CONCLUSIONS:** Despite a relevant speed up in the approval process in the last 2 years compared to previous publications (247,5 days in 2013-2015 vs. 205 days in 2015-2017 for CTS assessment of oncological drugs), the subanalysis by category reveals a variety of pathways, impacting on approval timings. The analysis also reveals that the majority of the overall timing is linked to administrative steps.

**PHP47: GENE-THERAPY, THE WAY FORWARD IN EUROPE – THE PAYER PERSPECTIVE**

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**OBJECTIVES:** Gene-therapy is a novel treatment area that includes stem-cell and genetic products and procedures. Perception of gene-therapy; its use, its value, and appropriate price varies between stakeholders. This research will support the understanding of payers’ perceptions, on the last three gene-therapy launches (alipogene tiparvovec, talimogene laherparepvec, autologous CD34+ enriched-cell-fraction), withdrawal of alipogene tiparvovec and understand ways to incorporate gene-therapy into healthcare budgets. **METHODS:** Secondary research was conducted using systematic literature review (PRISMA methodology) aiming to understand the gene-therapy environment in key markets - Germany, Italy, and the UK. The review included publicly available documents of HTA evaluations and scientific articles. The review served as a base for an online survey of payers in the three countries. An online survey of six payers was conducted; consisting of multiple choice and open-ended questions on their respective country’s experience and readiness for gene-therapy. **RESULTS:** While payers considered the opportunity of gene-therapy as positive, only one payer rated their (Italian) health-system as ready for gene-therapy. Major concerns were insufficiently robust clinical programmes (50%), lack of predictability (80%), lack of experience (100%), and high anticipated prices (100%). One payer (Germany) expects non-curing gene-therapy to be equivalent in cost to a standard drug therapy with similar effects. Payers expect gene-therapy to be curative, and industry needs to effectively demonstrate this. All respondents confirmed a dialogue between industry and payers is needed to agree how to provide satisfactory evidence of value. **CONCLUSIONS:** The findings are in line with the previously identified literature. Work remains to be done to increase payers’ understanding of gene-therapy, its curative and/or symptom relieving potential to effectively prepare for future launches. Optimal evidence and amenable funding will be the key areas for industry to address to ensure gene-therapies are successfully launched in Europe.

**PHP48: ORPHAN DRUGS IN THE UK, DO THEY MEET THE NICE HIGHLY SPECIALISED TECHNOLOGY THRESHOLD?**
OBJECTIVES: Orphan Medicinal Products (OMPs) for rare diseases undergo health technology appraisals (HTA) by the National Institute for Health and Care Excellence (NICE). Drugs for ‘very rare’ conditions undergo further extensive Highly Specialized Technology (HST) reviews, to establish the overall magnitude of their therapeutic benefits, cost effectiveness, and budget impact. On April 1, 2017, NICE published an incremental cost-effectiveness ratio (ICER) threshold for OMPs set at £100,000 per quality-adjusted-life-year (QALY) gained, in addition to a QALY weighting dependent on the QALY gain offered by the new treatment. The objective of this analysis was to investigate the OMPs previously recommended by NICE and assess to what extent they meet this new guidance. METHODS: Currently, 96 drugs possess European Medicines Agency (EMA) orphan designation and market authorization. This list has been reviewed to establish which OMPs have acquired NICE recommendations. All publicly available ICER data were collated from NICE consultation, appraisal and committee papers between January 2007 and June 2017. RESULTS: As of June 2017, a total of 33 EMA authorized OMPs have undergone a standard HTA appraisal, while 7 have been reviewed via the HST process. Of those appraised, 27 ICER’s have been published. NICE recommended 27 OMPs; twelve of these involved Patient Access Schemes (PAS) of which three (therapeutic areas: pulmonary and musculoskeletal/nervous system) had ICERs greater than the £100,000 threshold. The majority of the products approved before April 2017 involved a PAS, making it unclear to which level the ICER was reduced to allow for the product to receive a positive opinion from NICE. CONCLUSIONS: Considering the publicly available information, the majority of OMP drugs recommended before April 2017, fell within the threshold of £100,000. For the exceptions, applying the new guidelines on the QALY weighting resulted in ICERs unlikely to fall within the thresholds adjusted for therapeutic benefit.

PHP49: NICE’S NEW BUDGET IMPACT THRESHOLD – WHAT PROPORTION OF DRUGS IS THIS LIKELY TO AFFECT?


OBJECTIVES: Since 2006, the National Institute of Health and Care Excellence (NICE) have issued guidance on whether new health technologies should be adopted by the National Health Service (NHS) in England and Wales. The cost-effectiveness of a new technology expressed as the incremental cost per Quality Adjusted Life Year gained is a key appraisal criterion. However, recent affordability challenges in reimbursing some new innovations resulted in NICE introducing an additional annual budget impact threshold of £20 million in April 2017. If a new therapy was anticipated to exceed this threshold during any of its first 3 years on the market, it would need to enter a second process of price negotiation before it can be made available on the NHS. This research aims to evaluate the proportion of technologies likely to be impacted by this new process. METHODS: NICE single technology appraisal Resource Impact reports were screened (15/04/2012-31/05/2017) to extract the number of patients and annual budget impact. For technologies with a patient access scheme, the budget impact data are considered commercial in confidence. In such cases, the cost per patient was extracted from the corresponding Scottish Medicines Consortium report. RESULTS: Of 133 appraisals screened, annual budget impact data was calculated for 51 technologies. The mean and median annual budget impact was £33,422,815 and £6,599,808 in year 1, £47,623,183 and £10,659,825 in year 2, and £70,730,456 and £14,886,400 in year 3, respectively. The anticipated budget impact exceeded the annual £20 million threshold within the first 3 years in 43% (22/51) of appraisals. CONCLUSIONS: The new budget impact threshold introduced by NICE is likely to impact a substantial proportion of appraisals. The precise consequences of this second round of price negotiations are not yet clear but this additional reimbursement hurdle will likely negatively impact market access for innovative new therapies.

PHP50: PRICE LIFE CYCLE MANAGEMENT OF ORPHAN DRUGS IN FRANCE

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OBJECTIVES: The objective of this analysis is to describe economic regulation of orphan drugs[1] in France and identify key criteria influencing price life cycle management. METHODS: We reviewed literature published from 2006 to 2016 to comprehensively research any decision or regulation informing orphan drug market access management in France. Then, we screened all non-oncologic orphan drugs launched on the French market since 2006 (n=32) and analyzed their pricing history by categorizing each price cut based on rationale (n=33). Finally we clustered products based on HAS evaluation (SMR, ASMR, target population), years since launch and turnover/sales volume since 2010 extracted from QuintilesIMS MIDAS® database (drugs dispensing at retail pharmacies). RESULTS: Two major regulation components appear specific to orphan drugs in France: exemption from safeguard clause (conditional to turnover <30M€) and opportunity to reach a cost per patient-year up to 50K€. Pricing analysis showed that the first
price-cut occurred on average 5.1 years [0.2; 11.3] after launch, mean decrease was -8% [-2.25%; -25.45%] and did not seem to be linked with turnover level. Extension of indication led to price-cuts in most of cases (75%) in 1 to 1.5 years following HTA opinion publication, correlated with an increase of target population. Most price cuts were attributed to number of years on the market since launch. Neither SMR or ASMR level nor any other HTA evaluation components seem to be strongly correlated to price life cycle management. CONCLUSIONS: Orphan drug price life cycle does not differ as much as one would expect from general regulation, apart from 5 years price stability sometimes granted regardless of ASMR level. Extension of indication generally led to a price cut regardless of orphan status of new indication or ASMR level. [1] (excluding oncology orphan drugs)

**PHP51: AVOIDING A MARKET FOR LEMONS WITH PHARMACEUTICALS: HOW RISK-SHARING MECHANISMS CAN IMPROVE ALLOCATION**

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**OBJECTIVES:** To analyze a potential market failure in the interaction between pharmaceutical companies and consumers, which is relevant to key ethical, financial and social objectives, and to explore the feasibility of a risk-sharing mechanism to reduce system-wide inefficiency. **METHODS:** We reviewed trends in pharmaceutical spending across OECD countries and analyze the process of accepting new drugs into the Israeli Health Services Basket (HSB). We constructed two theoretical models to explain a sub-optimal allocation of pharmaceuticals in the economy. The first method uses a dynamic pricing game framework, while the second method uses a constraint theory scheme. **RESULTS:** The economic analysis revealed several insights regarding market players' behavior: extensive uncertainty drives pharmaceutical companies to overstate prices, while it drives health plans to overestimate the number of potential users. The empirical analysis revealed a national pharmaceutical expenditure increase in Israel, reflected by a 4 to 10 percent yearly change in nominal expenditure since 2010, and inadequate pharmaceutical care, revealed by a 2016 national survey in Israel. The survey showed that 10 percent of low income and 9 percent chronically ill households forwent prescribed drugs due to costs involved, compared to only 5 percent of the overall population. The combined analysis showed that each model does allow for an introduction of risk-sharing mechanisms that increase efficiency and overall welfare. **CONCLUSIONS:** By reducing uncertainty and mitigating the effects of asymmetric information between pharmaceutical companies and consumers, risk-sharing mechanisms can allow for better clinical outcomes, improved population well-being, and more efficient economic allocation. Further analysis could quantify preferences and benefits, optimizing a risk-sharing mechanism in Israel and other health-care systems.

**PHP52: USE OF PRAGMATIC CLINICAL TRIALS TO SUPPORT DRUG LAUNCH**

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**OBJECTIVES:** Pragmatic clinical trials (PCTs) are currently an important topic of interest in drug development. Increasing external validity of trials, PCTs have the potential to close the gap between internal validity of explanatory trials and real-life practice. The objective of this study was to assess the current use of PCTs to support drug launch. **METHODS:** Peer-reviewed articles on PCTs were searched in Medline/Embase through Ovid. In addition, search of the EUnetHTA and EU Commission websites was performed, supplemented by Google search of grey literature. **RESULTS:** PCTs are currently on the rise; however, their use to support drug launch is uncommon. PCTs have several limitations, i.e., 1) methodological/analytical issues inherent to the potential risk of bias of more flexible designs, 2) operational issues with coordinating the recruitment of large patient populations from different settings, 3) concerns of regulatory and ethical nature, e.g. securing rights and interests of participants while remaining pragmatically flexible, 4) substantial costs incurred to conduct large PCTs. In the United States, PCTs are currently mainly promoted through public sector funding, while their potential use by regulators and payers is still uncertain. Before PCTs can be used for decision-making, academic experience (e.g. from the National Institutes of Health Health Care Systems Research Collaboratory, the National Patient-Centered Clinical Research Network, the Clinical Trials Transformation Initiative) with these trials should broaden. In Europe, PCTs are usually considered by decision-makers as complementing (but not replacing) standard randomised clinical trials. Evidence from PCTs seems more acceptable for drugs with a known benefit/risk profiles, while less acceptable for drugs with novel mechanisms of action. **CONCLUSIONS:** PCTs are currently underused for initial drug regulatory/reimbursement dossier filing. Currently, multi-stakeholder initiatives are undertaken to enhance pragmatism in clinical trials and reduce decision-making uncertainty through developing tools, guidelines, and research on new trial designs and statistical methodologies.
**PHP53: A TYPOLOGY-BASED DECISIONAL FRAMEWORK TO SUPPORT MARKET ACCESS AND REIMBURSEMENT DECISIONS FOR PERSONALISED MEDICINES**

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**OBJECTIVES:** New co-development approaches in personalised medicine challenge current decisional frameworks of health-technology access and reimbursement procedures. We aim to conceptualize an efficient typology-based decisional framework which takes into account the development and market access synchronism between therapeutic (Tx) and diagnostic (Dx) components of personalized medicines. **METHODS:** Following systematic literature review, a focus group discussion study was conducted with Belgian personalised medicine industry stakeholders: BeMedTech (Dx-component), Pharma.be (Tx-component), and the Belgian health payer (INAMI). The discussions resulted in Tx-Dx cases to be used to support the personalized medicine access and reimbursement decision-making. **RESULTS:** ATx-Dx typology-based decision support framework was derived and agreed upon by the stakeholders for implementation in the Belgian healthcare system. Within the personalised medicine industry, different strategic development approaches were unfolded for either in vitro diagnostics and therapeutics. The proposed Tx-Dx co-development and market access typology takes into account the synchronism of the strategic development approaches and translates them into access and reimbursement pathways to be used by assessment committees. In the framework, we distinguish different access and reimbursement pathways based on personalized medicine development strategies; (1) The co-development of an innovative therapeutic and companion diagnostic combination (e.g. Vemurafenib and BRAF-case), (2) the novel therapeutic development on a targeted patient population characterized by an already marketed diagnostic (e.g. Olaparib and BRCA-case). (3) The novel diagnostic development on a patient subpopulation within an already marketed therapeutic treatment (e.g. Cetuximab and KRAS/NRAS-case) and (4) the development of an innovative improved diagnostic on an already marketed diagnostic stratification technology [e.g. Immunohistochemistry products and Fluorescence in situ hybridization products-case]. **CONCLUSIONS:** The proposed typology-based decisional framework might allow for a more efficient and effective assessment and budget impact analysis of personalised medicine products. Accepted for guiding decisions in the Belgian healthcare system, the framework can function as a conceptual basis for other agencies outside Belgium.

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**PHP54: RELAXING RULES FOR PHARMACEUTICALS AND BENEFIT COVERAGE EXPANSION IN KOREA: THE IMPACT ON THE PHARMACEUTICAL EXPENDITURE**

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**OBJECTIVES:** Korea has gradually extended the benefit coverage of National Health Insurance. For pharmaceuticals, reimbursement restriction that limits use on disease or patient for approved indication is to manage new medicines or oncology treatments. Strengthening benefit for serious diseases has been forwarded by reimbursing new drugs and relieving the restrictions. This study aims to investigate the effects of the coverage expansion on the pharmaceutical expenditure trends. **METHODS:** The National Health Insurance Claims data for year 2015 and 2016 was used. We analyzed the increase of total pharmaceutical expenditure by dividing it into 1) newly reimbursed drugs in the year 2015~2016, 2) drugs which have alleviated the reimbursement restrictions during 2015~2016, and 3) the residual which has not changed their reimbursement area. **RESULTS:** Korea's national drug expenditure has increased by 118 million dollars (9.8%) during 2015 and 2016. The expenditure of the newly reimbursed drugs accounted for 20.7% of the total pharmaceutical increase. The drugs reimbursed in the year 2015 and 2016 have contributed 12.0% and 8.7% respectively. The drugs which have lifted the reimbursement restriction between 2015 and 2016 have contributed to the 23.1% of the total increase of expenditure. Anti-tumor drugs accounted for 30% among them expanded on use. The increase of the expenditure due to the residuals which have remained the reimbursement conditions accounted for 56.2% of the total increase. As an individual product, Herceptin(trastuzumab) treating breast cancer showed the largest increase. **CONCLUSIONS:** Korea's new government is likely to drive force to expand the national health insurance coverage. It is not inconclusive whether relaxing pharmaceutical restriction contributes to the goal of the benefit extension plan policy yet. We examined only short term effect and presented the estimates maximizing the effect on expenditure rather than optimizing.

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**PHP55: EARLY ACESS BUT THEN WHAT? THE UK EARLY ACCESS TO MEDICINES SCHEME THREE YEAR REPORT CARD**


**OBJECTIVES:** In April 2014 the UK Medicines and Healthcare products Regulatory Agency (MHRA) launched the
Early Access to Medicines Scheme (EAMS) to enable patients with severe, life-threatening diseases without adequate treatment options to access medicines prior to their marketing authorization. EAMS is a voluntary scheme whereby the medicine is provided free of charge by the manufacturer. EAMS comprises two key steps: (i) Promising Innovation Medicine (PIM) designation and (ii) EAMS scientific opinion. We aimed to systematically evaluate all EAMS appraisals to date. METHODS: Publically-available EAMS documentation was screened from the MHRA website (to 08/06/2017). RESULTS: Of 50 PIM designation applications, 68% were granted; 18% refused; 4% withdrawn, with 12% pending. Only 40% (20/50) of medicines granted PIM status had applied for an EAMS scientific opinion, 75% (15/20) of which were awarded. 73% (11/15) of awarded opinions were in oncology. 82% (9/11) oncology agents were for anti-PD-1/L1 therapies: nivolumab, pembrolizumab and atezolizumab. Only 1/15 was from a small-medium-size enterprise (SME). 73% (11/15) awarded opinions had expired when EU marketing authorization was granted. Medicines were available under EAMS for an average of 93 days (range: 18–327). In the mean of 441 days (range: 128–720) since these EAMS opinions had expired, only 6/11 had been NICE-appraised (all recommended) and 8/11 SMC-appraised (75% accepted/restricted) at an average delay of 202 and 270 days post-EAMS expiry, respectively. CONCLUSIONS: Over the past three years, EAMS has enabled medicines for nine drugs across fifteen indications (mostly within oncology) to be made available to patients with severe unmet prior to marketing authorization. However, this was for an average time period of only three months and was followed by an average delay of over six months until NICE/SMC appraisal completion. Reforming EAMS to ensure patients can continue to access therapies post-marketing authorisation until a NICE/SMC appraisal should be considered.

**PHP56: IDENTIFICATION OF IMPORTANT CRITERIA FOR DRUG REIMBURSEMENT DECISION-MAKING AND THEIR RELATIVE IMPORTANCE**

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**OBJECTIVES:** In healthcare technology assessment for reimbursement decisions, it is important to consider multiple aspects and public preferences. We aimed to identify important decision-making criteria for reimbursement of drugs to treat life-threatening diseases and to reveal their relative importance for the general public (GP) and healthcare professionals (HCPs) comprising physicians and pharmacists. **METHODS:** We selected some decision-making criteria for drug reimbursement from a literature review and conducted a two-step online cross-sectional survey. In the first step, participants were asked to rate each criterion on a 7-point scale. The criteria with high ratings were selected based on means for each group. In the second step, the same participants were asked to allocate 100 points among these criteria to measure their relative importance. **RESULTS:** The first survey was completed by 719 participants (GP: 499, HCPs: 220) and 8 criteria were selected: out-of-pocket cost (Mean=5.73 [GP], 5.47 [HCPs]), adverse event (5.66, 5.74), symptom relief (5.61, 5.79), cost effectiveness (5.57, 5.73), productivity loss (5.54, 5.39), life expectancy (5.41, 5.55), significant innovation (5.30, 5.49), and budget impact (5.29, 5.36). There were 613 respondents to the second survey (GP: 421, HCPs: 192). The most important criterion among the GP was symptom relief (relative importance=16.2 vs. 15.6), but the difference with HCPs was not significant. Similarly, no significant differences were found in budget impact (9.7 vs. 8.7) and life expectancy (8.8 vs. 10.5). The criteria in which there were significant differences were out-of-pocket cost (15.2 vs. 9.7), productivity loss (12.7 vs. 10.0), adverse event (11.8 vs. 9.3), significant innovation (11.3 vs. 16.2), and cost effectiveness (14.2 vs. 20.1). **CONCLUSIONS:** This study shows the relative importance of reimbursement decision-making criteria both for the GP and HCPs. These findings will provide valuable insight for an appropriate method for drug reimbursement decisions.

**PHP57: REVIEW OF THE REIMBURSEMENT ENVIRONMENT FOR ADVANCED THERAPEUTIC MEDICINAL PRODUCTS (ATMPs) IN THE UK**

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**OBJECTIVES:** To review current processes for reimbursement of ATMPs in the UK and consider mechanisms to improve patient access to these therapies. **METHODS:** Structured desk research was conducted to assess the health technology assessment (HTA) status and reimbursement of products classified by the European Medicines Agency (EMA) as ATMPs in the UK. A review of decision drivers and consideration of potential policy solutions to support wider access was undertaken. **RESULTS:** Appraisal processes in the UK are no different for ATMPs than non-ATMPs. The only determinant of which reimbursement process applies to an ATMP is the size of the eligible patient population. Eight ATMPs have received marketing authorisation in Europe, seven launched commercially, but four were subsequently withdrawn from the market due to low uptake. Imlygic was recommended for restricted use by NICE with a patient access scheme, ChrontdoCelect was not recommended by NHS England and Strimvelis is scheduled for a NICE Highly Specialised Technology appraisal. Provenge was not recommended by NICE and the company has subsequently withdrawn marketing authorisation. Scottish Medicines Consortium has not appraised any ATMPs. **CONCLUSIONS:** Despite UK Government rhetoric in support of gene therapies and innovation, there has been limited access to ATMPs on the NHS. Although the EMA has introduced measures to support early regulatory
approval of ATMPs, premature data combined with high costs appear to deter companies from applying to UK HTA bodies. Only one ATMP has received reimbursement. Initiatives to support the life sciences industry and gene therapies research need to be backed up with flexible HTA assessments. Early negotiations between companies and NHS bodies should be used to identify managed access agreements, limiting the NHS financial risk whilst allowing patient access to innovative products. Where products deliver a cure following a single use or single course of treatment, longer-term payment plans may help to manage NHS budgets.

**PHP58: INVESTIGATING COMPARATOR REQUIREMENTS FOR DRUG SELECTION FOR COST-EFFECTIVENESS**

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**OBJECTIVES:** The cost-effectiveness (CE) is a concept where the incremental costs of a new molecule versus comparator treatment has a serious influence on the HTA assessment. The use of cost-effectiveness analysis within the decision making processes in public health is increasing globally. Many methodological shortcomings may limit the results from its practical application for the novel treatments, because the choice of a comparator could reflect that ratio. The present study investigated the requirements and the selection criteria of comparator medicines in Bulgaria in comparison to nine Central and Eastern European (CEE) countries to survey and analyze that approach and the different selection criteria. **METHODS:** To investigate the requirements for alternative treatment for cost-effectiveness analysis we conducted a review of legislation, guidelines and selected ISPOR pharmacoeconomic guidelines in Bulgaria and 9 CEE countries (Latvia, Lithuania, Estonia, Croatia, Slovak Republic, Slovenia, Hungary, Poland, Romania). **RESULTS:** 100% of the selected CEE countries require justification of the comparator, where 90% of the countries, with exclusion Poland, use the best/current practice treatment. Two countries (20%), Hungary and Poland, require standard therapy which can be selected from multiple alternatives, whereas Poland weights the average of the prices (using the market share as weight), or the lowest of the prices can be applied. Three countries, Bulgaria, Hungary and Croatia (30%), require guidelines/pharmacotherapeutic guidelines. Poland requires the comparator to be reimbursed. Many other comparator indicators in CEE have been reviewed. **CONCLUSIONS:** The results of our review would contribute to assess the comparator treatment policy in CEE for improving the quality of the indicators' choice in Bulgaria in order to value the assessment of pharmaceutical interventions.

**PHP59: TRENDS IN FDA DRUG PROMOTION ENFORCEMENT LETTERS OVER A TEN-YEAR PERIOD**

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**OBJECTIVES:** The Office of Prescription and Drug Promotion (OPDP), a division of the U.S. Food and Drug Administration (FDA), routinely evaluates pharmaceutical product promotion to ensure truthful, balanced, and accurate promotion. When an ad violation is discovered, OPDP responds through the issuance of enforcement letters to the company responsible. We provide a descriptive review of such letters over the period 2005-2015 and provide categorical analysis based on company revenue. **METHODS:** Information extracted from publicly available enforcement letters included the type of enforcement letter (warning letter vs. untitled), violation-type category (e.g. risk minimization), promotional material venue (e.g. brochure), and intended audience for the promotional material (consumer vs. provider). Global pharmaceutical revenue was recorded for each company via public sources or direct contact. **RESULTS:** A lower frequency of letters were issued in the last five years of observation, with warning letters as a particular rarity. Websites were the most common venue cited, with a high in 2009 of 41.46% of letters referencing website materials. Insufficient reporting of risk information was the most frequent violation over the ten years. Throughout the observation period, providers were the intended audience for the majority of violative promotions. From 2007-2011, large companies received the most letters; with very small companies predominating from 2013-2015. **CONCLUSIONS:** This research highlights trends of FDA regulatory enforcement letters from 2005-2015. Risk minimization was the most frequent violation. The decreased frequency of letters in the second half of our observation period may reflect either OPDP resource levels directed at compliance, a more compliant industry, or both. The maintained trend for website violations over the last seven years observed reflects its mainstream presence in drug promotion. The higher proportion of smaller companies with violative promotions may reflect suboptimal internal competencies and experience with compliant promotion or aggressive promotion with acquired legacy products.

**PHP60: HEALTH TECHNOLOGY ASSESSMENT IN SINGAPORE: SHINING A LIGHT IN THE DARKNESS**

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OBJECTIVES: The Agency for Care Effectiveness (ACE) was established in 2015 by the Singapore Ministry of Health to expand Health Technology Assessment capabilities for subsidy decisions. The first tranche of drug guidance recommendations was published in May 2017 and the aim of this study was to explore possible factors influencing subsidy decisions. METHODS: All eleven published appraisals were reviewed and the factors considered by the Drug Advisory Committee extracted and assessed. Further information was obtained from ACE at the Industry Briefing held in May 2017. RESULTS: Out of the eleven appraisals of ten drugs, three led to subsidy listing on the Standard Drug Lists (SDL 1 or 2), six led to inclusion in the Medication Assistance Fund (MAF) and two did not result in subsidy. Ten evaluations were expedited evaluations, with only trastuzumab considered as a full evaluation due to high technology cost. Of the subsidised medications, low-cost drugs were recommended for SDL subsidy (broader subsidy than MAF) while high-cost drugs were recommended for MAF subsidy. Most subsidised medications were in diseases with substantial unmet clinical need. In the absence of clinical need, the price relative to existing alternatives was a key consideration. In three technology appraisals (gliclazide, golimumab and trastuzumab), restrictions were imposed on the formulation covered by the subsidy based on price concerns. Although budget impact was a key consideration across all appraisals, a low budget impact alone did not guarantee a positive subsidy decision. Only five evaluations reported incremental cost-effectiveness ratios, with an upper limit of S$75,000 per quality-adjusted life-year gained considered cost-effective in this tranche of appraisals. CONCLUSIONS: While limited by the small number of published appraisals, this analysis highlights the importance of technology cost in ACE decision-making for subsidy listing. However, cost-effectiveness and budget impact are also important factors, with clinical need being relevant in some cases.

PHP61: EUROPEAN INITIATIVES TO ENHANCE BIOSIMILAR ADOPTION

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OBJECTIVES: European Union (EU) is the most advanced biosimilar market, with 28 products already authorised. Since establishment of the regulatory pathway for biosimilars in 2005, much effort has been made at EU level to stimulate biosimilar adoption. The objective of this research was to identify the most important initiatives undertaken in the biosimilars field. METHODS: Websites of the European Commission (EC), European Parliament (EP) and European Medicines Agency (EMA) were searched to identify Pan-European projects enhancing launch and adoption of biosimilars. RESULTS: 1) Initiatives to stimulate marketing authorization of biosimilars: Since 2005, the EMA has issued 40 different documents including 1 reflection paper, 3 overarching, 8 product-specific and 4 other guidelines relevant to biosimilars. In 2016, the EMA put in place a tailored scientific advice to support step-by-step development of new biosimilars; 2) Initiatives to stimulate adoption of biosimilars: Following creation of the Project Group on Market Access and Uptake of Biosimilars in 2010, a document on the concept of biosimilars and 2 consensus papers – for patients and professionals – were published in 2013, 2016 and 2017, respectively, and 3 workshops were organized by the EC. In 2016, a workshop on EU options for improving access to medicines was held at the EP, with different stakeholders participating. On 2 March 2017, the EP voted on a resolution “Options for improving access to medicines”, indicating the importance of biosimilars for the debate on access to medicines. The EP has also adopted 4 other resolutions underlying the need for provisions enabling launch and export of biosimilars, and calling to boost competitiveness of the biosimilar industry. CONCLUSIONS: Given their potential to generate savings on pharmaceutical expenditures, new biosimilars are eagerly awaited by health authorities. While drug policies remain under Member States’ competences, EU initiatives contribute to boosting national policies dedicated to biologics and biosimilars.

PHP62: GENERICS POLICIES: A SYSTEMATIC REVIEW OF THEIR EFFECTIVENESS

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OBJECTIVES: A generic medicines policy mix, stands as an aggregate of several measures that cover different aspects of the pharmaceutical market. They promote an internal generic medicines market and influence the relation between generic and reference medicines. This systematic review’s aim was to assess the impact and effectiveness of these policies and examine several obstacles arising when promoting generics. METHODS: A literature search was conducted between September to October 2016. The PICOS (Population, Intervention, Comparator, Outcome and Study design) principle was used to develop and approach a focused research question. Two electronic bibliographic databases were searched; ScienceDirect and PubMed. The included studies, identified through pair consensus, were primary research studies published during the period of January 2006 to October 2016, in either English or Greek. A qualitative evidence synthesis was chosen, as inconsistency of type of intervention and outcome being reported was highly evident among studies. Risk of bias was assessed by one reviewer, with the use of the 2011 Mixed Method Appraisal Tool. RESULTS: 2,188 articles were found, after removing duplicates, checking for language and access to full articles. From those articles, 2,109 were excluded. According to the analysis of the 79
included studies, educational and informative interventions on the advantage of generic medicines use, created the basis for making other generics policy measures effective. Furthermore, the effectiveness of regulatory interventions is reinforced by accompanying financial incentives to key stakeholders, affecting prices and market competition conditions. Finally, patients’ treatment non-adherence, generic medicines availability and deficient monitoring of stakeholders’ behaviour have been identified as key obstacles when promoting generics. CONCLUSIONS: The study showed how different measures can increase generics’ use and market share in the pharmaceutical market. However, it also brought forward several impeding factors arising when planning and implementing generic medicines policies that need to be closely monitored.

**PHP63: MECHANISMS OF TRADE MARGIN REGULATION OF PRESCRIPTION DRUGS: COMPARISON OF 15 EU COUNTRIES**

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**OBJECTIVES:** (i) To identify and analyze the trade margin regulation schemes for prescription drugs, applicable to wholesalers and pharmacists, in 15 EU member states (AT, BE, CZ, DE, DK, ES, FI, FR, GR, IE, NL, PT, SE, SK, UK); (ii) to understand and evaluate the incentives created by the former. **METHODS:** Systematic review of country-specific regulatory frameworks: (i) extraction of quantitative and qualitative regulatory elements from relevant portals, (ii) interviews with national experts. Modelling and visualization of extracted information (regulated margins) in MS Excel. Bilaterally agreed rebates were not included in the analysis. **RESULTS:** Four main principles of trade margin regulation in relation to product price could be identified: proportionality (constant percentage), regressivity (declining percentage), fixed markup, and ‘no regulation’ (permission/obligation to negotiate within set boundaries). Those four mechanisms are often applied jointly, a combination of fixed markup and additional declining percentage being the most common one. The basis for margin calculation is typically the ex-manufacturer price, but exceptions apply (e.g. ES). Independently of the product price, pharmaceutical counselling is remunerated separately in some countries (e.g. DK), even if the result is non-dispensing due to concerns (e.g. IE). Trade margin calculations are based on different price thresholds (giving rise to few or many price bands), with margins often being capped at a given ceiling level. Margin levels may be determined by thresholds on pharmacy sales volumes (e.g. IT) or the classification as generic/brand (e.g. SE); they may apply on a per-item, per first or per follow-up prescription level. **CONCLUSIONS:** The numerous schemes unfold different incentives for stocking and dispensing behavior. Most regulations are plausible; some appear rather random, a few seem implausible. Regulations may impact professional behavior as well as quality and timeliness of access to medicines. Thus, their scrutiny and interpretation are vital to professional deontology and public health.

**PHP64: ACCEPTANCE OF INDIRECT COMPARISONS IN THE GERMAN EARLY BENEFIT ASSESSMENT**

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**OBJECTIVES:** Since 2011, newly marketed drugs undergo an early benefit assessment (EBA), in which the drug’s additional benefit (AB) compared to an appropriate comparator (AC) defined by the Federal Joint Committee (G-BA) is assessed. Often, there is no evidence available from head-to-head studies with the AC. In such cases indirect comparisons (IC) may be used to prove an AB against the AC. To investigate the acceptance of IC to demonstrate an AB, EBA were retrospectively analysed. **METHODS:** All EBA until January, 5th 2017 were considered in this analysis. The reasons for the passed resolutions („Tragende Gründe“) published by the G-BA were screened for keywords („indirekt“, „historisch“) to preselect potential assessments. Relevant assessments were examined regarding the type of IC (historic i.e. unadjusted vs. non-historic i.e. adjusted), outcome (IC accepted, AB), and reasons for IC rejection by G-BA (if applicable) in each assessed patient population. **RESULTS:** A total of 82 assessments were identified during the keyword-screening, of which 68 included an IC for at least one patient population. 24 assessments contained historic ICs, of which 13 were accepted and 12 resulted in an AB (mostly drugs for the treatment of hepatitis C). In contrast, 47 assessments contained non-historic ICs, of which only 8 were accepted and 4 resulted in an AB. Hence, only a small proportion of assessments with an IC resulted in an AB. Most IC were rejected by the G-BA due to methodological issues. Those issues most frequently concerned inappropriate patient populations, inappropriate statistical methods, and incomplete study pools. **CONCLUSIONS:** It seems reasonable to plan pivotal studies not only to comply with the requirements for marketing authorization but also with the rules of the EBA. Further promotion of the IC methodology accepted by the G-BA is recommended as this may improve the chances to have an AB granted.

**PHP65: PRICING PRESSURES AND MARKET ACCESS OUTCOMES OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS) IN THE EU5**
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OBJECTIVES: To evaluate the pricing and market access potential for ATMPs in the EU5. METHODS: HTA outcomes, market access status and schedules, and innovative pricing contracts for EMA approved ATMPs within the EU5 were analysed. RESULTS: Many HTA outcomes result in a conclusion that ATMPs offer little or no clinical benefit against comparators. Lack of adequate data to quantify clinical benefits in the long-term is often claimed, with subsequent P&R implications for ATMPs. In Germany, none of the gene therapies that got through G-BA assessment has been labelled as providing a quantifiable added benefit compared to appropriate comparator therapies, and failed to secure additional in-hospital payments through NUB. In the UK, talimogene laherparepvec is the only ATMP that is currently reimbursed and has an ICER of £24,000 per QALY; this includes patient access scheme price discounts. An initial appraisal for another ATMP found that the ICER was greater than the organisation’s threshold of £30,000 per QALY. Italy appears to be leading the way in terms of innovative pricing agreements with two ATMPs reimbursed on payment-by-results contracts with manufacturers. NICE has also released a report detailing how novel CAR-T therapies may be affordable on a ‘leasing’ scheme for as long as patients are alive. CONCLUSIONS: Few ATMPs have been approved by the EMA, even so, the rate of ATMPs achieving successful market access across the EU5 is low. This is often due to insufficient clinical data needed to quantify mid to long-term clinical benefits. In the upcoming era of CAR T-cell therapies, which come with the promise to significantly improve clinical benefits and a matching price tag, innovative pricing contracts, where manufacturers are willing to share the risks of relatively unproven ATMPs may be needed to relieve the pressures on payers within the EU5 in order to optimize patient access.

PHP66: HOUSEHOLD STORAGE OF MEDICINES AND ASSOCIATED FACTORS IN TIGRAY REGION, NORTHERN ETHIOPIA

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OBJECTIVES: This study aimed at investigating the prevalence and factors associated with home storage of medicines in Tigray Region, Ethiopia. METHODS: A community based cross-sectional study was conducted in April 2013 in Tigray Region, Ethiopia. A total of 1034 participants were enrolled in the study. A multi-stage sampling method was employed to select households. Data were collected with the help of a pre-tested structured questionnaire and analyzed using descriptive statistics and bivariate and multivariate logistic regression. RESULTS: Of the total households visited, 293(29%) stored drugs. The mean number of drugs per household was 1.73. The most common classes of drugs found in households were analgesics 149(29%) and antibiotics 128(25%). Most of the medicines kept in households were used for ongoing treatments 316(62%) and available in tablet dosage form (70%). More than half of the medications kept at homes were not adequately labeled while drawer 180(36%) were reported as the main place of drug storage. The proportion of home storage of medicines in rural area (AOR = 0.56, 95% CI: 0.39-0.81) was lower than that of urban area. However, households having family member(s) working in health facilities (AOR = 2.03, 95% CI: 1.09-3.77) were associated with an increased home storage of medicines. CONCLUSIONS: Most drugs kept at home were not appropriately labeled and stored in a safe place. Residence area (rural versus urban) and the presence of health professional(s) in the households affects household drug storage. Hence, public education campaign should be considered as an intervention to improve the storage condition of medicines in the households.

PHP67: THE UTILISATION OF BIOSIMILAR INFliximab BY ENGLISH ACUTE TRUSTS

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OBJECTIVES: During 2014-2015, infliximab was the fourth most expensive drug for the National Health Service (NHS) in England. The availability of less costly infliximab biosimilar products (IFX-BSPs), might help in relieving the financial burden of prescribing infliximab. Since the IFX-BSP launch in February 2015, there have been many initiatives to promote IFX-BSP utilisation. This study aimed to categorise English Acute Trusts based on their dominant prescribing practice of infliximab (IFX-BSP or the reference ‘R-BMP’ i.e. original biologic). METHODS: Prescribing percentages from the medicines optimisation dashboard and purchasing data reported by NHS Digital were obtained. Over a one year period, for each trust, total R-BMP prescribed per quarter was calculated by combining both datasets. The quarterly change in both total infliximab purchased and R-BMP prescribed were calculated. Trusts were categorised into as initiators; switchers and initiators; or non-users by comparing change in total infliximab with change in R-BMP. Wherever there was a greater decline in the R-BMP
prescribed compared to the change in total infliximab the trust was categorised as switcher and initiators. Where an increase in total infliximab was greater than an increase in R-BMP trusts were categorised as initiators. Data were descriptively analysed. RESULTS: 146 Acute Trusts were included. The proportion of Trusts prescribing IFX-BSP increased from 48% to 83% between July 2015 and June 2016. The number of Trusts categorised as Switchers and initiators increased from 66% to 93% during the same period. While some Trusts gradually introduced IFX-BSP by initiating new patients then switching established patients, some switched and initiated concurrently. CONCLUSIONS: There is a suggested growing acceptance of IFX-BSPs in English Acute Trusts. However, there is a need to understand factors influencing early utilisers and reasons for lack of uptake of IFX-BSPs.

PHP68: DRUG UTILIZATION STUDY OF ANTIBACTERIAL IN THE MEDICAL INTENSIVE CARE UNIT (MICU) OF A CHITWAN MEDICAL COLLEGE TEACHING HOSPITAL(CMCTH), BHARATPUR, CHITWAN, NEPAL.

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OBJECTIVES: Antibiotics, miracle drug, are efficient in treating various bacterial illnesses. Excessive or irrational use of antibiotics are major global public health challenge leading to antibiotic resistance. In Nepal bacterial infections (lower respiratory infections, diarrheal diseases and tuberculosis, urinary tract infections and sexually transmitted infections) diseases are significant public health burden. Commonly used antibiotics are found to be resistance to the local isolates of these diseases. This research aims to the measurement of antibiotics utilization in terms of defined daily dose(DDD)/100 bed-days in MICU in the CMCTH, Nepal according to ATC (anatomic-therapeutic-chemical) classification system. METHODS: A prospective observational study was conducted on 157 patients MICU of the CMCTH from 17 July to 18 September 2016. The demographic data, disease state, clinical history and investigation, prescription of antibiotics and their cost were recorded. RESULTS: ICU mortality rate was 15.6% with median length of stay was 5 days. E.coli, Actinobacter and Pseudomonas were found to be resistance to drugs. Piperacillin/tazobactam (45.2%) was the most commonly prescribed antibiotic followed by ceftriaxone(34.4%), doxycycline(24.2%), metronidazole(28.7%), azithromycin(20.4%), meropenam(17.8%), levofloxacin(15.9%), cefotaxime(9.6%) and Amikacin(8.3). Number of drugs were from 1 to 5 per prescriptions and majority of prescription (46.8%) were with 2 drugs. Most preferred route for drug administration was Parenteral. The most of drug are prescribed for empirical therapy(72.0%) followed by prophylaxis therapy (18.5%) and definitive therapy (9.6%). The most of drug are prescribed for infections of respiratory system (21.7%) followed by gastrointestinal (15.3%), renal (12.7%), poisoning (11.5%) and septicemia (9.6%). The total cost of antibiotics ranges from Nepalese Rupees 450 to 73699 and median cost of NRs 5175/Patient. Total antibiotic consumption was 49.494 DDD/100 bed-days. CONCLUSIONS: A high utilization of Antibacterial and high cost of treatment were noticed. A rational antibiotic use policy should be framed. Longitudinal surveillance of ICU antibacterial used should be carried out.

PHP69: SEARCH OF HIGH ACTIVE AND LOW TOXIC NEWLY SYNTHESIZED DERIVATIVES OF PIPERIDINE FOR REGIONAL ANESTHESIA

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OBJECTIVES: comparative assessment of local anesthetic activity of newly synthesized derivatives of piperidine for regional anesthesia, depending on their chemical structure. METHODS: local anesthesia was determined by the method of "tail-flick" on white rats. RESULTS: For research of activity of the compound at the particular type of anesthesia the great important index is duration of complete anesthesia. The duration of complete anaesthesia of LAS-174 was similar to trimecaine, slightly higher than that of novocaine and a little bit less than lidocaine (p>0.05). Total duration of action of LAS-174 is higher than the novocaine and trimekain, and a few exceeding that of lidocaine (p>0.05). LAS-175 index of full anesthesia was 2 times higher than trimekain, 2.5 times than novocaine and a few more than lidocaine (p>0.05). By the total duration this compound exceeds the matched values of trimethoprim, lidocaine and novocaine in 3.4, 1.9 and 4.6 times, respectively. Replacement of the propyl radical to Amillic in the side chain at the 4-th carbon atom of the piperidine ring enhances local activity by the similar toxicity. In 1% solution duration of anesthesia of LAS-190 is similar to the trimecaine and slightly lower than the lidocaine. LAS-189 shows a weaker effect than trimekain and lidocaine (p>0.05). LAS-189 and 190 by the duration of anesthesia was more effective than novocaine, but this difference is not statistically significant. Replacement of the propyl radical (LAS-189) to the phenyl (LAS-190) contributes to increase of local anesthetic activity, especially for the total duration. Acute toxicity of LAS-189 is 750± of 35.56, LAS-190 - 1284±43.87. CONCLUSIONS: the introduction of a cyclopropane radical at the triple bond of the piperidine ring leads to increased local anesthetic effect, weighting of the radical at the 4th carbon atom contributes to the growth of activity and lower toxicity.

PHP70: FORECASTING PHARMACEUTICAL EXPENDITURE IN EUROPE: ADJUSTING FOR THE IMPACT OF REBATES AND DISCOUNTS
OBJECTIVES: European healthcare systems are under pressure to contain healthcare expenditure. Understanding future drug expenditure is an important consideration for payers when formulating policies. QuintilesIMS publishes European forecasts that are underpinned by its audited volume data and publicly available list prices. With increasing price pressures, list to net price divergence is growing, although some of this information is commercially sensitive and thus not publicly available. The objective of this study was to further develop an established forecast to account for this divergence and explore its impact. METHODS: QuintilesIMS forecast of pharmaceutical expenditure in EU5 countries through 2021 is developed based on its capture of medicines pack data and using previously described methodologies (QuintilesIMS Market Prognosis publications). The top-line forecast was adjusted for each country to account for rebates and discounts that are not reflected within QuintilesIMS data, including industry-level rebates and product-level discounts to national, regional and hospital payers. Average rebate/discounts levels were estimated from aggregate data reported by national health system organisations, industry associations and interviews with country experts. Sensitivity analysis was undertaken to address uncertainty around estimates. RESULTS: The QuintilesIMS forecast based on list prices predicts average compound annual growth rates (CAGR) of 3% across EU5. Using OECD data to account for rebates and discounts reduces the predicted expenditure growth rate by 1 to 2% points. Ongoing analyses are in development to explore extent and variation of this reduction across countries. CONCLUSIONS: The increasing frequency and magnitude of patient access schemes, rebates and discounts have led to a growing divergence between list and net prices for medicines in Europe. This is driven by policies such as external reference pricing, growth in risk sharing arrangements and a shift in pharmaceutical innovation from retail to hospital settings. Adjusting for these discounts is important to understand the future real pharmaceutical expenditure growth in Europe.

PHP71: PERSISTENCE AND CONCENTRATION OF PRESCRIPTION DRUG EXPENDITURE AMONG MEDICARE BENEFICIARIES 2006-2013

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OBJECTIVES: The rapid growth of prescription drug spending is a major concern for U.S. policymakers. In 2016, prescription drugs accounted for over 16% of total health care spending and are projected to grow more rapidly in the next decade. Using longitudinal Part D claims from 2006-2013, we examined the persistence and concentration of prescription drug spending among Medicare beneficiaries. METHODS: We followed beneficiaries’ claims histories for up to 9 years and defined the spending as the sum of out-of-pocket payment and Medicare plan payment. RESULTS: Total spending on prescription drug increased by 61% between 2006-2013 in Part D plans, with average spending per beneficiary increasing from $2,326 to $2,943 over this period. An increasing larger fraction of total spending is attributable to the top-decile of the beneficiaries. In 2013, 2% of beneficiaries accounted for one third of total drug spending, and 5% accounted for over 40% of the total in Part D. The top 2% beneficiaries spent twice as much in 2013 as in 2006, while the lower spending group had marginal increases or even decreases. In contrast to medical services, there was a high degree of persistence in drug spending. Beneficiaries in the top 2%/5%/10% of drug spending in year (t) were likely to remain in the top decile of spending in subsequent years. For example, 75%, 60% and 60% of the high spending beneficiaries in 2010 remained in the category for the subsequent 3 years, respectively. Subsidized beneficiaries (dual-eligibles for both Medicare and Medicaid, and Low-income-subsidy recipients) were disproportionately high users of prescription drugs, with 8 out of 10 beneficiaries in the top 5% of drug spending receiving subsidies for premiums and/or cost-sharing. CONCLUSIONS: Slowing the growth in drug spending will be challenging given the high degree of persistence and concentration in Part D expenditures, particularly for beneficiaries that face minimal cost-sharing.

PHP72: DIFFERENCES AND DECISION DRIVERS IN THE HTA-OUTCOME CATEGORY LOWER BENEFIT BETWEEN IQWiG AND G-BA ASSESSMENT IN THE GERMAN AMNOG PROCESS

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OBJECTIVES: The outcome of the HTA-process (early benefit assessment) is crucial for the successful launch and commercialization of pharmaceuticals in Germany. The aim was to assess how often the evaluation “lower benefit” varies between IQWiG and G-BA. Additionally, we wanted to evaluate what triggered these decisions. METHODS: IQWiG benefit assessments and G-BA decisions published on the G-BA website between
01.01.2011 and 15.05.2017 were screened using the QuintilesIMS HTA-database. Documents were screened for a “lower benefit” on a subpopulation-level and a descriptive analysis was performed to identify decision drivers. **RESULTS:** The database search identified 12 dossiers where “lower benefit” was determined for at least one subpopulation. The IQWiG split patient populations into 48, the G-BA into 32 subpopulations. “Lower benefit” was determined for 15 subpopulations by the IQWiG and 2 by the G-BA. Lower benefit categorization by the IQWiG was triggered by negative effects related to endpoints in the categories safety (12), morbidity (5), mortality (4) and quality of life (3). The G-BA decisions were driven by negative effects in mortality (1) and morbidity (1). **CONCLUSIONS:** While the G-BA decision generally follows the IQWiG benefit assessment, IQWiG benefit assessment and G-BA decision differ significantly with regard to “lower benefit”. The G-BA determines a “lower benefit” in fewer cases and decisions are much less driven by safety outcomes. Furthermore, the G-BA does not split patient populations into that many subpopulations compared to the IQWiG which might also influence lower benefit assessment.

**HEALTH CARE USE & POLICY STUDIES - Equity and Access**

**PHP73: INFLUENCE OF PEER PRESSURE MECHANISM ON QUALITY AND COSTS OF HEALTHCARE, ON EXAMPLES OF ISRAEL, FRANCE AND USA.**

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**OBJECTIVES:** Quality management is an essential element of health care. In countries where health systems are characterized by high level of efficiency, quality programs are employed to ensure certain standards of medical services and patients’ safety. This paper aims to explore what methods of implementation and forms of peer pressure mechanism, as a part of quality improvement initiatives, are present in selected health systems and what is their impact on quality and costs of healthcare. **METHODS:** A systematic review based on publications identified in PubMed database was conducted. A developed search strategy was used to select relevant papers published up to 30th May 2017. **RESULTS:** Of the 471 references identified, data was collected from 17 studies (15 prospective and 2 retrospective). Publications covered many areas of healthcare including primary, specialized, ambulatory and hospital care. Evaluation of outcomes in 4 studies was based on data collected from questionnaires completed by members of medical staff. In 15 studies healthcare providers and medical stuff received feedback concerning their performance of provided medical care. In majority of publications quality indicators were recognized as a useful tool for quality assessment. Researches selected for the systematic review confirmed presence of the peer pressure mechanism in examined health systems. Studied tool for quality improvement was implemented in different forms and with the reference to all identified publications, it applied to every level of healthcare. Its positive effect on quality and safety of medical services was demonstrated. **CONCLUSIONS:** The obtained results partly confirmed an initial hypothesis, in which positive impact of peer pressure mechanism on quality and costs of analysed health systems, was assumed. In order to fully confirm it, a further research, which would include publications referring to wider range of counties, is recommended.

**PHP74: THE EFFECT OF POLICIES FOR IMPROVING THE ACCESS TO NEW MEDICINES IN SOUTH KOREA: A RETROSPECTIVE ANALYSIS IN 2007 - 2016**

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**OBJECTIVES:** The aim of this study is to analyze the status of national reimbursement decision depending on influential factors and the effect of policy change such as risk-sharing agreement, PE exemption and price negotiation exemption with NHIS compared pre with post-policy. **METHODS:** A database was created based on publicly available information from 2007–2016 of the HIRA appraisals, certificates of regulatory approval, and MOHW listing announcement. For the categorical variable, Pearson’s Chi-squared test, or the two-side Fisher’s exact test is conducted and regarding continuous variables, Mann Whitney U test or Kruskal-Wallis Test is used. **RESULTS:** Out of 383 appraisals, the reimbursement rate is 72%, the successful price negotiation rate is 85%, and the final listing is 61%. Compared the first 5-year with the last 5-year, the final listing increased from 52% to 71%. The time from MFDS approval to listing is 392 days (median) and it has been shorten from 428(first 5-year) days to 373 days(last 5-year). Overall, the access to new drugs improved for 10 years. After conditional non-reimbursement, the listing rate increased slightly and the time to listing decreased, but not significant. Compared to pre-RSA, the listing rate meaningfully elevated. Since PE exemption, the listing rate rose but not significant. Due to the policy to shorten HIRA evaluation process, the time to listing decreased. After NHIS price negotiation exemption, the listing rate and the time to listing improved significantly. **CONCLUSIONS:** Compared to first 5-year period, the recent 5-year period showed the improvement on access to new drugs in the perspective of listing rate and time to listing. It could be achievable
due to various listing relevant policy changes. In particular, RSA and PE exemption was practically effective to anti-
cancer drugs and NHIS price negotiation exemption played a critical role to improve the access to low-priced

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**PHP75: ACCESS TO ORPHAN DRUGS (ODS) IN SPAIN COMPARED WITH EU4 COUNTRIES: INEQUITY AND LACK OF PRICE TRANSPARENCY ACROSS EUROPE**

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**OBJECTIVES:** Assess current access situation for ODS in Spain comparing results with EU4 countries (France, Germany, Italy and UK). **METHODS:** ODS approved by the European Commission (EC) between 2012-2016 and with a request for authorisation in Spain were included in the study and classified into three P&R categories: approval, undergoing decision and rejected. P&R approval timelines in Spain were analysed. Results were compared to ODS' reimbursement status in EU4 countries. ODS' prices were searched in EU5 countries using the following sources: AMELI database (France), LauerTaxe (Germany), Codifa webpage (Italy), Botplus (Spain) and MIMS database (UK). **RESULTS:** 40 ODS were identified, from which 17 (42.5%) had P&R approval in Spain, 16 (40%) were undergoing decision and 7 (17.5%) were rejected. The mean time from EC approval to P&R approval in Spain was 18.4 ± 10.8 months. From identified ODS, 37 (92.5%) were reimbursed in Germany, 19 (47.5%) in Italy, 17 (42.5%) in UK and 8 (20%) in France. The value of ODS is not perceived equally across Europe, as only 2 ODS (5% of all identified ODS) are reimbursed in all EU5 countries. Results from price search revealed a lack of transparency regarding pricing dynamics, moving from initial list prices to final price after negotiations of discounts and rebates with time. As such, Spain showed the highest listed prices, which suggests a difference in process across EU5 countries in making price evolution transparent. **CONCLUSIONS:** Access to ODS is inequitable within Europe, as availability of ODS to patients varies across countries. EU5 countries might have different value drivers to reimburse ODS, as no common criteria for reimbursement appear to exist. There is a lack of transparency when trying to understand and make comparisons of ODS’ prices, as real prices can vary between 10%-50% from the list price in certain countries.

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**PHP76: IS THE DISCONNECT BETWEEN EUROPEAN MEMBER STATE CONTROLLED COMPASSIONATE USE PROGRAMS AND THE CENTRALISED EMA PROCESS CREATING AN EARLY ACCESS LOTTERY FOR PATIENTS?**

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**OBJECTIVES:** Since 2001, 5 products have been given a CHMP opinion for compassionate use at EMA level, while in member states (MS), at any one time there are tens of products listed on compassionate use programs (CUP). Here we investigate the difference in EU to MS CUP listing processes and discuss what that means to a patient’s ability to access innovative therapies early. **METHODS:** Research focused on EMA and MS CUP lists and assessment documentation (where available), as well as targeted literature sources. Countries: France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. **RESULTS:** Of 28 European Union (EU) MS, 20 have CUP in place, 18 of these have national-level regulations; the remaining 10 have none. In the UK, the Early Access to Medicines Scheme (EAMS) has seen 41 submissions to date, but only 14 approvals. In 2016, the temporary authorisation for use (ATU) program in France approved 201 products, from therapeutics to devices and vaccines. The most common products to gain access to CUPs are those for oncology. Alectinib, gained access to French, German and Dutch CUPs in 2016, but not EAMS, whilst Nivolumab (for lung and kidney cancers) gained access to UK and Dutch CUPs (2015) but not French or German. **CONCLUSIONS:** There is considerable disparity between CUPs across MS for innovative treatments that target high unmet need conditions. Avoidance of EU-wide schemes by manufacturers is perhaps to be expected given the cost of CUP assessment processes, and supply of products for free to patients – a regulatory stipulation. However, the result is that only patients in targeted countries gain access to innovative therapies. While CUPs offer the chance to build clinical experience and real-world data, the targeting of MS for CUP launch could be creating an early access lottery for patients.

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**PHP77: EARLY ACCESS PROGRAMS; A USEFUL TOOL TO IMPROVE ACCESS FOR PATIENTS AND MANUFACTURERS**


**OBJECTIVES:** Early access programs (EAPs) are an innovative approach that manufacturers can use to provide patients with potentially life-changing therapeutics pre-EMA approval. To qualify for an EAP the therapeutic must treat a disease or specific patient population with a high clinical unmet need. The aim of this study was to assess the current perception of EAPs in the EU5 and how inclusion in an EAP may correlate or potentially lead to reimbursement challenges. **METHODS:** Qualitative research with physicians and payers in Germany, France, U.K.,
Italy and Spain was performed to understand EAP dynamics in each individual market. **RESULTS:** Our research identified insightful nuances and variation of interest across the EU5. In France, an EAP is known as a ATU and it is the most established EAP. Inclusion in an ATU can correlate with reimbursement. In Germany stakeholders, do not recommend EAPs but an investigator led clinical trial to collect data for NUB submission. In the UK EAPs are perceived positively and they can lead to fast track NICE appraisal and they ensure a constant engagement with the regulatory and reimbursement agencies. In Italy and Spain, inclusion in an EAP can be in a narrower patient population than the anticipated label, which can affect reimbursement upon approval. **CONCLUSIONS:** EAPs are, most importantly, an innovative mechanism for improving access to therapeutics for patients with a high clinical need but they can also provide added value to manufacturers in certain markets. Patients can get access to a therapy pre-approval and manufacturers can increase physician comfort and use in Europe of their product.

**PHP78:** EVOLUTION OF THE TIME-TO-MARKET OF HOSPITAL PRODUCTS IN SPAIN

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**OBJECTIVES:** To assess the evolution of the time-to-market of hospital products approved in Europe between 2013 and 2016, distinguishing the time for P&R (national) and the time to start regular hospital consumption (regional and local). **METHODS:** Hospital products approved by the EMA between 2013-2016 and commercialized in Spain were considered in the study. The time-to-market included the national access, estimated as the time for P&R in Spain (period between EMA approval and commercialization date in Spain), and the regional access (time to start regular consumption at the Spanish hospitals based on QuintilesIMS hospital panel). The time-to-market evolution was analyzed by products type: therapeutic area, chronic/acute disease and orphan/not orphan drugs. **RESULTS:** The time-to-market of hospital products in Spain has been reduced approximately 23% each year from 2013 (552 days) to 2016 (254 days). Besides a reduction in the national access (11.6% per year, from 346 to 239 days), this drop in time-to-market is mainly explained by a quicker regional access (reduction of 57.8% per year, from 206 to 15 days). Hepatitis C products showed a deep decline in time-to-market (59.7% per year), followed by the oncology and multiple sclerosis products (35.9% and 29.6% per year, respectively). The faster access of oncology and multiple sclerosis products in Spain is explained by an improvement in the national and regional access. Chronic/acute products presented a different evolution in time-to-market, showing the acute products a better yearly rate of improvement (reduction of 40.3% versus 21.4%, respectively). Finally, the time-to-market for orphan drugs in Spain has hardly changed (reduction of 8.3% per year), mainly due to a stagnating time for P&R (reduction of 1.0% per year). **CONCLUSIONS:** In recent years, the time-to-market of hospital products in Spain has considerably improved, mainly due to a faster regional access, although it is still necessary to continue improving in some specific areas.

**PHP79:** DAMNED IF YOU 'D'? EVIDENCE THE SELECTION OF THE APPRAISAL COMMITTEE MAY AFFECT NICE TECHNOLOGY ASSESSMET OUTCOMES

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**OBJECTIVES:** NICE (National Institute for Health and Care Excellence) makes recommendations on the public reimbursement of medicines based on their clinical- and cost-effectiveness. The recommendation is made by an Appraisal Committee (comprising a multi-disciplinary group of independent experts) as part of a technology appraisal. There are four Appraisal Committees (A,B,C,D); this research investigates whether appraisal outcomes vary by committee. **METHODS:** All publically-available Final Appraisal Determinations from NICE Single Technology Appraisals (STA) were screened (01/10/2009-30/05/2017) and key data were extracted. Homogeneity in rates of acceptance or rejection across the committees was assessed using Chi-squared tests. **RESULTS:** The Appraisal Committee was identified in 216 technologies, 59% (128/216) of which were ‘recommended’. The number of technologies assessed by each committee was similar (A:60, B:47, C:65, D:44). However, STAs conducted by Committee D were significantly less likely to receive ‘recommended’ outcomes (A:75% [45/60], B:70% [33/47], C:58% [38/65], D:27% [12/44]; =27.2, p<0.01). STAs for oncology indications had lower positive recommendation rates than those for non-oncology indications (70% vs. 90%). The lower ‘recommendation’ rates for committee D persisted across oncology (A:65%, B:80%, C: 52%, D: 27%; =11.0, p =0.01) and non-oncology indications (A:81%, B:63%, C:65%, D:28%; =20.0, p<0.01). However, STAs conducted by Committee D were significantly more likely to receive ‘optimised’ recommendations (A:10%, B:13%, C:26%, D: 43%; =19.4, p<0.01) and when considering the rates of ‘recommended’ and ‘optimised’ outcomes compared to ‘only in research’ and ‘not recommended’ outcomes, no significant differences were found (A:85%, B: 83%, C:85%, D:70%; =4.5,p=0.21). Over time, rates of non-recommendations decreased similarly across committees. **CONCLUSIONS:** STAs undertaken by NICE Appraisal Committee D was associated with a significantly lower rate of ‘recommended’ outcomes but tended to an ‘optimised’ recommendation significantly more than the other committees. Further research is needed to determine if this reflects any deviation in uniform implementation of NICE methodology between Committees.
PHP80: HOW TO MAINTAIN PHARMACEUTICAL ACCESS IN CRISIS: THE IRAN FDA EXPERIENCE

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OBJECTIVES: In the past decades, economic sanctions have been frequently used on a worldwide scale for political intentions. Economic sanctions not only cause economic problems for the country which is the subject of the sanction, but also cause many other problems in other sanctions such as health. For example, the recent international sanctions against Iran, resulted in many pharmaceutical shortage due to financial barriers restricted the procurement of medicines. However, there are short-cuts and solutions in the case of medicine shortages. So, Iran was highly successful to maintain its quality of the pharmaceutical services by applying economic resilience strategy. METHODS: This paper, by reviewing historical data, aimed to evaluate the IFDA strategy in handling crisis during sanctions and recommended successful polices, which could improve access to medicines in such a situation. These policies may be also recommended to other countries in such a situation as effective solutions for today’s vulnerable economics situations. RESULTS: While, the crisis reached its peak in 2012, to reduce the negative impact of the sanctions, some changes were proposed by the IFDA at different policymaking levels from parliament legislation to organizational procedures. Significant price reduction, decreasing market share of imported medicines, facilitating domestic manufacturing, attracting foreign investment for domestic manufacturing, managing drug shortages, and increasing financial protection of patients in general and patients with catastrophic payments in particular were the main achievements of the new strategy of the IFDA, leading to better accessibility and availability in the country. CONCLUSIONS: Iran’s experiences on the boost of domestic manufacturing and cost containment approaches so that it withstood and recovered pharmaceutical sector from negative impacts of the sanctions, while the health system was shocked by the international sanctions, could be a successful example of economic resilience strategies.

PHP81: THE IMPACT OF SCOTTISH MEDICINES CONSORTIUM (SMC) PROCESS CHANGES ON ACCEPTANCE RATES FOR NEW MEDICINES FOR END OF LIFE AND VERY RARE CONDITIONS


OBJECTIVES: The SMC advises NHS Scotland on the clinical and cost-effectiveness of all new medicines. Methods changes introduced in 2014 aimed to increase access to medicines used at the end of life and for very rare conditions. This research examines the impact of the changes on the acceptance rates for all full submissions. METHODS: A quantitative analysis was undertaken of assessments under the new process up to May 2017. A direct comparison of acceptance rates before and after the process changes is not possible as new criteria for end of life (EoL) and medicines for very rare conditions were introduced in 2014. The acceptance rate for decisions published from January 2011 to December 2013 for orphan and cancer medicines (as a proxy measure) was compared with those for medicines assessed as end of life and orphan under the new processes (decisions published October 2014 - May 2017). The acceptance rates for all medicines during these time periods were also compared. RESULTS: From January 2011 to December 2013 the acceptance rates were: for medicines assessed as a full submission 114/175 (65%); for cancer and orphan medicines 15/31 (48%). From October 2014 to May 2017 the acceptance rates were: for all medicines assessed 154/180 (86%); for medicines assessed under the new process 61/78 (78%). The acceptance rate for EoL medicines was 42/46 (91%) and for very rare conditions medicines it was 52/68 (76%). Note that medicines may be categorised as both EoL and for a very rare condition. CONCLUSIONS: These findings show that the changes have met the Scottish Government’s policy imperative of increasing access to new medicines used at the end of life and for very rare conditions that may not have been accepted under the previous assessment process. The analysis was limited by the inability to undertake a direct comparison.

HEALTH CARE USE & POLICY STUDIES - Formulary Development

PHP82: AN INTRODUCTIVE ANALYSIS OF THE TIMEFRAME FROM EUROPEAN DRUGS APPROVAL TO THE SICILIAN HOSPITAL FORMULARY INCLUSION

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OBJECTIVES: Drugs centrally approved by the European Medicine Agency (EMA) are automatically granted marketing authorization by Italian Drug Agency (AIFA), which is responsible for pricing and reimbursement (P&R) negotiation at national level. In most Italian regions, a Drug Formulary Committee (DFC) must admit those drugs in the Regional Hospital Formulary before use at regional level. Some authors have argued that the timing from National to Regional formularies inclusion may lead to important disparities in patients’ access to new drugs. The aim of this work is to present data on the timeframe/lag time between EMA, AIFA and Sicilian DFC (SDFC) for newly approved drugs in Europe. METHODS: Newly approved drugs, for which dossiers were presented to SDFC, were identified from 1st January 2013 to 1st April 2016. Publicly available sources were used to retrieve relevant information on approval decisions. Both median and mean values were used in the analysis to estimate the timeframe/lag time. RESULTS: On 117 drugs, 100 newly approved medicines were included in the analysis while 17 were excluded due to missing data. The median lag time from EMA to AIFA (LTEA) was 448 days (1st quartile = 315 days; 3rd = 635 days) and 112 days (54 – 231) from AIFA to SDFC (LTAS). The data showed the presence of some outlier drugs, in particular for LTAS, which impacted results when considering mean values. Indeed, the mean value of LTEA was 484 days with a standard deviation (SD) of 225 days, but for LTAS it was 249 days with an almost double SD (400 days). CONCLUSIONS: Homogeneity lack on admission of new drugs in the regional formularies may lead to access disparity among patients across Italy. However, our analysis shows that such timeframe/lag time mostly depends on AIFA P&R negotiation at national level.

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

**PHP83: HAEMORRHOIDAL ARTERY LIGATION PROCEDURE FOR THE TREATMENT OF SYMPTOMATIC GRADE II–III HAEMORRHOIDS: A TRIAL-BASED AND LONG-TERM MODEL-BASED ECONOMIC EVALUATION**

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OBJECTIVES: To evaluate the cost-effectiveness of haemorrhoidal artery ligation (HAL) procedure versus rubber band ligation (RBL) for the treatment of symptomatic grade II–III haemorrhoids using data from the HubBle study, a UK-based, multicentre randomised controlled trial. METHODS: An economic evaluation was undertaken from the UK National Health Service (NHS) perspective including short-term trial-based and long-term model-based analyses. In the primary trial-based analysis, a seemingly unrelated regression model was fitted for estimating the mean difference in total cost and quality-adjusted life-years (QALYs) over 12-month time horizon. Cost-effectiveness results were expressed in terms of cost per QALY gained and cost per recurrence avoided. A parametric analysis and various deterministic sensitivity analyses were performed to address uncertainty around the primary cost-effectiveness result. In the long-term analysis, a three-health-state Markov model was built to extrapolate the analysis for a 4-year time horizon using data from HubBle (costs, utilities and recurrence) and external studies (long-term recurrence). A probabilistic sensitivity analysis was performed to address uncertainty around the long-term cost-effectiveness result. RESULTS: In the short-term trial-based analysis, the difference in mean cost for HAL versus RBL was £1027 (95% confidence interval [CI], £782–£1272), p<0.001. The difference in mean QALYs was 0.01 (95% CI, -0.02–0.04). This led to an incremental cost-effectiveness ratio (ICER) of £104,427 per QALY gained. The cost per recurrence avoided was £4882 (95% CI, £3628–£6135). The primary cost-effectiveness results were robust to all sensitivity analyses. In the long-term analysis, the probabilistic ICER was of £21,798 per QALY, generated from an incremental total mean cost of £1125 (95% CI, £1117–£1133) and incremental mean QALYs of 0.05 (95% CI, 0.048–0.055). CONCLUSIONS: HAL procedure was not cost-effective compared with RBL for the treatment of symptomatic grade II–III haemorrhoids at a cost-effectiveness threshold of £20,000 per QALY.

**PHP84: EMPIRICAL STUDIES ON THE ECONOMIC VALUE OF A STATISTICAL LIFE YEAR (VSLY) IN EUROPE: WHAT DO THEY TELL US?**

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OBJECTIVES: Health economists and health care policy makers often conceptualize value for money in terms of cost effectiveness or cost per (quality-adjusted) life year gained. Whether used in isolation or alongside further drivers of social value (such as priority for younger or more severely impaired patient groups), for example within a multi-criteria decision analysis framework, a benchmark or anchor “value of a statistical life year” (VSLY) will be required. Ideally, the VSLY should be based on the observed preferences of the population(s) in question. Here we report insights from a systematic review of empirical European economic studies, which were published during the last two decades (i.e., from 1995 to 2015). METHODS: Our systematic literature search (using the EconBiz and EconLit
Hyperkalaemia (HK) increases the risk of major adverse cardiovascular events (MACE) and mortality. Patients with heart failure (HF) or chronic kidney disease (CKD) are susceptible to HK due to impaired renal function, older age, comorbidities, and concomitant medications. This study aimed to develop a novel cost-effectiveness model to estimate cost and health outcomes associated with effective HK management in HF or CKD.

**METHODS:** A lifetime patient-level simulation was developed in Microsoft Excel. Disease progression was modelled in HF via progression through New York Heart Association (NYHA) classes and in CKD via continuous estimated glomerular filtration rate (eGFR) decline, leading to end-stage renal disease (ESRD). Time-dependent potassium (K+) trajectories were simulated utilizing mixed-effects regression equations and linked to mortality, hospitalisation, MACE and changes in renin-angiotensin-aldosterone system inhibitor use via published risk ratios. Two hypothetical scenarios were evaluated from a UK payer perspective, independent of long-term K+ management costs: lifetime maintenance of normokalaemia (NK) compared to fluctuating K+ levels resulting in HK rates consistent with clinical practice.

**RESULTS:** Published utilities and disease costs (2015) were applied and discounted at 3.5%. **RESULTS:** In patients aged 60 at baseline with CKD (eGFR=50 ml/min/1.73m2) predicted life expectancy (LE), quality-adjusted life years (QALYs) and total costs (TC) were 9.0 years, 6.7 QALYs and £65,231 in the HK group compared to 8.6 years, 6.3 QALYs and £69,606 in the NK group.

**CONCLUSIONS:** Our results suggest that the empirical willingness-to-pay for a statistical life year might be substantially higher than the thresholds currently used by the international HTA community.
at baseline with HF (NYHA III) predicted LE, QALYs and TC were 7.8 years, 5.6 QALYs and £7,881 in the NK group and 5.9 years, 4.3 QALYs and £6,374 in the HK group, respectively. **CONCLUSIONS:** Optimising K+ management in CKD and HF patients has the potential to increase LE and QALYs, while influencing direct healthcare expenditure and allowing for an efficient use of resources.

**PHP87: FACTORS CONTRIBUTING TO THE NATIONAL DRUG EXPENDITURE OF KOREA, 2010-2015: FOCUSING ON THE CORE THERAPEUTIC CLASSES**

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**OBJECTIVES:** Korea's drug expenditure as a share of total health spending is 20.6% (OECD, 2016) and it is increasing by +1.7% CAGR (Compound Annual Growth Rate). The aims of this study were to explore the factors contributing to the growth of pharmaceutical expenditure and decompose the growth focusing on the core therapeutic classes. **METHODS:** From the National Health Insurance (NHI) Claims Data of year 2010 to 2015, eight core therapeutic classes were extracted - 1) anti-hypertensives, 2) anti-hyperlipidemics, 3) anti-infectives, 4) anti-diabetics, 5) anti-tumor and immune depressants, and drugs acting on the 6) nervous system, 7) genito urinary system and sex hormones, and 8) muscular system. Laspeyres' decomposition method which appraises the expenditure change caused by each contributing factor was used. The factors included were price effect, volume effect, entrance drug effect, existing drug effect, exiting drug effect, NHI coverage expansion effect, and cross effect. **RESULTS:** The drug expenditure of eight core therapeutic classes (80 billion dollars) has increased by 15.2% between 2010 and 2015. The factors contributed to the increase were entrance drug effect (+24.2%), volume effect (+20.3%), and NHI coverage expansion effect (+6.5%). On the other hand, price effect (-24.6%), existing drug effect (-3.4%), and exiting drug effect (-2.2%) have led to the decrease of drug expenditure. The entrance drug effect was significant for anti-diabetics, anti-tumor and immune depressants and anti-hypertensive drugs while substantial volume effects were observed for the drugs acting on the genito urinary system and sex hormones and anti-tumor and immune depressant drugs. **CONCLUSIONS:** Although price effect has contributed to the substantial decrease of Korea's drug expenditure, the total pharmaceutical expenditure has increased because entrance drug effect and volume effect were large enough to offset the price effect. Therefore, to control Korea's pharmaceutical expenditure, policies for monitoring the price of new drugs and managing the volume of drug utilization are required.

**PHP88: COSTS OF OWNERSHIP OF READY-TO-ADMINISTER PRE-FILLED STERILIZED SYRINGES IN A DUTCH HOSPITAL: A COST MINIMIZATION ANALYSIS**


**OBJECTIVES:** Preparation errors occur frequently during conventional multiple step preparation of parenteral drugs at the bedside, causing potential adverse drug events (ADEs), which can be a burden to the patient and involves high costs for the national healthcare system. The use of ready-to-administer (RTA) pre-filled sterilized syringes (PFSS) produced by the hospital pharmacy can prevent a significant part of preparation errors and reduces the risk of bacteremia due to contamination of the intravenous fluid. This research aims to compare the total cost of the conventional preparation methods (CPM) with the PFSS method. **METHODS:** In the analysis, costs related to the preparation of the drugs, bacteremia due to contamination, ADEs as a result of medication errors and wastage of syringes were taken into account. Annual costs in a general Dutch hospital were consistently calculated. Three scenarios were investigated: (i) all preparations CPM (864.246 administrations per year); (ii) all preparations as PFSS; and (iii) 200,000 PFSS and the remaining part CPM (reflecting a transition state as currently present). Deterministic and probabilistic analyses are performed. **RESULTS:** The first scenario shows higher annual costs at €10,862,609 compared to the second scenario. The current situation (third scenario) already shows savings of €2,420,545 compared to the old situation (first scenario). Sensitivity analyses revealed that cost savings of PFSS were mainly the result of decreased risks of medication errors and contamination of intravenous fluids. Extrapolating these results nationwide indicates potential savings over €300 million if only PFSS were used. **CONCLUSIONS:** The use of PFSS prepared at the hospital pharmacy yielded cost-savings compared to conventional preparation at the bedside in the Dutch hospital.

**PHP89: COMPARISON OF HOSPITAL RESOURCE UTILIZATION BETWEEN ELECTIVE AND EMERGENT ADMISSIONS AMONG PATIENTS UNDERGOING INPATIENT COLORECTAL SURGERY**

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OBJECTIVES: To compare hospital resource utilization between elective and emergent admissions among patients undergoing inpatient colorectal surgery. METHODS: This retrospective, observational study used hospital billing data from >600 hospitals in the U.S. (Premier Healthcare Database). Patients included were admitted for inpatient colorectal surgery between 1/1/2008-12/31/2014 (first observed admission=index) and were aged ≥18 years as of index. Patients were classified as having either an elective or emergent (admitted through the emergency room) admission. Study outcomes included total hospital costs (HC), length of stay (LOS), and operating room time (ORT). Outcomes were compared between elective and emergent admissions using multivariable Generalized Estimating Equations (GEE) models, which adjusted for patient, procedure, and hospital factors, and accounted for potential within-hospital clustering. Adjusted predicted outcomes were generated for each group using the least squares means method. RESULTS: Of the 227,632 patients with colorectal surgery (average age=63.3 years; 53.2% female), 94,902 (41.7%) had emergent admissions. Compared to elective admissions, emergent admissions had a higher proportion of patients with open surgeries (78.2% vs 49.5%), and lower proportions of surgeries with colon/rectal specialty surgeons (9.6% vs 21.3%) or with diagnoses of colorectal cancer (28.7% vs 43.5%). In the GEE models, HC was 50.8% (95% CI: 48.1%-53.6%, p<0.0001) higher in emergent versus elective admissions (adjusted HC=$28,966 emergent, $19,209 elective); LOS was 61.1% (58.0%-64.2%, p<0.0001) higher in emergent versus elective admissions (adjusted LOS=11.2 days emergent, 6.9 days elective); and ORT was 6.3% (5.5%-7.2%, p<0.0001) shorter in emergent versus elective admissions (adjusted ORT=187.0 minutes elective, 199.6 minutes emergent). CONCLUSIONS: Among patients undergoing inpatient colorectal surgery, substantial differences were identified between elective and emergent admissions in terms of surgical approach, surgeon specialty, indication, and hospital resource utilization among patients with inpatient colorectal surgeries. Emergent admissions are complex in nature; further research is warranted to understand drivers of the observed outcome differences.

PHP90: ECONOMIC IMPACT OF NURSE SENSITIVE OUTCOMES IN IRISH HOSPITALS

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OBJECTIVES: Since the financial crisis of 2008 there has been increased pressure on public health care services like that in Ireland to “do more with less”. This has direct consequences for front line personnel such as nurses, whose work load has increased in subsequent years. Also during this time technologies are advancing and the availability of treatment interventions in and outside of hospitals is increasing, placing increased demands on already scarce resources. As a result front line staff, such as nurses, had to increase their workloads care and provide efficiencies. Recently, nurse sensitive outcomes are used as a means of evaluating nurse staffing. Nurse sensitive outcomes are adverse events sensitive to nursing which are often reported as secondary diagnoses but have an economic impact on an episode of care. This study estimates of nurse sensitive outcomes on inpatient casemix costs in Ireland. METHODS: Data (N=2,014) was sourced from patient discharge information from six acute wards amongst three Irish hospitals from July 2016 to January 2017. (These hospitals were enrolled in national pilot of a Nurse Safe Staffing and Skill-Mix Project.) The National Ready Reckoner DRGs (version 8) was used to value the relevant inpatient casemix cost per case (i.e. episode of care) for each patient from the health care provider’s perspective. Ordinary least squares regression was performed (Stata version 14) to estimate the impact of nurse sensitive outcome on inpatient casemix cost per case. RESULTS: Controlling for length of stay the average cost associated with the presence of a nurse sensitivity outcome is estimated to be €1,093 (p=0.011). CONCLUSIONS: Nurse sensitive outcomes do impact on inpatient costs. The estimated average cost of nurse sensitive outcomes can be used to estimate the cost of nurse sensitive outcomes avoided in economic evaluations, budget impact analysis etc. of interventions in an acute care settings.

PHP91: DIFFERENCE BETWEEN ANNUAL NATIONAL HEALTH STATISTICS AND 1-COMPLETE-YEAR MEDICAL USE IN COST-ESTIMATION.

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OBJECTIVES: Annual national health statistics are valuable reference for healthcare-related cost researches. However, there is a gap between cost of 1-calendar-year and that for 1-complete-year, depending on the patient’s date of first hospital visit. This research aims to quantitatively identify the difference between healthcare cost in the annual national health statistics and that for 1-complete-year according to chronic or acute diseases. METHODS: Annual cost per patient was calculated by two methods: the 1-calendar-year method in which the study period spanned from January 1 to December 31, 2012 regardless of patient’s date of first visit, and the 1-complete-year method which estimated the cost for one year from patient’s date of first visit. The target diseases were the 20 most prevalent diseases in South Korea, divided into acute (acute tonsillitis, common cold, etc.) and
chronic diseases (hypertension, diabetes mellitus, etc.). National Sample Cohort data provided by the South Korea National Health Insurance Service was used, and patients coded with applicable diseases were selected in 2012. To provide basis for the results, we additionally investigated the distribution of the date of first visit and consequent annual cost of each patient. **RESULTS:** The average ratios of 1-calendar-year cost to 1-complete-year cost for acute and chronic diseases were 0.87 (± 0.03) and 0.85 (± 0.02), respectively. When the dates of first visit were analyzed according to quarters, significantly more patients with chronic diseases were identified in the 1st quarter than acute diseases. The annual cost increased as the first visit occurred earlier, which was more apparent in chronic than acute diseases. **CONCLUSIONS:** Healthcare cost reported by annual national health statistics was 85-87% level of 1-complete-year cost, which was similar for both acute and chronic diseases. These ratios could compensate the structural limitations of annual national health statistics and enable researchers to make elaborate estimations in socioeconomic burdens from diseases.

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**PHP92: DRUGPRICE DEVELOPMENTS AFTER PATENT EXPIRY**

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**OBJECTIVES:** To investigate the impact of patent expiry on drug prices in the Netherlands. **METHODS:** All drugs that faced patent expiration in the Netherlands between January 1999 and December 2016 were identified. Patent expiration was defined as the time at which the first generic drug entered the market (obtained a list price) with a ATC code identical to the originator drug. Monthly drug prices and prescription were extracted from a national price and sales database. This data was used to calculate the average monthly price per DDD for every drug weighted by the corresponding prescriptions of every strength, package size and administration form. All data was combined to calculate the overall price ratio, the generic to brand price ratio and the price development of the originator compared to moment of patent expiry. **RESULTS:** In total 257 drugs faced generic competition between 1999 and 2016. The relative price decreases after 24 months differed significantly among different drugs varying from -89% to +89%. The overall price ratio 24 months after patent expiry was 0.66 (0.19-0.99;10:90th percentile range). The generic to brand price ratio was 0.56 (0.15-0.94;10:90th percentile range) and the price ratio of the originator decreased to 0.80 (0.45-1.00;10:90th percentile range). Sales revenue before patent expiry significantly impacted the price decreases after patent expiry with higher sales resulting in lower price ratios. **CONCLUSIONS:** Patent expiry leads to significantly lower drug prices. As drug prices are dynamic over time and generic entry leads to savings on the national healthcare budget, this should be taken into account when making predictions on future healthcare expenditures.

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**PHP93: THE ECONOMIC IMPACT OF FIBRIN SEALANTS USED FOR HEMOSTASIS IN CORONARY ARTERY BYPASS GRAFTING SURGERY; AN ITALIAN PERSPECTIVE**

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**OBJECTIVES:** Bleeding is a serious complication related to Coronary Artery Bypass Grafting (CABG) surgery with a potential high impact on clinical outcomes and health care services expenditure. The aim of this study is to evaluate the impact on economic resource consumption associated with the use of fibrin sealants in a comparative analysis between Evicel and Tisseel. **METHODS:** Analysis was developed to estimate the impact on costs associated with use of Evicel and Tisseel from the Italian National Healthcare System perspective with a 30-day time horizon, including the following item costs: fibrin sealant use, blood transfusion, readmissions. A literature research was performed to assess efficacy data in terms of blood transfusion rate and 30-day readmission rate associated with both fibrin sealants. The economic data on blood transfusion and fibrin sealant use were estimated on basis of the corresponding national reimbursement fees, while the costs associated with readmission were estimated according to DRG tariffs. Univariate sensitivity analysis was conducted to determine whether results were insensitive to variations in uncertain parameters. **RESULTS:** The literature research showed a lower blood transfusion rate on the index CABG surgery date (19% versus 34%) and after index date (9% versus 15%), as well as, a lower readmission rate (16% vs. 31.9%) in favor of use of Evicel. The economic analysis showed a lower transfusion cost for Evicel than Tisseel 22.64% (€ 65.60 versus € 84.80) and a lower readmission costs of 43.75% (€ 1,148.87 versus € 2,042.43), showing a total cost savings of € 1,045.20 per patient, including fibrin sealant cost. The sensitivity analysis shows that resulting cost-saving was most sensitive to 30-day readmission associated with the fibrin sealants. **CONCLUSIONS:** Detailed comparative analysis of the data has specifically shown that during CABG surgery, Evicel is associated with lower bleeding events and lower health-resource utilization/cost than Tisseel.
PHP94: EVALUATING THE COST-UTILITY OF IMMUNOSUPPRESSIVE REGIMENS IN LIVER TRANSPLANT RECIPIENTS IN CANADA

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OBJECTIVES: Liver transplantation is the only effective treatment option for patients with end-stage liver disease. While one-year graft survival rates are over 80% and longer-term graft and patient survival have increased dramatically since the first liver transplants, non-adherence to immunosuppression is still common and confers an increased risk of graft rejection and loss. Prolonged-release tacrolimus (PR-TAC) is a once-daily formulation of tacrolimus that may improve adherence and cause less interference with the daily activities of the patient. The present study evaluated the cost-utility of PR-TAC relative to immediate-release tacrolimus (IR-TAC) and cyclosporine in liver transplant recipients in Canada. METHODS: A three-state Markov model was developed to evaluate cost and utility outcomes in adult de novo liver transplant recipients using IR-TAC, PR-TAC, or cyclosporine as the primary immunosuppressive regimen. Costs were derived from Canadian sources and reported in 2016 Canadian dollars, with future costs and effects discounted at 1.5% per annum. Underlying probabilities of mortality were based on a least squares exponential model fit to data from the Canadian Organ Replacement Register, while incremental rates were determined by the results of a network meta-analysis (NMA). RESULTS: Over a 25-year time horizon, quality-adjusted life expectancy (QALE) increased from 12.22 quality-adjusted life years (QALYs) with IR-TAC to 13.04 QALYs with PR-TAC with an accompanying increase in costs of CAD 38,899, resulting in an incremental cost-effectiveness ratio of CAD 47,351 per QALY gained. Cyclosporine increased costs by CAD 4,478 and reduced QALE by 0.37 QALYs relative to IR-TAC. Sensitivity analysis showed the model to be most sensitive to mortality odds ratios and tacrolimus unit costs. CONCLUSIONS: Cost-utility modeling using modern data from a NMA and Canadian cost data showed that PR-TAC would likely be cost-effective relative to IR-TAC in Canada. Higher per-milligram acquisition costs need not, therefore, present a barrier to its reimbursement.

PHP95: COST-EFFECTIVENESS OF A PHYSICAL ACTIVITY PROMOTION INTERVENTION FOR PEOPLE WITH DISABILITIES: A MARKOV MODEL APPROACH

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OBJECTIVES: This study aims to evaluate the cost-effectiveness of a physical activity promotion intervention for people with disabilities in Korea. METHODS: A Markov model illustrating five disease states (ischemic heart disease, ischemic stroke, type 2 diabetes, colorectal and breast cancer) was employed to consider the long-term economic consequence of the intervention. The model was simulated over the lifetime of the 2012 Korean population with disabilities by age and gender. For the estimation of model inputs, incidence and mortality of the diseases related to physical activity among people with disabilities were obtained from Korean National Health Insurance Claims Database. Health care cost and utilization incurred among them by experiencing those diseases was also derived from the same source. The result from a meta-analysis was used for an intervention effect on physical activity promotion. Costs were estimated from the health care system perspective. Health outcomes were measured by Disability-adjusted Life Years (DALYs). In accordance with the recommendation of World Health Organization (WHO), Incremental Cost-Effectiveness Ratio (ICER) was assessed by the amount of Gross Domestic Product (GDP) per capita in Korea. RESULTS: Considering that currently there is no nationwide intervention promoting physical activity for people with disabilities in Korea, implementing the intervention across the country may cost 13 million US dollars (Intervention cost: $ 13,824,024, Cost offsets: $ 710,491) and averted 476 DALYs. The ICER of the intervention is $ 27,538 per DALY averted. CONCLUSIONS: Based on the cost-effectiveness criteria, $ 25,722 (the Korean GDP per capita in 2012), implementing a physical activity promotion intervention for people with disabilities is cost-effective compared to no intervention.

PHP96: INCREASING TREND ON TURKISH UN-LICENCED MEDICINE MARKET: A GENERAL OVERVIEW ANALYSIS

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OBJECTIVES: Turkish Medicines and Medical Device Agency(TITCK) leads non-licensed innovative medicines to access patients under name patient sales. If commission under TITCK approves for the use of patient, then Turkish Pharmacist Association imports the medicine and delivers to patient for out-of-pocket or under reimbursement by Social Security Institution(SGK). The former studies reported that unlicensed medicines market increased in from 232 billion TL to 747 billion TL between 2011 and 2013. SGK has already started direct import process of unlicensed...
medicines to lowering budget since May 2017. The aim of this study is to estimate current situation with the latest published data. METHODS: Published data of consumption of unlicensed medicines in first half of 2016 has been taken from official web page of TITCK. Full year consumption was estimated for 2016. Average TL/EURO exchange rate has been taken as 3.54 for 2016. Only reimbursed medicines were included. Descriptive analysis has been conducted for top 100 unlicensed reimbursed medicines market and compared with former data. RESULTS: 307.133 units of unlicensed medicines had been imported in 2016. Total market volume was calculated as 1.820.003.274 TL for top 100 unlicensed medicines market. Cost per unit was calculated as 5925 TL. Compound annual growth rate was calculated as 40.93% from 2011 to 2016 in TL. CONCLUSIONS: Turkey has a government funded social security system. Depending on that, Turkey is one of leading country to access innovative medicines with the individual patient evaluation and import process of un-licensed medicines as named patient sales. However, total cost to government for reimbursed medicines reached 1.8 billion TL which is 8.2% of total pharmaceutical budget of SGK. It is needed to take into account these results by authorities for building a sustainable healthcare system in Turkey. New implementation like importing medicines directly by SGK is needed to be evaluated with further studies.

PHP97: BUDGET IMPACT OF NEWLY APPROVED DRUGS BY THE SICILIAN DRUG FORMULARY COMMITTEE: AN INTRODUCTIVE ANALYSIS

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OBJECTIVES: The Italian National Health Service (INHS) is highly decentralized and Regions are responsible for planning healthcare services and allocating financial resources. Local autonomy implies stronger financial accountability leading to different economic strategies across regions. The Sicilian Drug Formulary Committee (SDFC) must approve drugs before hospital use at regional level and drug companies must present a specific dossier for the approval. Budget impact is a critical information for decision makers, therefore the aim of this study is to perform a pharmaceutical budget impact analysis (BIA) of drugs dispensed by the Sicilian Healthcare System (SHS) after one year from their approval. METHODS: From 1st January 2013 to 1st April 2016, all approved 117-drugs, for which dossiers were presented to SDFC, were identified and stratified according to the Anatomical Therapeutic Chemical (ATC) classification. To perform the BIA, the following data were considered: the main indication of use for an average adult patient (i.e. average body weight of 70kg or body surface of 1.8m2), treatment duration of 12 months, the highest drugs’ strength, ex-factory prices. The average annual cost per patient was then multiplied for the eligible cohort as estimated in the drug dossier presented by the manufacturers. RESULTS: The BIA showed that in the first year from approval, drugs were associated with a total estimated annual pharmaceutical cost of € 500.9 million in charge of the SHS. The highest total expenditures were observed in three drug classes: respiratory system (ATC R) = €215,021,396 (494,782 patients), antineoplastic and immunomodulating agents (ATC L) = €177,185,744 (7,028 patients) and alimentary tract and metabolism (ATC A) = €47,335,649 (68,360 patients). CONCLUSIONS: In the past three years, the SDFC approved drugs accounted for €500 million for one year treatment at steady state. Further analyses and monitoring are needed to validate the estimation.

PHP98: BIOSIMILARS AND REFERENCE BIOTECHNOLOGIC DRUGS: COMPARISON OF THE BIOSIMILARS’ EFFECT ON REFERENCE DRUG’S PRICE FOR EU, USA AND TURKEY

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OBJECTIVES: The use of biotechnology-derived products has increased over the last years. In this regard, biosimilars are considered as an alternative to decrease the total biologic drugs cost for countries. To investigate biosimilars cost saving effect on pharmaceutical budget, our research question was based on whether there are considerable price differences between biosimilar and reference biotechnological product. Considering the probable price differences between biosimilar and reference drug, substitution of biosimilars with reference drugs are expected to result in relatively lower price differences compared to price differences between generic and original conventional drugs. In this regard, in this study, it was aimed to analyze the price differences between biosimilar and reference biotechnology drugs in Europe, USA and Turkey. METHODS: A systematic literature review was performed by using keywords of “Biosimilars Pricing Europe”, “Biosimilars Pricing USA” and “Biosimilars Pricing Turkey” in Pubmed. For Turkey, there was lack of literature with these keywords. Therefore an analysis was made using the local prices of biosimilar drugs whose reference products are also being reimbursed in Turkey. RESULTS: In light of the systematic literature review, the price differences between biosimilar and reference drugs were changed between 0.51% and -38% in Europe. Price differences were found to be between +0.53% and -39.60% in Turkey. As the first biosimilar drug in USA was registered in April 2015, there was lack of literature based on real data with the keywords used in this study. But the price differences assumptions for USA were close to the numbers observed in studies based on EU markets. CONCLUSIONS: Although the price difference between biosimilar and reference
biotechnological product is relatively lower compared to the conventional drugs, which can be up to 80%. price differences in EU countries, with only by the competition of biosimilar and biotechnology drugs, cost savings could be more than 10 billion $.

**PHP99: IMPACT OF HEALTH POLICIES ON CATASTROPHIC HEALTH EXPENDITURES IN TURKEY**

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**OBJECTIVES:** Turkish Health Transformation Program has been launched in 2003, to improve the availability, quality, and the use of primary health care services. The program aimed to rebuild Turkish health system and establish a national based health insurance coverage. According to TURKSTAT figures, the proportion of households with catastrophic health expenditure decreased from 0.81 in 2002 to 0.14 in 2012. However, the ratio increased to 0.31 in 2014. The aim of the study is to investigate the determinants of catastrophic health expenditure and investigate the impact of health policies and factors on catastrophic health expenditure in Turkey. **METHODS:** Catastrophic health expenditure is calculated from a national representative data derived from TURKSTAT. Household Budget Survey, belonging to the time period 2010 - 2015. Proportion of households facing catastrophic health expenditure are calculated by using the methodology proposed by Ke Xu (Xu 2005). **RESULTS:** The average spending values of household with positive health expenditure have been decreased on pharmacy-related products(-36%), medical services (doctors)(-71%), hospital services(-84%), dentistry, and laboratory services. However, there was an increase in the average spending value on other medical products(+76%), medical aids(+79%) and other services. The average spending values of household with catastrophic health expenditure have been decreased on pharmacy-related products(-64%), medical services (doctors)-57%, dentistry, and laboratory services. However, there was an increase in the average spending value on other medical products(+79%), medical aids(+193%) and hospital services(+93%). **CONCLUSIONS:** As a result, the increase in the number of households with catastrophic health expenditure could be the result of changes in health policy may impact on medical products, tools and equipment for treatment, other medicinal products, medical aids, other services and hospital services. Further studies should be done to investigate this effect.

**PHP100: COST ANALYSIS OF DELIVERY NEONATAL DRUG THERAPY SERVICES AT MINISTRY OF HEALTH IN SAUDI ARABIA**

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**OBJECTIVES:** To explore the estimation of cost calculations for delivery drug therapy distribution (unit dose, floor stock, and discharge) for neonates by using American Model with local cost. **METHODS:** It is a 6-months cross-sectional analysis of drug distribution services for neonates in 2016. It was at 300-Bed Maternity and Pediatrics Hospital in Riyadh, Saudi Arabia. The cost calculated pediatrics drug therapy management services delivered to 82 beds. The physician prescribed the medications. The pharmacist reviews and prepared drugs and distributed through unit dose system, floor stock distribution, and discharge medications services. The medications prepared through ASHP standards and facilities. The nurse administers drugs and follows up by doctors. The fast moving oral and topical medications included in the study. The cost Model calculated based on variable expenses including personal cost, material, and supply cost. Fixed cost was including direct cost, non-salary cost, and overhead cost. All cost used of US dollar currency and local prices **RESULTS:** The estimated cost of delivery of drug therapy services for all total number adults beds per day was (1,253.9 USD). It contained three types; the unit dose system (792.43 USD), floor stock distribution system (368.98 USD), and discharge medication order (92.48 USD). The cost of delivery of medicines to single bed per day was (32.66 USD) with the highest estimated cost of delivery discharge medication (18.5 USD), followed by unit dose services (9.66 USD) and floor stock therapy (4.5 USD). The majority of cost came from overhead cost, and material and supply in floor stock services and discharge medication delivery; while the personal cost in unit dose services delivery. The total estimated annual expenditures of Drug distribution services were (457,673.01 USD). **CONCLUSIONS:** The estimation cost of delivery neonatal medication therapy is a part of pharmaco-economic program at pharmacy services and future vision 2030 in Saudi Arabia.

**PHP101: COST ANALYSIS OF DRUG-RELATED PROBLEMS IN SAUDI ARABIA, PATIENT AND HEALTH CARE PROFESSIONAL’S PERSPECTIVE**

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**OBJECTIVES:** To explore the cost analysis of drug-related problems in Saudi Arabia from patient and healthcare provider’s perceptive **METHODS:** It is a 4-months cross-sectional survey of cost analysis drug-related problem in Saudi Arabia from patient and healthcare provider’s perceptive. The study consisted of two-part a demographic data.
The second part contained the questions about the occurrence of drug-related problems with the patient, the economic burden of cost of drug-related problems. American Society of Health-System Pharmacist (ASHP) definitions of drug-related problem used. The survey distributed through social media. The questionnaire made of an electronic format, and it analyzed through survey monkey system. RESULTS: The total responders were two hundred and one; the Saudi nationality was 188 (93.5%), and non-Saudi was 13 (6.5%) patient. The gender distribution was female 180 (89.6%), and male was 21 (10.4%). The majority of them in age (18-44) 88% and located in Riyadh region 84 (41.8%) and Asir region 59 (29.4%). Of those 44 (22.1%) were health care providers. The responders showed a high percentage of drug related problem occurrences for public and health care providers was drug non-compliance (70.45%, 70.9%), and indication without medication (52.27%, 49.35%). The health care providers spent ($63,728.53 USD) annually as average cost of drug-related problems, while the public spent (888,433.24 USD) annually. The highest cost of drug-related problem was medication adverse reaction (1733.33 USD) and medication errors (762.67 USD) per each event. The total estimated cost of drug-related problems was ($60,996,726,906.27 USD) annually in Saudi Arabia. CONCLUSIONS: The drug-related problems are very high-cost burden on health care system in Saudi Arabia. Targeting to improve role of pharmacist and prevent drug-related misadventures is highly recommended through Saudi Health Care Vision 2030

PHP102: FLUOROQUINOLONE-RELATED ADVERSE EVENTS RESULTING IN HEALTH CARE USE AND COSTS: A SYSTEMATIC REVIEW

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OBJECTIVES: The aim of this systematic review was to identify health care use and subsequent costs associated with fluoroquinolone-related adverse events (AEs). METHODS: A literature search covering Medline, SCOPUS, Cinahl, Web of Science and Cochrane Library was performed in April 2017. Two independent reviewers systematically extracted the data and assessed the quality of the included studies. All costs were converted to 2016 euro in order to improve comparability. RESULTS: Of the 5687 references found in the literature search, 19 observational studies, of which 5 were case-controlled, fulfilled the inclusion criteria. Hospitalization was an AE-related health care use outcome in 17 studies. Length of stay associated with AEs varied between <5 - 45 days. The estimated cost of an AE episode ranged between 140 and 18,252 €. Clostridium difficile infections were associated with the longest stays in hospital. However, a mere 10 studies reported AE-related length of stays and only 5 evaluated costs associated with AEs. CONCLUSIONS: Although rare, serious fluoroquinolone-related AEs can have substantial economic implications, which seldom appear to be acknowledged or reported. It seems that further measures are required to prevent and reduce fluoroquinolone-related AEs, in addition to health care use and costs associated with them.

PHP103: PHARMACOECONOMIC ANALYSIS OF DALBAVANCIN USE IN ACUTE BACTERIAL SKIN AND SOFT TISSUE INFECTIONS

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OBJECTIVES: Dalbavancin is a new generation anti-infective agent; it was licensed in the US in 2014 and in the EU in 2015 for the treatment of acutec bacterial skin and soft tissue infections (ABSSTI) caused by gram-positive microorganisms. The purpose of this study is to perform a pharmacoeconomic comparison of the use of dalbavancin versus vancomycin and dalbavancin versus vancomycin-oral linezolid for the treatment of ABSSTI due to gram-positive microorganisms in Turkey and in the US. METHODS: A decision tree model has been designed from the perspective of reimbursement institutions. Efficacy and safety data were obtained through clinical trials in the published studies and costs were obtained by the prices announced by the reimbursement institution, and the literature. The primary outcome was the incremental cost-effectiveness ratio, expressed as $ and € per successfully treated patient. RESULTS: The cost-effectiveness ratios for dalbavancin and vancomycin were $6,049 and $1,357 respectively, in Turkey, while the cost-effectiveness ratios were $13,911 and $9,112 per successfully treated patients, respectively, in the US. Due to the fact that dalbavancin is licensed and already priced in the US, the threshold analysis was performed over the hospitalization days in that context. In order for dalbavancin to be cost-effective in US, patients should be hospitalized less than 0.62 days. The model was not sensitive to the hospitalization duration and the hospital costs in Turkey. The model was sensitive to the hospitalization duration in the US. CONCLUSIONS: Vancomycin was more cost-effective compared to dalbavancin in Turkey, whereas vancomycin-linezolid was more cost-effective compared to dalbavancin in the US in treating ABSSTI. Thus in countries such as the US where hospital costs are high, dalbavancin may be a cost effective alternative for patients.
who are eligible for outpatient treatment. Furthermore, the use of dalbavancin in Turkey may be beneficial in reducing the intensity of care in hospitals.

PHP104: COUNTERFACTUAL DECOMPOSITION OF HEALTH CARE EXPENDITURES: FROM COST-BASED PAYMENT TO GLOBAL BUDGET SYSTEM

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OBJECTIVES: This study employs patient-level data to investigate the growth of health care expenditures by decomposing outpatient, inpatient and prescription drug expenditures into observable effect and structural change in a health care system that experiences the shift of payment schemes from cost-based to global budget system in 2002. METHODS: The National Health Insurance claim data which include around three-million patients was used to create a patient-level data set for the year 2000, 2005, and 2010 in Taiwan. This study employs the (recentered) influence function (RIF) unconditional quantile regression to decompose health care expenditures into observable effect and structural change. RESULTS: The payment shift results in negative structural changes on the growth of outpatient and prescription drug expenditures at the lower percentiles in the short run. In the long run, the observable effect still dominates the growth of health care expenditures at the higher percentiles. Specifically, population ageing accounts for the growth of inpatient expenditures and top prescription drug expenditures. The adoption of high technology mainly contributes to the growth of outpatient expenditures at the higher percentiles. CONCLUSIONS: Although cost control policy, like the global budget system, can lower the growth of health care expenditures in the short run, population ageing and adoption of high technology still likely drives the expenditures of high-cost patients in the long run.

PHP105: COST-OF-ILLNESS ANALYSIS FOR LYMPHOEDEMA IN A REGIONAL HOSPITAL IN EAST BOHEMIA

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OBJECTIVES: Lymphedema is a chronic progressive disease of the lymphatic system that can cause patient disability at a later stage. Patients are most often treated with a complex decongestive therapy, which is a combination of manual and instrumental lymphdrainage, external compression by bandaging, special motion and breathing exercises, and regimen arrangements. The aim of this study is to calculate the total costs of lymphedema in a regional hospital in East Bohemia. METHODS: The cost-of-illness analysis was used. Data collection was based on the bottom-up disease-based approach. The data necessary to calculate the costs of the disease were obtained from the hospital’s internal information system, and completed with those from statistics for 2013, 2014 and 2015. RESULTS: A total of 463 patients were enrolled in the study (147 patients in 2013, 151 patients in 2014 and 165 patients in 2015). The personnel (salary) costs of the attending physician, nurse and/or physiotherapist were calculated. These costs accounted for 68% of the total costs of treatment. Moreover, maintenance and operational costs of medical devices and facility overhead costs were included, amounting together about 2% of the total costs. The overhead costs covered 30% of the total costs. Finally, the total costs per patient for the complex decongestant therapy was CZK 5 582 in 2013, CZK 5 285 in 2014 and CZK 5 296 in 2015. The total costs of the lymphoedema treatment in the particular healthcare facility was CZK 1 168 808 in 2013, CZK 1 143 202 in 2014, and CZK 1 219 090 in 2015. CONCLUSIONS: This study was based on prevalence data from the particular facility. The number of patients with lymphoedema is not monitored in the Czech Republic; hence, it is not possible to calculate the costs of illnesses for the whole country.

PHP106: ANALYSIS OF FINANCIAL STATUS AND THE INVESTMENT STRATEGY OF NATIONAL HOSPITAL ORGANIZATION (NHO) IN JAPAN FROM 2004 TO 2015.

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OBJECTIVES: Ministry of Health, Labour and Welfare of Japan revises medical fee schedule biennially. The revision is performed in line with the government’s budget policy at national level. NHO has been requested every five-year management plan by government. Thus, to study the financial change and the investment strategy of NHO gives us the overview of the changes in business conditions of Japanese healthcare system. In this study, we analyzed all 143 NHO hospitals from 2004 to 2015. METHODS: We analyzed the financial change of all 143 NHO hospitals using an indicator of the OPP (Operation profit per one monetary unit of personnel cost) reported before (Nakagawa. et al, Journal of Medical Systems. 2011 Aug; 35(4):625-37) and the data of Cash flow statement (CF). RESULTS: The financial situation of NHO is demonstrated by OPP. In the 1st period of the management plan, from 2004 to 2008, the OPP was 0.100, in the 2nd period, 2009 to 2013, it was 0.074 and in the 3rd period, there are still only the data of 2014 and 2015, it was 0.012. The results means the OPP had been gradually and continuously reduced. The
personnel expense was the most increased cost. The growth rate of the personnel cost in the 1st and 2nd period was 3% and over 4.5 % in the 3rd period. And also the growth rate of depreciation cost was increased in 2nd and 3rd period. Especially in 2nd period, it was about 7%. And the investment activity in cash flow statement, that was always in minus condition, in 2st and 3rd period the minus flow was increased about 60% from the 1st period. **CONCLUSIONS:** The government cannot continue the growth rate on the reward, so the investment of personnel and capital expenses was getting to the risk of the hospital management.

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**PHP107: EXPLORING DISINVESTMENT DECISIONS IN THE NHS VIA HEALTH ECONOMICS**

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**OBJECTIVES:** A core assumption across Health Economics analyses is that disinvestments across the wider healthcare system would free up resources to enable maximum health outcome and economic advantage. However, this is seldom explicitly dealt with. This project aims to explore methodological alternatives to the currently value-demonstration paradigm in the NHS across the UK that could adequately address the assumption of systemic disinvestment. **METHODS:** A comprehensive review of existing approaches was conducted via PubMed, Google Scholar and grey literature. Critical appraisal of the gaps in the existing approaches was conducted and case studies identified. Next, actionable methodological suggestions for the current NHS environment were identified and research recommendations made. **RESULTS:** Structured searches resulted in 140+ hits on PubMed and 6000+ hits on Google Scholar and grey literature. 25 articles were selected based on title and abstract screening. Even newer approaches like Socio-Technical Allocation of Resources (STAR) appear not to focus deeply on disinvestments as a key part of the complex systemic solution matrix. Early discussions on relevant approaches were from the WHO regarding Generalised Cost Effectiveness (GCEA) methods. More recent papers have focused on options like the Programme Budgeting Marginal Analysis (PBMA) and Sustainability in Healthcare by Allocating Resource Effectively (SHARE). **CONCLUSIONS:** A key finding was the lack of focus on disinvestment in the UK in academic literature. Techniques like GCEA and Cost Minimisation Analyses (CMA) have been around for long; however, have not generally been reported or evaluated for disinvestment decisions. Newer techniques like PBMA and SHARE show promise. The topic of disinvestment requires more use, research, and validation.

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**PHP108: COST-EFFECTIVENESS ANALYSIS OF INVASIVE FUNGAL INFECTIONS THERAPIES IN FEBRILE NEUTROPENIC PATIENTS WITH HEMATOLOGICAL MALIGNANCIES IN THE TURKISH CONTEXT**

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**OBJECTIVES:** Incidence of invasive fungal infections (IFI) often occurs as a complication of immunosuppression in patients with hematological malignancies. These infections reflect an important cause of morbidity and mortality in patients with Acute Myeloid Leukemia (AML) and in hematopoietic stem cell transplant (HSCT) recipients. Early diagnosis and treatment of patients with an IFI can have a major impact on patient outcomes. For this reason, new approaches for diagnosis and treatment have been developed. However, due to lack of accurate diagnostic tools for making an early diagnosis, the debate is still ongoing about how and when to initiate therapy. Notably, the empirical approach advocates to begin antifungal therapy for those patients who have fever lasting 4–7 days despite using broad-spectrum antibiotics. The preemptive approach concerns initiation of antifungal therapy for patient after considering clinical and mycological evidence pointing to a highly probable IFI. The aim of this study is to compare both alternatives in terms of cost-effectiveness. **METHODS:** A decision tree was developed according to the Turkish reimbursement authority’s perspective. The data used in the model were derived from the published literature and specific Turkish sources. Cost-effectiveness was expressed as net costs per extra surviving patient. **RESULTS:** It was found that the preemptive approach is less costly, but the empirical approach more effective. Ergo, none of the methods was dominant. Cost-effectiveness of the empirical approach as compared to the preemptive one was estimated at TR186,577. **CONCLUSIONS:** Major shares of the costs of the preemptive approach to patient with suspected IFI concern the CT-scan with contrast media increased nephrotoxicity. If CT-scans would be made without contrast media though, costs of the preemptive method can be reduced with only slight reductions in effectiveness and the preemptive method might be considered preferably with huge cost savings associated (ICER at - TR19,124,297).

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**PHP109: ASSESSING UPTAKE OF MEDICINE USE REVIEWS IN ENGLISH COMMUNITY PHARMACIES**

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OBJECTIVES: The National Health Service (NHS) reimburse English pharmacies for providing Medicine Use Reviews (MURs). MURs are pharmacist-led consultations on a patient’s medicine use that aim to improve patient adherence and outcomes and reduce medicine wastage (1). MURs can be conducted in patients who have received 1+ medicine from a pharmacy for 3+ months and may be repeated annually. Pharmacies are reimbursed £28 per MUR and may claim for up to 400 MURs per financial year. While there are limited health-economic studies available relating to MURs in England, available data suggest increased patient satisfaction and cost-savings due to better disease control (1). We assessed current uptake of MURs in English community pharmacies. METHODS: Monthly dispensing data for English pharmacies that had (i) submitted MUR data to the NHS Prescription Services for the last financial year and (ii) made at least one MUR claim during this period were retrieved from the NHS Business Authority. This resulted in monthly data for the period 01/04/2015 to 31/03/2016 being retrieved for 10,772 pharmacies. Opportunity loss was calculated by subtracting the total number of MURs declared from the maximum each pharmacy could conduct (n=400) and multiplying the subtraction with the reimbursement tariff (£28). RESULTS: The median English pharmacy declared completing 96.5% of the MURs they could be have been reimbursed for, representing a median opportunity loss of £392 (£0-£11,172) per pharmacy. Total opportunity loss in England was £29,170,204. However, regional variations were observed, with total opportunity loss being highest in North East London (£1,771,868) and lowest in Bath, Gloucester, Swindon & Wiltshire (£37,112). CONCLUSIONS: Overall uptake of MURs was high although regional variances were observed. More studies are needed to understand reasons for regional variation and the impact on patient outcomes and indirect NHS cost. REFERENCES: (1) Wright (2016) https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/12/rapid-evdncrev-dec-16.pdf

PHP110: LIVING WITH CHRONIC DISEASES IN GREECE: INVESTIGATING HEALTH SERVICES UTILIZATION PATTERNS AND ECONOMIC CONSEQUENCES

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OBJECTIVES: The aim of this study was: a) to bring to light the health services utilization patterns of patients suffering from chronic diseases in Greece and b) to investigate the affordability of the households to use the services METHODS: A cross-sectional study was carried out between 01/02-30/06, 2016. The study sample consisted of 1,009 patients with chronic diseases (convenience sampling), residing in areas of the Northern and Western Greece. A structured questionnaire based on national and international literature with closed-ended questions was developed by the researchers to collect the data. The response rate was 90.1%. A pilot study and a test-retest reliability test was carried out among 52 patients (Cronbach’s alpha = 0.884). RESULTS: Almost 47% of the study population reported visiting public primary polyclinics (PEDY units), 58.3% Public Hospitals and/or Health Centres, 51.6% private practices and 14.2% Municipal Health Clinics/NGOs. One out of five chronic patients reported that the economic conditions most often affect their decision to visit health care facilities or to undergo necessary laboratory testing, while 60% have experienced moderate and/ or serious economic difficulties due to their health problems. Nearly 40% of the respondents did not have the financial means to cope with health care costs A 30% reported that faced problems in taking their medications on a regular basis (as prescribed). Before the onset of the economic crisis, 88.8% used original/prototype medication, while at the moment only half of them are using original medicines, 24.8% get generic, and 24.2% get original and generic medicines. More than one third of the patients (35.3%) reduced the frequency of laboratory tests required to monitor the course of their disease. CONCLUSIONS: The use of health care services and in the long run patients’ compliance to the management of their chronic disease is affected by the socio-economic conditions.

PHP111: THE INTRODUCTION OF A THRESHOLD FOR THE ICER AND THE IMPLICATIONS FOR REIMBURSEMENT OF DRUGS IN THE DUTCH HEALTHCARE SYSTEM

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OBJECTIVES: The National Health Care Institute (ZIN) advises the minister of healthcare (MOH) if a drug should be reimbursed. Recently it was suggested to implement a threshold value for the incremental cost-effectiveness ratio (ICER) that is related to the burden of disease (BOD). The higher the BOD, the higher the threshold of cost per QALY. This research aims to explore how the introduction of a threshold for ICERs based on BOD for drugs would influence the current reimbursement of drugs using a retrospective analysis. METHODS: All reports of economic
analyses that were part of an HTA assessment published by ZIN from 1-jan-2010 to 1-jul-2016 were used and data were collected using a standardized case report form. From these publications, the appraisal outcomes, ICERs and BOD were extracted. If the BOD calculation using the proportional shortfall method was missing it was completed using the WHO-rapport “Burden of disease”. Several possible thresholds as suggested in ZIN guidelines were used as threshold values. RESULTS: ZIN published 219 recommendations on reimbursement. 35 publications included a pharmacoeconomic analysis from which an ICER and a BOD could be obtained. Without a threshold linked to BOD 83% of all drugs were reimbursed. If a threshold linked to three BOD strata was used, i.e. €20,000 per QALY for a BOD between 0-0.4, €50,000 per QALY for a BOD between 0.4-0.7 and €60,000 per QALY for a BOD between 0.7-1, only 32% of drugs would be reimbursed. CONCLUSIONS: Based on our data the use of a threshold based on BOD would substantially decrease the number of reimbursable drugs in the Netherlands. More research is needed on the impact of using a threshold on prices and reimbursement rates and the best form of implementation to assure overall system equity and efficiency.

PHP113: WILL IT BLEND? INCORPORATION OF IRP WITHIN HTA SYSTEMS

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OBJECTIVES: International Reference Pricing (IRP) is used extensively in most EU countries, as well as beyond the continent. Over the past two decades, health technology assessment (HTA) has become the higher profile, somewhat because entirely new agencies and review frameworks need to be developed, but also because IRP may lead to significant patient access delay given that manufacturers may postpone launch to optimise pricing opportunity. Hence, this research was undertaken to understand the degree to which each policy intervention leads to key milestones. METHODS: Analogues for assessment were selected, based on their relative clinical innovation and pricing expectations. The decisions were categorised in terms of access achieved, evidence under consideration, and the presence of local IRP rules. RESULTS: The analysis of 22 product analogues demonstrated significant convergence in reimbursement decisions across countries where HTA is the chief means of managing expenditure. Among the markets of interest, NLD had the highest frequency of access achievement followed by GER and ENG – countries where there is a clear favour towards HTA relative to IRP. SWE, which does not officially incorporate IRP within its decision-making process had the lowest number of positive access achievement, suggesting that IRP may be both a more justifiable and effective method of ensuring that patients have access to clinically and economically effective therapy. CONCLUSIONS: The lack of clear correlation between access, and policy intervention suggests that the rationale for a system for high access to the latest innovation is derived largely by an evidence-based HTA approach in addition to other factors such as societal expectation, the media, patient advocacy – all areas that are more visible and hence more vulnerable to pressure mounted by local healthcare stakeholders. IRP while clearly playing a role in negotiations is a less visible target for these same healthcare stakeholders.

PHP114: WILLINGNESS TO PAY FOR QALY IN THE CZECH REPUBLIC BETWEEN 2013 AND 2017: A REVIEW

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OBJECTIVES: A cost-effective medicine has been defined by the Act on Public Health Insurance as a medicine dominating its relevant comparator, being cost-minimizing, or generating an incremental cost-effectiveness ratio (ICER) similar to those shown in already reimbursed medicines. The primary aim of this study was to review, for the first time, the ICERs already accepted for reimbursement within administrative proceedings by the State Institute for Drug Control (SUKL). The secondary aim was to report the ratio of cost-minimization analysis relative to cost-utility analysis. METHODS: We analyzed all proceedings of the SUKL since 2013 and selected those where the pharmacoeconomic analysis fulfilled our prespecified selection criteria. We considered only applications for permanent reimbursement having acceptable quality of the submission without any confidential agreement on price and excluded proceedings where additional criteria were considered since these represent exceptional cases. In the case that the submitting company requested reimbursement for more than one indication or presented results for different subgroups of patients and, therefore, more ICERs were available, only the highest value was used in the base case analysis. The exchange rate considered was 27 CZK = 1 EUR. RESULTS: Out of 355 proceedings in which economic evaluations have been required, we identified 35 in which the medicine under review was either dominant or cost-minimizing and 30 proceedings where ICERs were shown. The mean positive ICER value was 22,712 EUR per QALY, the maximum was 57,407 EUR per QALY. In 57% of proceedings, the ICERs were lower than 22,200 EUR per QALY and in 97% of proceedings, they were lower than 44,400 EUR per QALY. CONCLUSIONS: The results prove long-term consistency of SUKL’s judgments in standard proceedings and can be used as basis for future decisions in compliance with the legislative requirements on evaluating cost-effectiveness in the Czech Republic.
PHP115: COULD HEALTHCOIN BE A REVOLUTION IN HEALTHCARE?

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OBJECTIVES: Blockchain consists of a shared database used to maintain a continuously growing list of transactions, called blocks. Blockchain technology has started in 2008 with the first decentralized digital currency "Bitcoin". Bitcoin is a cryptocurrency and a digital payment system that can be exchanged for other currencies or products. New potential uses of blockchain are under investigation among which its application in healthcare “healthcoin”. Our aim was to review the available information on healthcoin to gain a better understanding of this concept and its applicability. METHODS: A literature review was conducted in Pubmed and the grey literature using the keywords: Healthcoin, blockchain, healthcare, financing, breakthrough therapies. Articles in French and English were included and no timelines restrictions were applied. RESULTS: Founded in 2016 by Diego Espinosa and Nick Gogerty, healthcoin was the first blockchain based platform for rewarding prevention of diabetes. Users submit their biomarkers (hemoglobin A1c) into the blockchain that automatically calculates the improvement and awards the patient digital tokens: “healthcoins”. For each healthcoin earned, a tax break can be offered by the government; a discount on fitness brands can be offered to reward patients. This same currency concept was adapted by Basu et al. 2016 as a new financing method for breakthrough therapies for diabetes. It converts the incremental benefits produced by the novel therapy to a common numeraire such as life years gained. It is a currency that could be traded between the private payers and Medicare in the United States, rewarding the former to invest in breakthrough therapies that provide important efficacy for patients before the age of 65. CONCLUSIONS: Healthcoin may potentially constitute a revolution for the healthcare sector. Healthcare industry can share and store information transparently through healthcoin. Further studies to assess the feasibility of healthcoin payments may be interesting for payers and decision makers.

PHP116: AGING OF HEALTH CARE PROFESSIONALS IN HUNGARY

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OBJECTIVES: Recent years have seen an increase in focus, at an international level, on changes regarding the number and the income of health care professionals. Better circumstances, higher salary prospects are major sources of motivation for health care professionals to work abroad. Efforts at keeping them home have become one of the most emphasised targets of the government. The aim of our study was to analyze the aging of health care professionals in Hungary. METHODS: Data were derived from the database of the Health Registration and Training Center (OSAP Nr. 1626 data collection programme). We created three age groups within headcount between 2003-2015 in point of the following health care professionals working in health care sector: general practitioners, specialist physicians, dentists, specialist dentists, pharmacists, specialist pharmacists, nurses, dieticians, physiotherapists, midwives, health visitors, ambulance men. RESULTS: While the proportion of nurses (-33%), and midwives (-26%) decreased most in the age group 39 and below, the highest increase was observed in the age group of 40 to 59 years (+31%, +22%). Dentists showed the biggest decrease (-30%) in the age group of 40 to 59. The proportion of specialist physicians increased the most from 5% to 24% (2003-2015) in age group 60 and above. CONCLUSIONS: Between 2003-2015 there was a remarkable increase and decrease in the age groups of health care professionals in Hungary. The changes showed significant differences among different professions. In order to prevent the rapid aging of health care professionals, further improvement of salaries is required.

PHP117: THE ATTITUDE OF POLISH PHYSICIANS TOWARDS INTRODUCTION OF E-PRESCRIPTION – A QUESTIONNAIRE SURVEY

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OBJECTIVES: At present, there is a problem in Poland regarding under-quality and incompleteness of health records. EHealth solutions, including and electronic prescription (e-prescription), provide an opportunity to correct these irregularities. In Poland, work on the implementation of these solutions is ongoing since 2011. This survey was to examine the attitude of Polish physicians towards introduction of e-prescription. The main aim was to make recommendations for the decision makers responsible for the implementation of the system in Poland, based on the results of the survey. METHODS: A questionnaire research was conducted, with 100 primary care family medicine physicians as responders. Quota selection was applied, reflecting the number of respondents in particular voivodships. The selection included 3 categories of workplaces: main provincial cities, medium-sized towns (less than 70,000 inhabitants) and small towns (less than 10,000 inhabitants). The questionnaire contained 27 questions. RESULTS: Physicians are generally convinced, that e-prescribing will eliminate prescription illegibility and solve the problem of incompleteness. Doubts are associated also with visit time, legal issues, patients’ difficulties with
adaptation to system and costs. Despite many concerns, most physicians declare willingness to use the system in their everyday practice, however, it was significantly more often among physicians from main provincial cities than among respondents from smaller towns. **CONCLUSIONS:** In order to ensure the success of the implementation of the e-prescription system, cooperation and acceptance of medical environments is essential. The eHealth service system should be designed taking into account the needs of its target participants, since it is the only way to achieve positive effects. It is recommended to carry out information and education actions, in particular in smaller locations.

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**PHP118: IMPACT OF WEIGHT CHANGE AFTER QUITTING CIGARETTES ON ALL-CAUSE AND CAUSE-SPECIFIC MORTALITY IN MIDDLE-AGED MALE SMOKERS: NATIONAL HEALTH SCREENING COHORT STUDY**

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**OBJECTIVES:** We aimed to investigate the association between weight change after smoking cessation and the risk of all-cause and cause-specific mortality among middle-aged male smokers. **METHODS:** We conducted a prospective cohort study using the National Health Insurance Service National Health Screening Cohort (NHIS-HealIS) database. Male Participants (n=102,403) without critical conditions aged between 40 and 79 at baseline who underwent biennial health examination were included in this study. Participants were categorized into continued smokers, recent quitters (within 4 years), long-term quitters (more than 4 years), and never-smokers based on the self-reported smoking status. Weight change was determined by the change of Body Mass Index (BMI) between the first (2002-2003) and second (2004-2005) health examination records. We followed patients from January 1, 2006 to December 31, 2013. To assess the risk of all-cause, cancer, cardiovascular disease (CVD) mortality, and non-cancer, non-CVD mortality according to smoking cessation and weight change, we computed Hazard Ratio (HR) and 95% Confidence Interval (95% CI) using Cox proportional hazard models. **RESULTS:** Severity of weight gain was more prevalent among recent quitters compared to long-term quitters. After adjusting for covariates and weight change, both recent quitters (HR:0.74; 95% CI: 0.63-0.87) and long-term quitters (HR:0.53; 95% CI:0.45-0.61) had decreased risk of all-cause mortality compared to continued smokers. Similarly, both recent and long-term quitters had decreased risk of cancer, CVD, non-cancer, and non-CVD death regardless of weight change following smoking cessation. Compared to continued smokers, non-smokers also had a lower risk of overall and cause-specific death. **CONCLUSIONS:** Post-cessation weight change did not modify the protective association of smoking cessation with reduced risk of all-cause and cause-specific death. From a public health perspective, smoking cessation program may contribute to reducing risk of death in middle-aged male smokers despite the concern on weight change after quitting smoking.

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**PHP119: EVALUATION OF AN ATTITUDES TOWARD MEDICAL ERRORS SCALE IN PHARMACY AND HEALTHCARE PROFESSIONAL STUDENTS**

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**OBJECTIVES:** To develop and evaluate an attitudes toward medical errors scale in pharmacy and healthcare professional students with the goal of improving patient safety and outcomes in healthcare. **METHODS:** In 2012, St. Louis College of Pharmacy students (N=111) as well as students from eight additional health professions at a medium-sized Midwestern university (N=154) participated in an anonymous online survey. Ninety-five items evaluating attitudes toward medical errors (ATME) and eleven demographic questions were included in the survey. **RESULTS:** Following item and factor analysis, a 24-item ATME survey (final version) was developed from three dimensions: cognitive [8 items], affective [8 items], and behavioral [8 items]. Results showed that students with positive ATME tend to learn from errors; students with negative ATME, however, tend to have no intention of taking steps to learn from their errors. Of the 111 pharmacy students, ATME was lower among men (ATES=78.77, N=32, s.d.=8.19) than women (ATES=79.16, N=79, s.d.=8.86, range=58-105). In addition, ATE was lower among pre-pharmacy students (ATES=77.13, N=32, s.d.=9.00) than P1 and P2 pharmacy students (ATES=79.63, N=42, s.d.=9.13) or P3 and P4 pharmacy students (ATES=80.05, N=37, s.d.=8.64). Interestingly, results from the 8-item cognitive scale indicated that male students increased as they progressed from pre-pharmacy through the professional program; however, female students showed a reduction in the cognitive scale mean as they progressed through the six-year program. Pharmacy students in years P3 and P4 who had clinical experience showed statistically significantly higher learning goal orientation than those with no clinical experience; respondents with a learning goal orientation were more likely to have a positive ATME. **CONCLUSIONS:** The ATME scale shows potential value to healthcare professionals and educators in designing curricula and training programs to better understand ATME and its three subscales (cognitive, affective, and behavioral). Improvements in training and education can minimize future medical errors and enhance patient healthcare outcomes.
PHP120: INTERCONTINENTAL LINKS AMONG HEALTH TECHNOLOGY ASSESSMENT ORGANIZATIONS

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OBJECTIVES: A health technology assessment (HTA) system reflects a nation’s culture and private organizations. HTA systems originated in European countries and are more coordinated when compared to those in the United States. Thus, European countries led the development of network links with other countries to strengthen global HTA efforts. However, little is known about intercontinental links among HTA organizations; thus, this study aims to visualize those global links. METHODS: The total number of HTA organization memberships in ISPOR, HTAi, INAHTA, EuroScan, EUnetHTA, HTAsiaLink, and RedETSA were examined to create intercontinental linkage among HTA organizations. A total of 373 HTA organizations from 72 countries and 7 continents were included in the study. A network parameter was determined using frequencies and percentages to summarize different countries’ number of HTA organization memberships. “Map,” “diagram,” and “plotrix” packages were used in an R program to illustrate the intercontinental links and visually identify major hubs in this worldwide network. RESULTS: An intercontinental link map, including connections drawn as circles, shows that European countries are at the center of global HTA networking. Additionally, membership in only one international HTA society is high for European (n=141, % =43.1) and North American (n=98, % =30) organizations, and the number of memberships in five international HTA societies is high for Asian (n=1, % =50) and North American (n=1, % =50) organizations. CONCLUSIONS: Strengthening international collaboration should remain a high priority for global HTA decision makers for many years to come. However, international HTA society memberships remain driven by geographic region. Improving international HTA organizations’ roles in translating and disseminating knowledge throughout different parts of the world, building platforms for achievement discussions, and creating common data-sharing strategies are advisable goals to improve the quality of HTA activities and to make health technologies and evidence-based medicine available for everyone.

PHP121: PHARMACEUTICAL CARE WORKLOAD AND WORKFORCE REQUIREMENT AT MINISTRY OF HEALTH PRIMARY CARE CENTERS DURING TEN YEARS MASS GATHERING HAJJ (2006-2015) IN MAKAH REGIONS, SAUDI ARABIA

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OBJECTIVES: To explore the pharmaceutical care services workload and workforce requirements at Ministry of Health primary health care centers during mass gathering Hajj ten years (2006-2016), Saudi Arabia METHODS: It is a retrospective analysis of ten years (2006-2015) of primary healthcare center (PCC) pharmacies workload during mass gathering Hajj period. The duration of workload collection was 15 days. The pharmacist and pharmacy technicians provide pharmaceutical to all patients either Pilgrim or not Pilgrim at Makah region. The workforce requirements calculated based on MOH workforce standards of primary health care center and the workload drives as central pharmacy services, patient specific pharmacy activities, and general administration specific pharmacy activities RESULTS: The total number of prescriptions (226,824-505,753) with average (411,317), it represented (7.12-20.25%) with average (16.77%) of all pilgrims. The average number PCC prescription at holy places were (274,316) and (137,001) from Makah city. The average number of PCC order at sacred sites was (9,133) per day and contained (27,399) medications, while at PCC in Makah city was (18,288) prescriptions per day and contained (54,864) drugs. The average time of dispensing PCC prescription was 4 minutes. The average number of pharmacist needed (24.81 FTE) per each PCC at holy places, and (27.72 FTE) per each PCC at Makah city. The average number of pharmacist based on MOH standards per each PCC was (4 FTE) while the mean number pharmacist needed based on workload was (52.53 FTE) per each PCC. It is (13.13 fold) more incremental than MOH pharmacist workforce standards per PCC. CONCLUSIONS: The pharmacy workload analysis at primary health care center reflected the real demand for pharmacists. Clinical pharmacy activities at PCC missed with emphasis on patient-specific clinical pharmacy. There is a high shortage of pharmacists at PCC during mass gathering Hajj period in Makah Region, Saudi Arabia

PHP122: LANDSCAPE OF REPORTED DRUG SHORTAGES IN EUROPEAN COUNTRIES


OBJECTIVES: Drug shortages are a known problem in Europe. However, detailed information about the affected drugs remains missing. The aim of this study is to estimate the scope of the reported drug shortages in European countries. METHODS: Fifty national medicine authorities in Europe were asked to share their database of reported drug shortages between January 2011 and December 2016. If a database was obtained, additional information was
The acceptance rate of intervening clinical pharmacist recommendation and change in drug therapy was found to be 26.11% for dispensing errors, 17.22% for improper drug selection, and 14.4% for untreated indications. Male predominance (71.66%) was noted over females (28.33%). Most drug-related problems observed were in inconsistency in prescription orders, physical drugs, necessity of additional medication, and more proper alterations in parameters: dose, rate of administration, presentation, and dosage form. Presence of inappropriate/unnecessary medication was also noted. These problems were resolved by clinical interventions made during mass gathering Hajj period in Makah Region, Saudi Arabia.


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**OBJECTIVES:** To explore the pharmaceutical care services workload and human resources requirements at Ministry of Health (MOH) Hospitals during mass gathering Hajj ten years (2006-2015) in Saudi Arabia. METHODS: It is a retrospective of ten years (2006-2015) of hospital pharmacies workload during mass gathering Hajj period. The duration of workload collection was 15 days. The pharmacists provide pharmaceutical to all patients either Pilgrim or not Pilgrim at Makah region. It included Mona holy places hospitals; Arafa holy places hospitals, and Makah city. The workforce requirements calculated based on MOH workforce standards per bed and the workload drives as central pharmacy services, patient specific pharmacy activities, and general administration specific pharmacy activities. The pharmacy technician workforce excluded in the calculations. RESULTS: The total number of prescriptions (99,886-257,545) with average (180,120), it represented (5.11-12.07%) with average (7.86%) of all pilgrims. The average number Ambulatory care prescription were (69,517) while (22,959) was an emergency prescription, and (2,935) inpatient prescriptions. The average number of pharmacist needed (9.49 FTE) for inpatient services per hospital, (48.85 FTE) for Emergency services per hospital, and (21.85 FTE) for Ambulatory care services per hospital. The average number of pharmacist calculated per hospital was (37.1 FTE), while the mean number pharmacist needed to base on workload for all services was (80.19 FTE) per hospital. It is (2.16 fold) more incremental than MOH pharmacist workforce standards per bed. There were not any central pharmacy activities, and clinical pharmacy services or administrative pharmacy activities. CONCLUSIONS: The Workload analysis of pharmaceutical care services as a part of total quality management indicators during mass gathering Hajj. Clinical pharmacy activities missed with emphasis on patient-specific clinical pharmacy. There is a highly demand of pharmacists workforce during mass gathering Hajj period in Makah Region, Saudi Arabia.

**PHP124: HEALTH TECHNOLOGY ASSESSMENT TO IMPROVE PATIENT CARE THROUGH PHARMACEUTICAL CARE: CLINICAL PHARMACIST’S PERSPECTIVE**

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Drug Related Problems could result in the medication errors, adverse events, drug interactions and harm to patients. AIM: The main aim of the study was to assess and evaluate the Clinical Pharmacist’s interventions in health care i.e., HTA and its application to improve and optimize patient care through pharmaceutical care and to achieve accuracy in patient treatment. METHODS: A prospective, observational and interventional study. Ethical approval was obtained before starting the present study. The inpatient medication charts and orders drug related problems were identified, analysed and rectified by ward and practicing clinical pharmacists within the inpatient pharmacy services, using the parameters: dose, rate of administration, presentation and/or dosage form, presence of inappropriate/unnecessary drugs, necessity of additional medication, more proper alternative therapies, presence of relevant drug interactions, inconsistencies in prescription orders, physical-chemical incompatibilities/solution stability. From this evaluation, the drug therapy problems were classified, resulting clinical interventions made. RESULTS: out of 360 clinical pharmacist interventions followed, male (71.66%) predominance was noted over females (28.33%). Most of the DRP observed were dispensing errors (26.11%), improper drug selection (17.22%), followed by untreated indications (14.4%). Majority of the clinical pharmacist recommendations were on need for proper dispensing (26.11%), and drug change (18.05%). The acceptance rate of intervening clinical pharmacist recommendation and change in drug therapy was found to be
OBJECTIVES: The loss of market exclusivity is a natural milestone in the lifecycle of a patent-protected pharmaceutical. Once the patent protection for a substance expires, generic equivalents can enter the market and compete with the original brand-name product. As generics typically are sold at substantially lower prices, the companies are challenged to keep their share of the market. A key to managing patent expiry and the impending decline in sales volume and revenue could be entering into rebate contracts with German statutory health insurance companies. Those contracts oblige the pharmaceutical companies to grant a discount on the list price. In turn, the health insurers restrict supply to the product to which the contract applies. METHODS: The analysis is based on substances that lost patent protection in Germany during the period from 2013 to 2016. Selected substance markets were analyzed by comparing the tender announcement by health insurers, the tender strategy of manufacturers, and price and volume trends. Key issues are the time of tender announcement and the preferred tender models by health insurers as well as the identified strategies of originators. RESULTS: 40 relevant substance markets were identified. Health insurers frequently announce tenders prior to patent expiry with “open-house-models”. The large majority of pharmaceutical companies use rebate contracts as a defense strategy. Especially shortly after patent expiry rebate contracts have proven a practicable strategy for protecting market shares. CONCLUSIONS: Rebate contracts could be an instrument for originators to prevent substitution at the pharmacy and to delay erosion of market share. In this context, the importance of so called “open-house-models” is increasing. In those models, the health insurers offer eligible requirements to all interested pharmaceutical manufacturers/importers. The implementation of an effective tender strategy requires early preparation and changes in the business models for concerned pharmaceutical companies.
OBJECTIVES: Emerging market (EM) countries dependent on single natural resource as the most viable source of revenue are vulnerable to cyclical government spending due to price volatility. During economic downturn, public healthcare expenditure falls due to an overall budget reduction and higher inflation rates. This research aimed to explore public healthcare expenditure in two oil dependent nations, Saudi Arabia and Nigeria, during cycles of volatile oil prices. METHODS: Publicly available data on oil prices, GDP growth rate, GDP per capita, PPP, Inflation rates, population and urbanisation growth rates, public health spending as a proportion of overall spending, and private healthcare investments as a proportion of total investments were analysed. Additionally, public health indicators representing crude outcome measure were assessed: infant mortality rates, life expectancy at birth, distribution of public and private hospital beds, and healthcare staff across the population. RESULTS: Analyses showed that both Saudi Arabia and Nigeria undertook significant healthcare budget cuts relative to other sectors during downturn of oil prices. In both countries, spending cuts affected the growth of the public healthcare infrastructure and service provisions. However, private healthcare investments continued to rise stimulated by income growth in the previous years. In contrast to Nigeria, Saudi Arabia significantly boosted investments in public health infrastructure during times of economic growth. Spending cuts limited the ability of public healthcare facilities to maintain and expand treatment access, thus facilitating outward medical tourism. CONCLUSIONS: Prices of natural resources significantly impact public health expenditure in single-resource dependent EM countries. During the upturn of natural resource prices, governments should invest more in healthcare so that the population can sustain the benefits during the downturn. While volatility is hard to control, ring-fencing policies for health care expenditures during higher prices of natural resources could help EM countries manage the downturn more effectively, without drastic cuts.


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OBJECTIVES: To explore the clinical pharmacy services and workforce requirements at Ministry of Health (MOH) Hospitals during mass gathering Hajj ten years (2006-2015) at Makah and Al-Medina Regions in Saudi Arabia METHODS: It is a retrospective analysis of ten years (2006-2015) of MOH hospital pharmacies during mass gathering Hajj period (15-30 days). The clinical pharmacist should provide pharmaceutical to all patients either Pilgrim or not Pilgrim at Makah region. The workforce requirements calculated based on MOH workforce standards of hospitals. The clinical activities drive from MOH critical care services, and emergency services, and mortality rate data. American College of Clinical Pharmacy (ACCP) model of clinical activities used. RESULTS: In Makah Region; The total number of prescriptions (99,886-257,545) with average (180,120), it represented (5.11-12.07%) with average (7.86%) of all pilgrims. In Al-Medina Region; the total number of prescriptions (35,149-207,444) with average was (142,080). It represented (1.48-8.35%) with an average (5.79 %) of all pilgrims. The average number of clinical pharmacists needed was (15.39 FTE) per each hospital at holy places, (21.69 FTE) per each hospital Makah city, and (18.54 FTE) per each hospital at Makah. The average number of clinical pharmacists needed was (15.6 FTE) per hospital in Al-Medina. The central pharmacy activities need (4 FTE) of clinical pharmacist per each hospital in Makah region, while in Al-Medina region was (3 FTE). The patient-centered clinical pharmacy services need (10 FTE) of clinical pharmacist per each hospital in Makah and Al-Medina regions. The administrative, clinical pharmacy activities need (4 FTE) of clinical pharmacist per each hospital, while (3 FTE) at Al-Medina region. CONCLUSIONS: The clinical pharmacy services are essential during mass gathering Hajj period. The clinical pharmacy services prevent drug-related mortality and morbidity during Hajj period. Also, improve patient clinical outcome, patient quality of life, and avoid the unnecessary cost

PHP129: DEVELOPMENT OF AN SPECIFIC EVALUATION FRAMEWORK FOR ORPHAN DRUGS BASED ON MULTI-CRITERIA DECISION ANALYSIS (MCDA) FOR HEALTH CARE DECISION MAKING IN CATALONIA

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OBJECTIVES: To develop a Multi-Criteria Decision Analysis (MCDA) framework specific for Orphan Drugs (OD) in Catalonia, aimed to facilitate and homogenize the assessment of OD by the decision-making committee of the Catalan Health Service (CatSalut). METHODS: A preliminary framework based on EVIDEM (v.4.0) was developed for its use in OD evaluation and was validated by representatives of the decision-making committee of CatSalut. The final version of the framework was agreed and tested by this committee in 3 OD (tolvaptan for autosomal dominant polycystic kidney disease, Alpha 1-antitrypsin for Alpha 1-antitrypsin deficiency and eliglustat for Gaucher disease). The committee members rated individually the EVIDEM matrix for each drug assessment according to their preferences and afterwards a reflective discussion was conducted amongst all the members. RESULTS: In the
validation phase, some criteria were removed or not considered from the standard framework based on EVIDEM (v.4.0) (i.e., "size of population", "non-medical costs", "rarity" and "rule of rescue") or adapted ("therapeutic benefit") for CatSalut purposes. The assessment of three OD was conducted to rate the evidence matrix. The reflective discussion was seen as very relevant to support inputs for health decision-making processes reflecting drug value and positioning medicines within therapeutic algorithms. **CONCLUSIONS:** A final MCDA framework specific for OD was developed and validated to be used for the orphan drug evaluations conducted by the CatSalut. The test of the three OD through the developed framework specific for OD showed that MCDA can be considered a useful methodology which adds transparency, predictability and allows a structured discussion that substantiates the agreements adopted by decision-making committees.

**PHP130: EVALUATION OF BRANDING IMPACT ON IRANIAN PHARMACEUTICAL MARKET: A QUALITATIVE STUDY**

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**OBJECTIVES:** Due to recent changes in global pharmaceutical marketing, companies' interests are switching to focus on branding strategies. Iran is one of the largest pharmaceutical markets in Middle East which experienced a suitable growth in recent years; therefore, a proper framework for Iran's pharmaceutical market branding strategy is necessary. This study aims to investigate branding impact on pharmaceutical market from Key Opinion Leaders (KOL) perspective. **METHODS:** At first a systematic review was done. Studies were identified via searching electronic databases, search engine and reviewing citations (1990 – June 2016). Only articles published in English were included. Ninety six articles were reviewed and sixteen studies met inclusion criteria. Based on the aforementioned systematic review findings, qualitative questionnaire was designed. Semi-structured questionnaire with open ended questions had been applied as data collection tool. We conducted interviews and after fifteen interviews, tape recorded with participants' consent, analysis showed that we had reached theoretical saturation. **RESULTS:** Based on systematic review, four types of main branding strategies were recognized within pharmaceutical industry: Therapy area, Corporate, Product, and Condition branding. These strategies were applied as as questionnaire dimensions. As result, 54% of interviewees indicated that corporate branding is the best strategy to be implemented in Iran pharmaceutical industry from interviewees' point of view. The rest of responses were as follows: 20% recommended therapy area branding, 26% recommended product branding and 0% recommended condition branding. **CONCLUSIONS:** This interview-based study provides new evidence on Iran's pharmaceutical market branding position. It becomes clear that companies must be focused on branding strategies. Corporate branding strategy, detected to be the most useful approach in Iranian pharmaceutical market. In order to these strategies implementation, major modifications are needed in both legislation and policies. Further branding studies should be carried out focusing on how to change this behavioral algorithms to reach a sustainable success in branding.

**PHP131: APPLYING THE INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW’S (ICER) METHODOLOGY TO CANADA: AN IMPROVED WAY TO TAKE INTO CONSIDERATION DRUG AFFORDABILITY CHALLENGES?**

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**OBJECTIVES:** In Canada, drug prices and healthcare system affordability are under high scrutiny in order to better meet the needs of Canadians. Current health technology assessments (HTA), do not consider financial capacity of Canadian payers. In contrast, the United States’ Institute for Clinical and Economic Review (ICER) combines cost-effectiveness evaluations and an assessment of the affordability of a new therapy. The affordability concept is translated into an annual budget impact threshold that represents the maximum willingness to pay for a treatment. This study aimed to adapt ICER’s affordability budget impact threshold to the Canadian environment and determine whether it could be a relevant tool for payers. **METHODS:** The affordability budget impact threshold was calculated according to ICER’s methodology using Canadian and Quebec data such as drug and healthcare spending, gross domestic products, etc. The primary data source was the Canadian Institute for Health Information. **RESULTS:** Following the ICER methodology, the estimated annual affordability threshold for each new drug was estimated to be $36.2 million in Canada, and $9.9 million for Quebec. To further adapt to a Canadian perspective, both thresholds were divided specifically for public and private payers, resulting in thresholds of $21 and $15.2 million, respectively. For Quebec, the thresholds were estimated to $4.5 and $5.4 million for public and private payers, respectively. **CONCLUSIONS:** The ICER methodology adapted to a Canadian perspective is a novel approach that could allow payers to have an improved vision of the drug value, and provide them with more tools to
make funding decisions based on the budget constraints. In addition, the affordability threshold, if incorporated into HTA recommendations could lead to more integrated, potentially faster and complete recommendations. It could, by the same time, reduce the need of bureaucratic discussions that may arise following official HTA recommendations in Canada.

**PHP132: THERAPEUTIC REFERENCE PRICING SYSTEM COST-SAVING ABILITY AND ITS IMPACT ON PATIENT OUT-OF-POCKET EXPENSES IN SLOVENIA**

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**OBJECTIVES:** Despite therapeutic reference pricing (TRP) being referred to as an effective cost-containment measure, its introduction in Slovenia was followed by a suspicion. The study aimed to assess economic outcomes of the first three therapeutic classes introduced in Slovenia - proton pump inhibitors (PPIs), angiotensin-converting-enzyme inhibitors (ACEIs) and lipid-lowering agents (LLAs) from the health-care payer and patient perspective. **METHODS:** Health claims data on all prescription-only medicines in Slovenia were analysed. The before-after study design was used to assess medicine expenditure covered by the compulsory and complementary health insurance and the maximum possible patients' out-of-pocket cost changes. Interrupted time series analysis was used to assess the TRP cost-saving ability from the health-care payer perspective. **RESULTS:** A downward trend of medicine expenditure was observed already before TRP introduction; however, in the first year after TRP introduction the health-insurance cost for ACEIs and LLAs fell 25% and 45%, respectively. The PPIs expenditure decreased by 10%, however greater PPIs' cost reduction was observed before TRP. After TRP introduction, the monthly medicine expenditure downward trend was less steep; coefficient changes from -20.798 to -363 for PPIs (p<0.001), from -18.175 to -4.862 for ACEIs (p=0.001) and from -10.669 to -2.761 for LLAs (p=0.105) were identified. Also, a significant increase in maximum possible patient out-of-pocket cost was observed for ACEIs for 82%, followed by the 42% and 37% increase for LLAs and PPIs, respectively. After TRP introduction the maximum possible patient out-of-pocket cost, expressed as the percentage of medicine expenditure covered by the health-insurance, increased by 2.4%, 2.6% and 16.5% for PPIs, LLAs and ACEIs, respectively, mostly due to lansoprazole, atorvastatin and perindopril. **CONCLUSIONS:** From the public payer perspective Slovenian TRP system is seen as an effective cost-containment measure. However, from the patient perspective it could represent a financial challenge, especially for patients using ACEIs.

**PHP133: PHARMACOECONOMIC RESULTS OF HIGHLY INNOVATIVE DRUGS APPROVED FOR TEMPORARY REIMBURSEMENT IN THE CZECH REPUBLIC**

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**OBJECTIVES:** Highly innovative drugs can be granted two plus one year of temporary reimbursement (TR) to provide timely access and to collect additional real-world evidence through registry. TR applicant does not need to comply with strict cost-effectiveness (CE) requirements and willingness-to-pay threshold (WTP) when there is no sufficient data about use in clinical practice or about CE at a time. After two/three years when switching to permanent reimbursement (PR), a drug must comply with strict CE and WTP requirements. The main objective was to analyse pharmacoeconomic results at the entry of drug into TR and compare them with results presented in consecutive PR procedure. **METHODS:** All drugs approved for TR until 5/2017 were identified. Pharmacoeconomic results (i.e. type of analysis, incremental cost-effectiveness ratios (ICERs), net budget impact (netBI)) at the time of TR and consecutive PR application were analysed. We also examined therapeutic class, and compared the length of approval of TR versus PR. **RESULTS:** 40 TR decisions were identified. Majority (70%) belonged to oncology drugs, 33% were orphans. After the expiration of TR, 92% had positive subsequent decision on PR. Price negotiation with payers was present in 50% of cases. 8% did not manage to receive PR. Cost-utility analysis was used to present results of cost-effectiveness in 44% of TR procedures. Mean ICER (cost/QALY) of TR products was €93,087 (SD €64,550). In the subsequent PR procedure, the mean ICER was €40,937 (lower by 56%). NetBI lowered by 32% and 50% in 1st and 5th year respectively when applying for PR. Mean decision time about TR was longer (404 days; SD 194) than consecutive decision about PR (259 days; SD 251). **CONCLUSIONS:** Costly innovative drugs are accepted for a TR with higher ICERs and netBI than usually accepted in PR procedure. 92% of these drugs succeed in consecutive PR procedure.

**PHP135: KEY FACTORS RESULTING IN DIFFERENTIAL REIMBURSEMENT DECISIONS BETWEEN THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) AND THE SCOTTISH MEDICINES CONSORTIUM (SMC) FOR MEDICINES AUTHORISED BY THE EUROPEAN MEDICINES AGENCY (EMA) TO TREAT RARE DISEASES (ORPHAN MEDICINES)**

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OBJECTIVES: Reimbursement decisions made by NICE or SMC may result in differential patient access to orphan medicines in the UK. This study identifies instances where NICE and SMC recommendations related to EMA-authorised medicines for rare diseases differ, and investigates the reasons for such differences. METHODS: EMA-authorised medicines for rare diseases were identified and categorised based on availability of NICE and SMC assessments. For completed assessments with differing decisions, available guidance documents were reviewed to establish the factors influencing the decision-makers’ judgements on value-for-money, including: robustness of clinical and cost-effectiveness evidence; plausibility of inputs and assumptions; range and plausibility of the ICERs; levels of uncertainty; patient access schemes (PAS’s); and modifiers considered for decision-making. RESULTS: From 96 EMA-authorised medicines for rare diseases, 23 had completed assessments by both agencies, 5 with differing recommendations. Four medicines were recommended by NICE and rejected by SMC; the opposite for the remaining medicine. Factors related to positive NICE recommendations included supplemental clinical and cost-effectiveness evidence presented during the appraisals to reflect decision-makers’ preferred approaches. Companies offered PASs for four medicines, and further financial arrangements were agreed as part of managed access agreements (MAAs) for two medicines. Rejections by SMC were related to uncertainty and high costs compared to health benefits, while the NICE rejection was related to lack of cost-effectiveness. An improved PAS and the evidence provided by the Patient and Clinician Engagement (PACE) process seemed key for the acceptance of one medicine by the SMC and not by NICE. CONCLUSIONS: Among orphan medicines with opposing recommendations between NICE and SMC, factors linked to positive NICE recommendations included: flexibility to present supplemental data and economic analyses during the appraisal; and agreed PASs and MAAs. The SMC’s acceptance of one orphan medicine seemed mainly related to an improved PAS and the consideration of PACE.

PHP136: PUBLIC FUNDING OF CANCER TREATMENT: CHANGES TO THE PROCESS AND SUCCESS RATE OVER TIME INAUSTRALIA

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OBJECTIVES: The complexity of manufacturing biologics and small patient populations means that oncology medicines are frequently high cost and struggle to meet the cost-effectiveness criteria in countries with HTA reimbursement systems. Further, data limitations due to cross-over designs and immature survival data mean there is uncertainty regarding long term clinical benefit. In 2012 we reported on the outcomes of submissions lodged to the Australian PBAC between 2005 and 2011 for oncology medicines seeking a price premium relative to the comparator. We repeated the analysis for 2012–2016 to explore changes to the process and success rate. METHODS: We searched our internal database of Public Summary Documents (PSDs) published 2012 – 2016 to identify submissions for oncology presenting an economic evaluation to support a price premium compared with the comparator. The dataset was supplemented with manual searching. RESULTS: We identified 116 relevant PSDs; 53 for first, 40 second and 23 for subsequent submissions. Of the 53 first submissions, 8 (15%) were recommended, 8 (15%) deferred and 37 (70%) rejected. The success rate increased for second (16/40, 40%) and subsequent submissions such that overall 82/116 (72%) eventually received a positive recommendation. The success rate for initial submissions was comparable to the 2012 analysis (9/45, 20%), however there was a higher success rate with the second submission (40% vs 32%). Overall success rate was slightly higher (72% vs 62%). A small number of submissions overcame a decision of rejection or deferral to be recommended at an out of session meeting. A number of others resubmitted after a positive recommendation to address pricing issues. CONCLUSIONS: As in the 2012 analysis, a small proportion of initial submissions receive a positive recommendation. There is evidence of a higher success rate for second submissions, as well as increased dialogue between sponsors and the PBAC to resolve outstanding issues.

PHP137: WELL THOUGHT THROUGH BUT BADLY CARRIED OUT: AN EVALUATION OF THE REPORTING QUALITY OF STATUTORY HEALTH INSURANCE CLAIMS DATA ANALYSES TO QUANTIFY THE TARGET POPULATION IN EARLY BENEFIT ASSESSMENT IN GERMANY

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OBJECTIVES: Pharmaceutical companies increasingly use statutory health insurance claims data analyses to quantify the target population in German reimbursement dossiers. We evaluated the analyses submitted by the manufacturers with a focus on reporting quality. METHODS:The database comprised all dossiers published until May 2017 (n = 257) on the Federal Joint Committee’s homepage (http://www.g-ba.de/). We included all dossiers in which a statutory health insurance claims data analysis commissioned by the manufacturer was applied to determine the number of patients eligible for the drug under assessment. To evaluate the reporting quality, a 27-items checklist...
specifically developed for the frameworks and requirements of the German health care system – STROSA (STandardized Reporting Of Secondary data Analyses) – was used. Two reviewers assessed all analyses independently; discrepancies were resolved through discussion. RESULTS: 18 claims data analyses used in 18 different benefit assessment procedures were eligible for inclusion. Detail and quality of reporting varied widely between reports. The evaluation with STROSA revealed several shortcomings: in most cases, facts on background and rationale were missing (n = 10). 10 analyses did not provide internal validation. The results section often contained no presentation of the characteristics of the study population (n = 5). Information on age and gender distribution relevant for the evaluation of the representativeness of the sample were frequently missing or incomplete (n = 12). Most analyses did not include a discussion of results (n = 7), internal validity (n = 12), strengths and weaknesses (n = 12) and transferability (n = 12). CONCLUSIONS: Claims data analyses may support the quantification of the target population in the early benefit assessment of drugs in Germany. To provide a reliable decision base, however, their reporting quality needs to be improved, in particular concerning the description of methods and the discussion of methods and results.

PHP138: THE ANALYSIS OF NEW DRUG REIMBURSEMENT DECISION MAKING IN SOUTH KOREA AFTER THE INTRODUCTION OF POSITIVE LISTING SYSTEM

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OBJECTIVES: In 2006, the Positive Listing System (PLS) was introduced to select effective drugs in terms of clinical and economic aspects for the national health insurance in Korea. The aim of this study was to review the new drugs’ listing rates and the time to patient access of new drugs after the PLS. Also, we aimed to analyze if the pricing system alteration after the PLS had any effect on the time to patient access. METHODS: All drugs evaluated by Drug Reimbursement Evaluation Committee under HIRA from July 2007 to December 2016 were included in the analysis. Based on disclosed reports, the characteristics of the drugs, listing rates and the time to patient access were analyzed. RESULTS: The total number of drugs was 307, of which the number of listed and non-listed drugs were 247 (80.5%) and 60 (19.5%). The overall listing rate was 80.5%, whereas the listing rate within 2 years from market authorization was 61.2%. Out of the total 44 oncology drugs, the listing rates were 65.9% overall and 31.8% within 2 years, and 71.9% and 48.4% in orphan drugs (n=64), respectively. The median time to patient access was 16.1 months in total drugs, 30.5 months in oncology drugs, 23.5 months in orphan drugs. Finally, the time to patient access for the drugs under the pricing system alteration after the PLS was 12.1 months, which depicted a drastic improvement when compared to the drugs before the alteration (17.1 months). CONCLUSIONS: In South Korea, the time to patient access was much longer compared to European or any other Asian countries. However, the patients’ enhanced accessibility by the alteration of pricing system had a definite improved outcome on oncology and orphan drugs. Therefore, the government is required to improve the drug reimbursement system by performing constant analysis on patients’ accessibility.

PHP139: 2017 BLACK BOX AMNOG REBATES: WHAT IS DRIVING THE REBATES?

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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 on the parameters that drive 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: Average Rebate size Rebate by added benefit rating Rebate by therapeutic area Difference comparator price before rebate and after negotiation RESULTS: By May 2017, 276 early benefit assessments have been conducted. Out of these 220 had been through price negotiation, with the rebate of the launch price ranging from 11.7-70.7%. For Orphan drugs the range was from 0-47.5% with an average at 22.1%. Rebates per rating: Considerable benefit: average: 20% Minor added benefit: 79% Not quantifiable benefit: 20% No additional benefit: 27% Products in central nervous system yielded an average rebate of (51.9%), followed by oncology (39.7%), endocrinology (31.1%), cardiovascular (20.4%), respiratory (17.5%) and infectious diseases (15.8%). CONCLUSIONS: The rebate per therapeutic area did not reveal obvious patterns: Assessments for central nervous systems products resulted in above average rebates, while rebates for products for infectious diseases were far below the average. Comparisons among annual therapy cost levels do not show a direct association between comparator therapy cost level and rebated annually therapy cost level of the innovative product.
**PHP140: THE IMPACT OF MODIFYING FACTORS ON ICER FOR PHARMACEUTICAL REIMBURSEMENT RECOMMENDATIONS IN KOREA OVER 10 YEARS**


**OBJECTIVES:** Health Insurance Review & Assessment Service (HIRA) is in charge of pharmaceutical reimbursement review and decision-making based on the Pharmaceutical Benefit Committee (PBC)'s recommendation. HIRA stipulated PBC to deliberate several factors for recommendation; clinical usefulness, cost-effectiveness, budget impact, foreign countries' reimbursement & price status, etc. While ICER is deemed the main determining factor and the others are involved as modifiers for its flexibility, to what extent they influence on the flexibility of acceptable ICER hasn't been studied. This study aims at investigating impact of other factors on ICER in PBC’s positive recommendation in a retrospective manner. **METHODS:** PBC’s positive recommendations having considered ICER from 2007 to 2016 were analyzed. Dependent variable was ICER value in million KRW. The independent variables of interest were absence of alternative (no, limited or others) disease severity (expected life expectancy less than 2 years or not), reimbursement & price of foreign countries (number of reimbursed countries, ratio of proposed price to average price of overseas), budget impact, and diseases causing catastrophic financial burden without reimbursement (cancer, rare disease). Univariate and multivariate regression analyses were conducted. **RESULTS:** A total of 42 cases were accepted by PBC and the average ICER was 24.6 millions KRW per QALY. In univariate analysis, all variables showed significant association with ICER. However, in multivariate regression analysis, three variables; absence of alternative, disease severity and cancer, rare diseases significantly increased ICER(p<0.05). The most influencing factor raising ICER was catastrophic disease, followed by disease severity, no alternative, and limited alternatives. The degree of impact were in 17, 14, 12, 8 millions KRW per QALY. **CONCLUSIONS:** This study confirmed that most of the factors were considered as modifiers of ICER on PBC’s deliberation in positively recommended cases. The coefficient estimates of variables probably give an impression to any stakeholders seeking reasonable approximate ICER threshold for pharmaceuticals.

**PHP141: DRUG COMMERCIALIZATION BEFORE THE PRICING AND REIMBURSEMENT IN ITALY: THE NON NEGOTIATED C CLASS (C-NN)**

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**OBJECTIVES:** Since 2012, all drugs receiving Marketing Authorization have been firstly included in the non-negotiated (C-nn) class, waiting for the decision on the reimbursement status by the Italian Medicine Agency (AIFA). Before Pricing & Reimbursement (P&R) resolution, Regions are nonetheless autonomous to allow the commercialization of these drugs, even without the reimbursement of the National Healthcare System. The research aims to understand the purchasing behavior of Italian Regions on the C-nn class, considering policies, therapeutic areas and trends. **METHODS:** A desk research gathered national and regional C-nn policies. Twenty-seven drugs registered in C-nn class from 2013 to 2016, were considered. Ten of them resulted commercialized before the P&R negotiation. Drugs in scope belonged to different therapeutic areas and categories. Information on first regional dispensation date were extracted from a QuintilesIMS Hospital database, which gathers data on hospital and local healthcare unit distribution. **RESULTS:** Thirty-seven percent of products registered in C-nn class were commercialized before the P&R negotiation and the majority of them were oncologic drugs. Among these, 67% and 22% were innovative and orphan drugs, respectively. Puglia was the only Region that bought all the 10 drugs in C-nn class, followed by Lombardy, Veneto and Tuscany. On the contrary, Emilia Romagna purchased only two products. AIFA’s C-nn approval guaranteed a fast access to the therapy in those Regions buying in C-nn, with a national first sale on average 7.2 months before the P&R negotiation. **CONCLUSIONS:** The research underlines a low adoption of drugs under the C-nn class, before the P&R resolution. The tendency is mainly observed for innovative drugs, especially with oncologic indications, supporting the crucial role of these treatments to meet patient's care needs. On the other hand, it is worth noting that the scenario is highly fragmented, causing disparities to the patient access across Italian regions.

**PHP142: COVERAGE-WITH-EVIDENCE-DEVELOPMENT (CED) IN GERMANY: STATUS QUO**

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**BACKGROUND:** For many novel medical devices (MD) and other non-drug interventions high-quality clinical studies are scarce. The German coverage-with-evidence-development (CED) regulation allows three different pathways to generate evidence on non-drug interventions. **OBJECTIVES:** We describe how the German CED regulation
(including the new legislation on mandatory assessment of novel high-risk MD) works. Further, we summarise which topics have been selected for clinical studies until now by the Federal Joint Committee (G-BA), the highest decision-making body regarding reimbursement. METHODS: Information on regulatory framework was collated from the law and the rules of procedure at G-BA. Information on medical topics under assessment was systematically searched using the websites of G-BA and IQWiG. RESULTS: The German CED model aims at testing the effectiveness of promising interventions. IQWiG usually assesses whether an intervention is promising (i.e. has ‘potential’). Clinical trials then can be started on topics a) that have been put under scrutiny by G-BA itself, b) that a MD manufacturer has applied for, or c) that have come under scrutiny because an invasive, novel, high-cost MD is involved. So far, 10 interventions have been proposed for CED, but a directive on starting a trial has been issued only for 2. Further, 6 methods are currently being discussed by the G-BA. For 2 interventions, CED was not started due to diverse reasons. Clinical study costs have to be borne by manufacturer or G-BA, or can be split between the two. LIMITATIONS: As no clinical trial has yet been started, it remains to be seen whether the German CED approach is successful. No information on unsuccessful manufacturers’ applications is published. CONCLUSIONS: The German CED regulation offers a promising pathway to generate evidence, but the speed of the process is constrained by regulatory complexity.

**PHP143: DRUG COST CONTAINMENT AND NEGOTIATION POWER**

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**OBJECTIVES:** In 2011, a new legislation in Germany (AMNOG) aimed both at introducing value based pricing as well as massively reducing pharmaceutical costs in a scientifically sound and socially viable way, basically creating a natural experiment on drug cost containment. This paper analyses strength and weaknesses of the approach. **METHODS:** While parts of the process are very transparent and can be analysed with simple literature analysis, others - mainly the negotiation process - are not. Therefore, over 20 in-depth interviews with participants from both pharmaceutical and social health insurance companies were conducted. **RESULTS:** The first part of the AMNOG – the benefit assessment – process works well. There are two major shortcomings in the AMNOG process: (i) there is no clear algorithm that leads from additional benefit to price; and (ii), the demand side lacks negotiation power. In addition, the negotiation process itself does not follow a scientific and structured procedure – rather, it can be described as a “bazaar”. **CONCLUSIONS:** According to our findings, it seems very difficult to combine the principle of providing innovative pharmaceuticals to everyone paid for by a social security system with the idea of achieving ‘reasonable’ prices through negotiations between payers and pharmaceutical companies. While some basic ideas of AMNOG are still valid, the negotiation process needs to be changed.

**PHP144: ARE P&R OFFICIAL CRITERIA RELATED WITH REAL P&R APPROVAL OF ORPHAN DRUGS (ODS) IN SPAIN?**

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**OBJECTIVES:** Identify if the official criteria of Spanish P&R process are related with P&R approval for ODs. **METHODS:** ODs approved by the European Commission between 2012 and 2016 were classified according to their P&R status in Spain (approved, undergoing decision and rejected). Hypotheses on likelihood of reimbursement for ODs were formulated based on the P&R official criteria established by Royal Decree Law 1/2015 of 24 July (disease severity, unmet needs of certain collectives, cost-effectiveness (CE), budget impact (BI), existence of alternative therapies and degree of innovation). Disease severity was related to an oncologic vs. non oncologic indication and to the availability of hard clinical trial outcomes; unmet needs of certain collectives was related to being indicated for ultra-orphan diseases affecting <1/50000 inhabitants; existence of alternative therapies was related to ODs without a therapeutic alternative for the approved indication and degree of innovation was related to ODs with a published Therapeutic Positioning Report (TPR) with a positive opinion, meaning that the drug offers an added therapeutic value. CE and BI were not assessed in this study because of lack of information. **RESULTS:** ODs were more likely to be reimbursed in Spain if approved for an oncological indication (56% with P&R approval), approval based on hard clinical outcomes (57% with P&R approval) and a TPR with a positive opinion (88.2% with P&R approval). Indications for a smaller group of patients or for those not having a therapeutic alternative, did not seem to have a positive influence for achieving P&R in Spain. **CONCLUSIONS:** P&R approval for ODs in Spain could be positively affected by an indication in oncology, availability of hard clinical outcomes and a positive TPR. BI would be an important variable for P&R approval, but could not assessed as information about sales forecast is not public.

**PHP145: COST-EFFECTIVENESS AND IMPACT OF NEW INNOVATIVE TREATMENTS ON PROGNOSIS OF MELANOMA AND OVARIAN CANCER FOR AUSTRALIAN PATIENTS**

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**OBJECTIVES:** Advanced melanoma and ovarian cancer have historically had limited treatment options and poor survival with 1,800 and 1,000 Australians respectively predicted to die in 2017. Since 2013, six new treatments for melanoma and two for ovarian cancer have been listed under the Pharmaceutical Benefits Scheme (PBS). We examined the impact in terms of Australian deaths prevented and the cost effectiveness to achieve public funding. **METHODS:** Using information in the Public Summary Documents (PSDs) we describe the pathway to reimbursement and estimate the number-needed-to-treat with the new treatment to avert one death at 2-years (NNT-2), based on overall survival (OS) for new treatment versus standard of care and online data. **RESULTS:** The two new ovarian cancer treatments were recommended for listing at an ICER of AU$45-75k per QALY based on acceptance of superior OS (median OS increment [months]: bevacizumab 9.4; olaparib 7.6) with risk due to uncertainty in longer-term survival mitigated with Risk Share Agreements (RSA). We estimate for every 10 bevacizumab patients treated one additional person will survive to two years (NNT-2=10). Olaparib was recently PBS-listed (NNT-2=5). In contrast, the new melanoma treatments had less mature OS data available for PBAC decision making (median OS not reached for four treatments) and often a managed entry scheme (MES) was required in addition to RSA to obtain early listing with ICER $45-75k. Ipilimumab was listed on the basis of median OS increment of 3.6 months (NNT-2=10). Survival will further improve in Australia with PBS-listing of pembrolizumab (NNT-2=8 vs ipilimumab). **CONCLUSIONS:** Despite the uncertainty surrounding the impact on OS of novel treatments for melanoma and to a lesser extent ovarian cancer, the Australian government and pharmaceutical companies have found ways to manage the risk. The availability of these products will extend survival for Australians.

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**PHP146: EXTERNAL REFERENCE PRICING IN GREECE. A COMPARATIVE ANALYSIS FOR 2015-2017**

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**OBJECTIVES:** To compare the results of performing External Reference Pricing (IRP) in Greece from 2015 to 2017, to model the changes on ex-factory prices in domestic market medicines and to forecast future impacts in Greece and other countries that take Greek Market Medicines as a reference. **METHODS:** Greek medicines pricing bulletins and research in EU28 medicine bulletins published by official sources. Comparison of price sources and price differences. **RESULTS:** We have compared all medicine prices from three Greek medicine bulletins for the period 2015-2017. External Reference Pricing is performed to calculate the average of the three lowest prices in EU for branded medicines that are not under price protection. Tiers of price protection affected the basket mix for External Reference Pricing. Nine Euro zone countries share 55-60% of the total sum of eligible medicines for reference pricing. Five non Euro zone countries contribute the remaining 40-45%. **CONCLUSIONS:** External Reference Pricing has been the main tool for pricing and repricing of branded medicines in Greek Reimbursed Market. Tiers of price protections and variation of calculation rules affect significantly the basket mix and the final medicine prices. Differences vary from 5% to 15% of x-factory price. Pharmaceutical companies should take under consideration these factors to forecast future price reductions in Greece primarily and then, the rest of the world.

**PHP147: MARKET ACCESS TRENDS ACROSS THE EU5: 2009 TO 2016- AN UPDATE**

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**OBJECTIVES:** Examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval in the EU5 and analyse potential changes in market access timelines in the EU5 countries between 2009 and 2016. **METHODS:** Examined new molecular entities, formulations and combinations with launches in the EU5 countries from 2009 to 2016. Time comparison for general medicines vs. orphan/oncology indications was made including shifts over time. Data gathered from official national HTA agencies and P&R bodies. **RESULTS:** 90% of all EMA approved drugs between 2009 and 2016 have been launched in Germany whereas only 57% launched in France. 30 drugs (10%) have been withdrawn in Germany since the introduction of the AMNOG procedure in 2011 likely due to failure in price negotiations. Overall time to market in Germany and the UK is 17-23 weeks, whereas in France, Spain and Italy it is 65-66 weeks. Time to market for oncology drugs is considerably lower in Germany whereas time to market for orphan drugs is significantly higher in Spain/Italy compared to all other drugs. Analysis of market access trends across the EU5 suggests a modest increase in time to market (for products being actually launched) in all countries except Italy. Peak in time to market during 2011-13 in Italy likely due to the renewal of the AIFA Commissions. **CONCLUSIONS:** Wide disparity exists in the number of EMA approved medications commercially available in each of the EU5 countries and the time to market. It is important to recognize variation in ability to launch and timing disparities when analysing market access timelines and their implications on the availability of new drugs to patients.
**PHP148: NON-QUANTIFIABLE BENEFIT WITHIN THE GERMAN AMNOG SYSTEM: FACTORS CONTRIBUTING TO TIME LIMITS SET FOR BENEFIT RESOLUTIONS AND POTENTIAL IMPLICATIONS ON PRICE DISCOUNTS**

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**OBJECTIVES:** The G-BA drug benefit assessment in Germany is evidence-based and can result in major, significant, marginal, non-quantifiable, no, or even less added benefits. Additionally, the G-BA can restrict the period of validity of its resolutions and request the submission of new evidence. This study explored the number of assessments with non-quantifiable resolutions and the set time limits relative to the clinical evidence, in order to evaluate the likelihood of getting time limitations and their implications on price discounts. **METHODS:** Information on G-BA resolutions with non-quantifiable outcomes was retrieved from a database of AMNOG dossiers published until 24 March 2017. The results identified as non-quantifiable were classified as orphan drug (OD) or non-OD assessments; information on time limits and clinical evidence was extracted. **RESULTS:** 58 resolutions with a non-quantifiable added benefit were identified, including 40 OD and 18 non-OD assessments. Time limits were set for 18 resolutions, with the majority for OD (83.3%). Of the OD assessments, 37.5% received time limits, whereas only 16.7% of non-OD assessments were time-limited. 53.3% of the time-limited OD assessments were based on single-arm studies and 40.0% on RCTs. In contrast, OD assessments without time limits were mainly based on RCTs (65.4%). 80.0% of the non-OD assessments without time limits were based on RCTs and 20.0% on non-RCTs. Price discount analysis revealed higher average discounts for time-limited OD resolutions (25.2% vs. 16.7%). **CONCLUSIONS:** The likelihood of time limits set by G-BA for a non-quantifiable added benefit increases with lower evidence level included in the dossiers. Since clinical trials for OD approval are often non-RCT, time limits are more likely for OD than for non-OD resolutions. Furthermore, time limits seem to increase the extent of price discounts.

**PHP149: IMPACT OF MULTI-DRUG RESISTANCE ON HTA ASSESSMENT OF ANTIBIOTICS IN FRANCE, GERMANY, UNITED KINGDOM**

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**OBJECTIVES:** The objective of this study is to investigate how the increasing awareness of multi-drug resistance (MDR) impacted payers during an assessment of recently launched antibiotics in France, Germany and UK. This aims to investigate whether antibiotics addressing the MDR issue benefit from a favourable recommendation for funding/reimbursement and/or price. **METHODS:** ADIS insight has been used to identify antibiotics with innovative mechanism of action launched in France, Germany and United Kingdom since 2012. Eleven antibiotics were identified as of 22/06/2017. Availability of HTA reports have been verified using websites of HTA agencies. HTA reports of these antibiotics have been extracted and analysed to measure the impact of MDR in their assessments. **RESULTS:** In France, 8 out of 11 antibiotics have a report available. All the antibiotics have been granted an SMR substantial; 2 antibiotics have been granted an ASMR III, 1 has an ASMR IV and 5 have an ASMR V. The MDR was considered for the SMR rating of these antibiotics. The addition of new antibiotics into the therapeutic arsenal is a priority from a public health perspective. This was key to justifying a substantial SMR. The MDR was not considered for the ASMR rating. In Germany, 1 HTA report has been published and MDR impacted benefit assessment. In the UK, 2 HTA reports have been published by NICE. MDR was mentioned in these reports. 4 HTA reports have been published by the SMC. 3 antibiotics were recommended for use within NHS Scotland and 1 was not recommended. MDR was considered for 2 antibiotics out of 4 to justify SMC recommendations. **CONCLUSIONS:** The MDR is taken into consideration by HTA agencies in France and Germany but not systematically in the UK. Evidence suggests that antibiotics addressing MDR are granted reimbursement/access and this element may be leveraged during price negotiation.

**PHP150: UNDERSTANDING HEALTH TECHNOLOGY ASSESSMENT OUTCOMES FOR PRODUCTS WITH CONDITIONAL MARKET AUTHORISATION IN FRANCE: INITIAL EVALUATION VS. RE-ASSESSMENT**

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**OBJECTIVES:** In January 2017, the European Medicines Agency (EMA) published a report on the experience of conditional marketing authorisation (CMA) pathway from over the past ten years. While it provides a valuable overview of drugs that have gained a CMA, there is little understanding of how these drugs perform in the market. This research aims to provide insights into the health technology assessment (HTA) outcomes for the CMA products at initial assessment and subsequent re-evaluation. **METHODS:** EMA report and website were assessed for updates on CMA products between June 2006 and July 2016. Reports from HTA body were analysed to understand the reimbursement decisions. Market-specific pricing websites were analysed to understand price levels. **RESULTS:** In France, almost all CMA products were assessed by HTA within a year after receiving the CMA. Among them, 11
CMA products received ASMR V or IV (no or minor improvement), and 15 CMA products received ASMR III or II (major improvement or more). When re-evaluated once full data was available and the full market authorization (MA) is given, a significant majority of these products were given the same ASMR rating (i.e. confirming the initial HTA decision). Concurrently, the price of the CMA products often did not change significantly after the full data was available and the full MA was given. CONCLUSIONS: The value of CMA drugs is recognized by HTA body, with over 40% received an ASMR of III or higher in France. In addition, the ASMR rates are rarely changed when re-assessed once full data become available. These findings suggest that EMA has been fairly successful in identifying innovative products via the CMA pathway. To ensure improved early access, continued and joint-up efforts between EMA and HTA bodies will be required.

**PHP151: THE ANALYSIS OF FINAL AND SURROGATE EFFECTIVENESS CRITERIA USED IN HEALTH ECONOMIC STUDIES OF DRUGS SUBMITTED INTO THE REIMBURSEMENT IN RUSSIA IN 2016.**

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OBJECTIVES: It is known that different outcomes used in health-economic studies make the comparative effectiveness and calculation of the cost of additional effectiveness complicated. The share of final outcomes used in health-economic evaluations is still unknown. OBJECTIVES. To evaluate the endpoints (final or surrogate) used in health economic studies submitted for inclusion into the reimbursement in Russia in 2016. METHODS: We used the health economic studies submitted in drug dossiers in accordance with the Governmental decree №871. We took into the database from each of the health economic study following parameters: the number of outcomes, the number of final and surrogate endpoints. RESULTS: We counted 161 outcomes in 138 health economic studies, 83 outcomes (52%) are final endpoints, 71 (52%) from 138 health economic studies have no final endpoints. The highest share of final endpoints was seen among the drugs with L01 ATC code – antineoplastic agents. The number of final endpoints was 75% and 63% in the group of drugs used in T2DM and CAD. The high total number of outcomes (submitted dossiers) was seen in the groups of drugs used for chronic hepatitis, asthma and COPD, rheumatic diseases but the share of final endpoints in these drug groups are low: 50%, 38% and 14%, consequently. We mentioned the absence of final endpoints in the drug groups used for arterial hypertension and benign prostate hyperplasia. CONCLUSIONS: 1). 52% of the total outcomes in the health economic studies submitted with the drug dossiers in 2016 have final endpoints. 2). The highest final endpoints share (80%) was seen in the group of antineoplastic drugs. 3). The low final endpoints share (<50%) was seen in groups of drugs used for the treatment of chronic viral hepatitis, HIV infection, asthma and COPD, rheumatic diseases.

**PHP152: 10 YEARS OF REIMBURSEMENT DECISIONS IN THE NETHERLANDS: AN OVERVIEW**

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OBJECTIVES: Since 2005, the Dutch National Health Care Institute (ZIN) has made it mandatory to include a pharmacoeconomic assessment of drugs that are submitted for reimbursement, with an informal, variable threshold for cost per quality adjusted life-year (QALY). The aim of this study is to create an overview of HTA submissions, and compare the reimbursement decisions to the informal threshold for highly innovative drugs used in the Netherlands (€80,000/QALY). METHODS: The database of the National Health Care Institute was addressed to obtain summaries of healthcare technology appraisals containing pharmacoeconomic sections that included an incremental cost-effectiveness ratio (ICER or cost per QALY). The following data, if available, was retrieved from the documents: ICER, drug costs, budget impact, and advice to the minister. Subsequently, all extractions were stratified by informal threshold and disease area. RESULTS: ZIN assessed the cost-effectiveness of 111 HTA submissions. It appeared that 21 (19%) drugs had an ICER higher than €80,000/QALY. Notably, in 14 of these assessments, it was advised to the minister to reimburse these drugs. In 2 cases, the advice was not to reimburse based on the unfavorable cost-effectiveness and/or high budget impact. In 4 cases, an official advice was postponed without reason, while in 1 case the advice was given to negotiate a lower drug price to achieve a more favorable cost-effectiveness. CONCLUSIONS: When focusing on reimbursement decisions for health technologies with ICERS over 80,000/QALY, it seems that ZIN allows a higher threshold than it informally communicates.


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OBJECTIVES: Pharmaceutical reimbursement in Ireland is governed by agreements between the pharmaceutical
representative organisation, the Irish Pharmaceutical Healthcare Association (IPHA), and the state-run Health Service Executive (HSE). The current agreement runs from 2016 to 2020 [IPHA/HSE Framework Agreement on the Supply and Pricing of Medicines]. We explored the effects of two previously completed agreements (commenced 2006 and 2012) on health technology assessment (HTA) submissions in Ireland. METHODS: A descriptive analysis was conducted, using publicly available information on HTA submissions since 2009, when the National Centre for Pharmacoeconomics (NCPE) introduced a rapid review (RR) process. A full HTA submission may be requested following RR. A total of 289 RR submissions were made during the period 2009 - 2016 [2009 to 2012 (A1) and 2012 to 2016 (A2)]. Submissions were examined to identify assessment process patterns, disease areas and sponsor IPHA membership. RESULTS: The number of RR requests available for analysis increased between agreements (A1: n=93; A2: n=193). The rate of requests for full HTA following RR submission increased (A1: 56%; A2: 62%). A reduction in the rate of HTAs submitted following request was observed (A1: 79%; A2: 60%). Applications where a HTA was requested, but not submitted, and ultimately lead to reimbursement occurred with increasing frequency in the A2 period compared to A1. The main disease areas submitted for RR (neoplasm, endocrine, circulation, and infections) remained similar between agreements, with a notable increase in the proportion of cancer therapies (A1: 15%; A2: 29%). There was no correlation between the rate of completed HTA submissions and IPHA membership. CONCLUSIONS: The trends in assessment display a modest increase in the rate of full HTA requests. However, the rate of completion of submitted HTAs has decreased, suggesting that the negotiation route post-RR, which is now formalised in the 2016 agreement, is a viable route to reimbursement.

**PHP154: AN ANALYSIS OF HTA AND REIMBURSEMENT PROCESSES IN EUNETHTA PARTNER COUNTRIES: IMPLICATIONS FOR IMPLEMENTING HTA COOPERATION**

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OBJECTIVES: This study analysed HTA and reimbursement processes in countries taking part in the European network for Health Technology Assessment (EUnetHTA) to identify how within their existing processes agencies could (1) engage in HTA cooperation, (2) use jointly produced HTA information, and (3) reuse national, regional and local HTA information from other jurisdictions. METHODS: Agencies were asked to provide procedural documents. Information was then abstracted into a standardised template. Where information was not available agencies completed the template directly. The similarities and differences in the procedures were analysed. RESULTS: Data were received from 58 agencies in 29 countries. Ninety-four percent of countries reported assessing pharmaceuticals and 68% of countries reported assessing non-pharmaceutical health technologies. In approximately 50% of countries, the HTA agency did not have a role in topic selection, organisations playing a role include: Industry, Ministries of Health and payers. In the majority of countries (57% and 81% for pharmaceuticals and non-pharmaceutical health technologies, respectively) the decision problem of the assessment is defined before the process formally starts. However, this is not normally undertaken significantly in advance. For pharmaceuticals in 71% of countries the HTA is provided by industry and evaluated by the agency. In contrast for non-pharmaceutical health technologies, in 86% of countries the assessment is completed by the HTA agency either using evidence from industry or by identifying the evidence itself. For pharmaceuticals in the majority of cases (79%) the timelines for completion are not defined by the regulatory timetable, rather the assessment is initiated by an application and follows timelines governed by the Transparency Directive. CONCLUSIONS: The study identifies differences in working practices for the assessment of pharmaceuticals and non-pharmaceutical health technologies. These differences affect how countries may engage in HTA cooperation and be able to use jointly produced HTA information.

**PHP155: IN WHAT SEQUENCE DO COMPANIES SUBMIT HEALTH TECHNOLOGY APPRAISAL (HTA) DOSSIERS IN THE UK AND IRELAND, AND IN WHAT SEQUENCE ARE THEY PUBLISHED?**

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OBJECTIVES: Identify trends in the sequence that manufacturers submitted HTA dossiers and the sequence in which guidance was published by the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), All Wales Medicines Strategy Group (AWMSG) and National Centre for Pharmacoeconomics (NCPE). METHODS: The 30 most recent NICE technology guidance publications (up to June 2017) were reviewed. Where NICE guidance was a review, the date of the original guidance was used. The sequence of publication dates of any corresponding SMC, AWMSG and NCPE guidance was calculated. AWMSG and NCPE start dates were obtained for the submission sequence. SMC guidance was assumed to take 18 weeks. NICE start dates were calculated as 8-weeks after the Final Scope date, where available, otherwise appraisals were excluded due to the variability in the length of the NICE process prohibiting estimation of start date. RESULTS: Six of the 30 appraisals were terminated by NICE while four were multiple technology appraisals, and were excluded. All remaining 20 appraisals had corresponding submissions to SMC. SMC guidance was published first in 75% cases. NCPE performed 12 appraisals, published at variable steps within the sequence. AWMSG reviewed three appraisals. The
most frequent first submission was to NICE (75%). The modal submission sequence was NICE followed by the SMC but the modal publication sequence was SMC followed by NICE. **CONCLUSIONS:** Submissions are most often made to NICE first but SMC are usually first to publish recommendations. This is likely due to the shorter timelines of the SMC process compared with NICE. Sequencing of submissions to NCPE were variable, which may be due to international reference pricing strategy, or due to limited manufacturer resource since some companies are structured with one team covering the UK and Ireland. AWMSG completed few HTAs owing to the applicability of NICE decisions to England and Wales.

**PHP156: A TREND TOWARDS INCREASED USE OF PATIENT ACCESS SCHEMES (PAS) TO GAIN UK REIMBURSEMENT**

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**OBJECTIVES:** The UK is a free-pricing country, meaning manufacturers can set a list price higher than elsewhere in Europe, which is beneficial in a global market with international reference pricing. However, to gain reimbursement in the NHS, manufacturers may have to offer confidential discounts. Our objectives are to assess whether PAS in National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) appraisals has increased since 2014 and if inclusion influences the outcome. **METHODS:** All submissions to NICE and SMC between January 2015 and June 2017 were reviewed. We hypothesised that the use of PAS is increasing and that the inclusion of PAS has an impact on recommendation rates, which was tested using one-tailed and two-tailed tests, respectively. **RESULTS:** The proportion of appraisals with PAS significantly increased between 2015 and 2016 (p=0.0001) and between 2016 and 2017 (p=0.0256). So far in 2017, 100% of NICE appraisals and 62% of SMC appraisals have included PAS. The proportion of appraisals with PAS gaining positive recommendations has remained consistently above 90% for NICE and has insignificantly increased from 74% to 87% for SMC. There is no significant difference in recommendation rates between appraisals with PAS and without PAS for NICE (92% versus 82% respectively, p=0.08) or SMC (77% versus 87% respectively, p=0.07). **CONCLUSIONS:** Despite the increasing trend in PAS observed, there is no significant association between offering PAS and receiving positive recommendations from NICE and SMC. The inclusion of PAS is unlikely to be independently predictive of outcome because the product may be cost-effective at list price. PAS enable companies to maintain high published prices whilst providing value for money to the NHS. Conversely, in their recent Council conclusions, EU health ministers have expressed the desire for pricing transparency, whereby companies will be encouraged to voluntarily share information to enhance affordability across the EU.

**PHP157: CENTRALIZATION AND COMPLEXITY OF DRUG MARKET ACCESS PROCESS ACROSS ITALIAN REGIONS**

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**OBJECTIVES:** In Italy, the National Healthcare Service is based on three different levels (National, Regional, Local) resulting in a decentralized and fragmented market access process. The national access is assured by AIFA, but Regions are autonomous in establishing the access within their areas. The aim of this research is to map the presence of formularies (Regional, Wide Area, Local) and assess the complexity and the centralization of the market access process within each Region. **METHODS:** A desk research on institutional portals explored the dynamics of 10 Italian Regions, for the drug access process. Furthermore, a mapping of formularies led to the identification of steps required for the market access and the process complexity evaluation. The analysis was validated with insights collected through 20 interviews with key stakeholders. Three weighted drivers permitted to evaluate the level of centralization: presence of regional formulary, regional influence pressure and homogeneity of drug access across regional territories. **RESULTS:** The presence of a single operative formulary at regional level markedly centralized the drug access process. Lombardy and Piedmont resulted decentralized, while five regions demonstrated a high level of centralization. Three Regions resulted in a mixed model with intermediate centralization: for example, Veneto revealed a decentralized access process, but keeping a strong regional coordination thanks to the lead of regional committees. **CONCLUSIONS:** The complexity of the access process among Regions is highly variable and should be evaluated considering multiple aspects. It depends on the centralization level as the number of evaluation steps needed for the inclusion on the formulary and the area of influence of the formulary itself. The presence of a regional formulary can facilitate the drug access because it binds local level to the regional decision. On the other hand, additional local level formularies make this process more complex, due to interactions with multiple stakeholders.

**HEALTH CARE USE & POLICY STUDIES - Health Care Research & Education**
**PHP158: SUSPECTED ADVERSE REACTIONS (SARS) TO SYSTEMIC GLUCOCORTICOID USAGE IN DOGS IN PRIMARY VETERINARY PRACTICE IN THE UK**

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**OBJECTIVES:** To describe and quantify systemic glucocorticoid usage in dogs in primary-care veterinary practice in the UK and to numerically rank major suspected adverse reactions (SARs) following therapy. **METHODS:** The VetCompass™ database was interrogated from clinical data relating to 455,557 dogs under care in veterinary practices across the UK during 2013. All systemic glucocorticoid pharmacotherapeutics administered or dispensed to dogs during 2013 were identified from the electronic patient records (EPR) and described. In a random sample of 2,110 dogs with dispensing and administering events, the EPR were reviewed in detail for evidence of SARs. A SAR was any unfavourable/unintended observation including side effects recorded in the EPR whether or not considered to be product-related and that occurred within 31 days of first glucocorticoid treatment. **RESULTS:** Overall, 28,472 dogs received at least one systemic glucocorticoid during 2013 (6.2% of study dogs, 95%CI 6.2-6.3) with 30,570 oral (60.0% of total) and 20,606 injectable (40% of total) glucocorticoid events. Prednisolone represented the most frequently used oral preparation (27,362 events (90.0%)) and dexamethasone preparations were the most common injectable therapeutic (19,671 events (96.4%)). After detailed review of the EPR from the random selection of 2,110 dogs receiving systemic glucocorticoids, 106 dogs (5.0%, 95% CI 4.1-6.0%) had a total of 169 SARs recorded. The most frequent of these were polydipsia (38 events, 22.5%), polyuria (27, 16.0%), vomiting (19, 11.2%), diarrhoea (16, 9.5%) and polyphagia (15, 8.9%). In 34 (20.1%) of these events the dose of the glucocorticoid was subsequently reduced whilst in 15 (8.9%) the therapy was discontinued. **CONCLUSIONS:** Systemic glucocorticoid therapy was a frequent treatment in dogs attending primary-care practice, with a clinically relevant minority experiencing at least one SAR. This is a conservative quantification as only the SARS that were reported or identified by the veterinarian were included in the study.

**PHP159: EVALUATING THE CONCEPTUAL EQUIVALENCE BETWEEN PAPER AND THREE ELECTRONIC DATA COLLECTION MODES OF THE EQ-5D-5L HEALTH STATUS INSTRUMENT**

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**OBJECTIVES:** The Electronic Patient-Reported Outcome (ePRO) Consortium and the EuroQol Research Foundation commissioned a study to assess the measurement equivalence of data collected using the EQ-5D-5L across various data collection modes. One study component examined equivalence of paper, handheld, web and interactive voice response (IVR) modes of the EQ-5D-5L using qualitative methods, in accordance with the ISPOR Task Force Report on Measurement Equivalence. **METHODS:** A single-visit, cognitive interview and usability testing (CI/UT) study was conducted. After providing informed consent, participants completed the paper format and one of three electronic modes (handheld, IVR, or web) of the EQ-5D-5L and afterwards participated in an interview. Following a semi-structured interview guide, participants were asked about their interpretation of the content between the modes and issues completing the measure using the assigned mode. Interviews were audio-recorded, transcribed, and analyzed qualitatively. **RESULTS:** Thirty UK participants, aged 20-70, participated in the CI/UT study, with 10 participants completing each electronic mode (handheld, IVR, or web). Most participants (n=23; 77%) had a chronic health condition. Overall, participants in all mode groups interpreted the measure content consistently and appropriately for each item of the EQ-5D-5L. When asked whether layout differences would impact their answers between paper and electronic formats, most participants (n=23) indicated there would be no difference. Reported potential discrepancies were mostly related to the 0-100 visual analogue scale (VAS), where four participants noted answer discrepancies due to difficulty selecting a precise response on the handheld and web versions. **CONCLUSIONS:** Consistent interpretation of items in the EQ-5D-5L, by participants using paper, handheld, IVR, or web, supports conceptual equivalence of the items across modes. Minor differences in presentation did not appear to undermine conceptual understanding of these items; however, usability issues potentially affected measurement equivalence for the VAS item, highlighting the importance of usability testing to address such issues prior to implementation.

**PHP160: COMORBIDITY INDICES BASED ON HEALTH-RELATED QUALITY OF LIFE ARE MORE STRONGLY ASSOCIATED WITH PATIENT OUTCOMES THAN MORTALITY-BASED INDICES**

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**OBJECTIVES:** To compare the association of two comorbidity indices, Charlson Comorbidity Index (CCI), and HRQL Comorbidity Index (HRQL-CI), with measures of healthcare resource utilization (HCRU) and work limitations among a
large sample of working adults. These indices are calculated based on the number and severity of comorbid conditions. The CCI was developed to predict mortality. The HRQL-CI uses a bi-dimensional algorithm (HRQL-CI Physical; HRQL-CI Mental) to predict SF-12v2 Health Survey physical and mental component summary scores (PCS; MCS), while a revised unidimensional algorithm was developed using the SF-6D. METHODS: Data [N=17,773] came from the Medical Expenditure Panel Survey (MEPS), a study representative of U.S. households with 5-rounds of interviews across 2 years. HCRU variables were total medical expenditures (MEx), number of medical events (MEv), number of lost work/housework days, and cognitive limitations (Yes/No), reported over round 5 (in year 2) of the study. Comorbidity indices were captured through conditions from year 2. Spearman correlations (rs) were used to assess the association between CCI, HRQL-CI, HRQL-CI Physical, HRQL-CI Mental and each outcome, except for cognitive limitations, for which the generalized coefficient of determination (was used. RESULTS: MEx and MEv were both most strongly associated with HRQL-CI-Physical (rs = 0.40, 0.49, respectively), followed by the unidimensional HRQL-CI (rs = 0.38). Number of lost work days and cognitive limitations were both most strongly associated with the unidimensional HRQL-CI (rs = 0.18, 0.12), followed by the HRQL-CI Mental (rs = 0.16, = 0.11). CONCLUSIONS: All four outcomes were more strongly associated with indices based on HRQL than a commonly-used index based on mortality. While the HRQL-CI Physical was more strongly associated with HCRU, the HRQL-CI Mental was more strongly associated with work limitations. Indices that take into account the effect of comorbid conditions on HRQL should be considered when predicting patient outcomes.

**PHP161:** RASCH MEASUREMENT ANALYSIS OF THE LOWER EXTREMITY FUNCTIONAL SCALE FOR FOOT AND ANKLE PATIENTS

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OBJECTIVES: Lower Extremity Functional Scale (LEFS) is a widely used 20-item patient-reported outcome instrument with five response categories. The purpose of this study was to investigate the measurement properties of the Finnish version of the LEFS among foot and ankle patients and refine the scale to measure more accurately that what matters to the patient. METHODS: Data were obtained from an earlier cross-sectional validation study of the Finnish version of the LEFS. Altogether 185 patients who had undergone foot and ankle surgery for various reasons were included. Rasch measurement theory was used to analyse construct validity, model and individual item fit, and reliability. RESULTS: Misfit of thresholds was noted in 13 of the 20 original LEFS items and thus scale unidimensionality was not supported. After collapsing the response categories 1 (“Quite a bit of difficulty”) and 2 (“Moderate difficulty”) together, two items (item 10 “Getting into or out of a car” and item 11 “Walking 2 blocks”) showed threshold misfit. As unidimensionality was not supported by deleting items 10 and 11, three more items were omitted. This new 15-item scale with four response categories supported unidimensionality (proportion of significant t-tests, 1.4%). All items had ordered thresholds and good item fit (fit residuals inside -2.5 and 2.5). Reliability of the revised scale was high as the Person Separation Index and Cronbach's alpha were 0.85 and 0.95, respectively. CONCLUSIONS: The new 15-item LEFS scale with four response categories has a unidimensional construct. The refined LEFS seems to be more valid than the original 20-item LEFS in assessing foot and ankle function. This scale should be further tested for its reliability, validity and responsiveness.

**PHP162:** THE APPLICATION OF BIG DATA ANALYSIS TO MEASURE AND BETTER UNDERSTAND MEDICATION ADHERENCE: A SYSTEMATIC LITERATURE REVIEW.

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OBJECTIVES: Medication Adherence (approximately 50% in developed countries) is widely recognized as a worldwide issue in public health leading with, among others, poor healthcare outcomes, poor quality of life and increasing cost for the National Health System. So far, many studies have investigated how to measure adherence, how to overcome barriers and how to solve them. The improvement on Information Technologies and Big Data analysis can be integrated in tools and support practices to measure medication adherence. The objective of this paper is to explore and map the recent literature that used Big Data as a tool or framework to measure and increase knowledge about medication non-adherence. METHODS: The study presents a systematic literature review using papers published between 01/01/2003 and 01/01/2017 on PubMed, ScienceDirect and Scopus about methods applied to measure medication adherence using Big Data strategy. RESULTS: A total of 152 potential relevant publications was identified. After the screening process, 22 articles used and on three main Big Data Healthcare categories: Omics (1), Medical Specialties (7); Endocrinology (3), Cardiology (2), Respiratory diseases (1), Neurology (1), Public Health (14), Bioinformatics (11), Electronic health Records (3). Adherence measurement methods classified in, Self Reported methods (4): interviews (2), questionnaires’ (2), Indirect methods
(10): administrative data (4), electronic monitoring (5), Pill count (1). Direct methods (3): Sensor/biological marker (1), telemedicine (2). Most of the studies use retrospective datasets like EHR, administrative data, or questionnaires (12), three studies apply real-time analysis and three studies develop data integration processes. **CONCLUSIONS:** A limited number of publications considered clearly the relationship between adherence and Big Data, using common definition, determinants or measurement methods. This lack of common approach how the medication adherence issues and highlight the necessity of setting up a common framework to improve the research about medication adherence.

**PHP163: EFFECTIVENESS OF OSTEOPOROSIS DRUGS IN PREVENTING SECONDARY HIP FRACTURES IN WOMEN ON DIALYSIS**

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**OBJECTIVES:** Osteoporosis is a major epidemic disease worldwide. Women over 50 years old and patients with dialysis are at high risk for osteoporosis. Hip fracture alone was estimated to shorten 11.2 years of lifespan in women. However, the clinical effectiveness of anti-osteoporosis medications (AOMs), including alendronate and raloxifene, in dialysis patients was unclear. The objective of this study was to investigate the effectiveness of AOMs in preventing secondary hip fractures in women on dialysis. **METHODS:** We used 2004-2012 National Health Insurance Research Datasets in Taiwan to conduct a retrospective cohort study. Women age 50 and older, undergoing long-term dialysis, and with newly diagnosed hip fracture were enrolled. The patients were divided into AOMs users and AOMs nonusers and 1:1 matched on age, the duration of dialysis, and comorbidities and co-medications with propensity score. The patients were followed for the occurrence of secondary hip fractures. **RESULTS:** We identified 1,079 dialysis women matched our inclusion criteria in the database. After the matching, there were 74 patients in AOMs users and nonusers, respectively. Use of AOMs exhibited a similar risk of secondary hip fracture ((adjusted hazard ratio(aHR): 0.60; 95% CI: 0.16-2.20) compared with the AOMs non-users. A similar effect of secondary prevention for hip fractures was also observed in the patients use of alendronate and raloxifene (aHR: 2.76; 95% CI: 0.22-35.30). **CONCLUSIONS:** This is the first population-based study to investigate the effectiveness of AOMs in women on dialysis. Our results demonstrated that AOMs did not significantly decrease the risk of secondary hip fractures. Further attentions to fit the unmet medical need in women on dialysis are warranted.

**PHP164: A SYSTEMATIC LITERATURE REVIEW OF THE MEASUREMENT PROPERTIES OF GENERIC UTILITY INSTRUMENTS IN EAST AND SOUTHEAST ASIA**

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**OBJECTIVES:** The aim of this systematic literature review was to summarize the measurement properties of generic utility instruments in East and Southeast Asian populations. **METHODS:** Medline, Embase, PsycINFO, Web of Science and the Cochrane Library were searched for original research that met the following criteria: 1) original research articles or brief communication/reports; 2) use of study subjects from China, Indonesia, Japan, Malaysia, the Philippines, Singapore, South Korea, Taiwan, Thailand, and/or Vietnam; 3) use of EQ-5D, SF-6D, HUI2, HUI3, QWB, 15D and/or AQLQ; and 4) assessment of validity, reliability, sensitivity, and/or measurement equivalence of one or more of the utility instruments in 3). The database search was conducted at October 2016. **RESULTS:** A total of 12,928 records were identified through searching of the five databases. After title/abstract selection and full-text assessment, sixty-four studies were included for the final review. Of which the most commonly assessed instrument was EQ-5D (n = 63), followed by SF-6D (n = 13), HUI3 (n = 3), HUI2 (n = 2) and QWB (n = 1). Construct validity (n = 48) and test-retest reliability (n = 25) were the most widely examined measurement properties in the studies. Generally, the instruments showed validity in 93.7% of studies, reliability in 87.5% of studies, and responsiveness in 76.9% of studies. EQ-5D was shown to have poor agreement with SF-6D (n=4) but good agreement with QWB-SA (n=1). The majority of the studies were from Singapore (34.4%) or China (including Hong Kong) (26.6%). There was none from Indonesia or the Philippines. **CONCLUSIONS:** EQ-5D and SF-6D are the most psychometrically validated generic utility instruments in East and Southeast Asia. This review may provide useful guide for users of utility instruments as to which instrument(s) to use in Asian populations.

**PHP165: POPULATION HEALTH STATUS BASED ON THE EQ-5D-3L-Y AMONG ADOLESCENTS IN SWEDEN - RESULTS BY SEX, AGE AND SOCIO-ECONOMIC STATUS**

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OBJECTIVES: The EQ-5D-3L-Y is a generic health-related quality of life measure developed for children and adolescents from eight years old. This research aims to investigate population health status, based on the EQ-5D-3L-Y, among adolescents in Sweden. Population data can be used to compare health status of specific groups with the general population, to monitor population health status over time and to identify groups in the general population with greater risk of poor health. METHODS: Data were derived from a general population survey conducted in year 2014 among Swedish adolescents aged 13–20 years. Pupils answered anonymously, using paper and pencil, during school hours. Socio-economic status was assessed by parents’ occupation. RESULTS: The response rate was 79.7%. A total of 6,870 participants answered all dimensions of the EQ-5D-3L-Y (mean age 16.1 years; same proportion of boys and girls). Girls reported significantly more problems than boys in the dimensions doing usual activities, having pain or discomfort and feeling worried, sad or unhappy, and had significantly lower mean VAS score. Nearly 52% of girls reported problems in the mood dimension. Mean VAS scores for both boys and girls decreased by age, 78.0–71.2. Participants with lower socio-economic status reported more problems in all EQ-5D-3L-Y dimensions. CONCLUSIONS: The high prevalence of reported problems in the dimension feeling worried, sad or unhappy among girls gives reason for concern and is a base for policy, especially in the age group 15–16 years where nearly 10%, reported a lot of problems.

PHP167: AGREEMENT BETWEEN PATIENT AND CLINICIAN RATINGS OF DISEASE SEVERITY IN HIDRADENITIS SUPPURATIVA, RHEUMATOID ARTHRITIS, AND CHRONIC PLAQUE PSORIASIS

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OBJECTIVES: There are often discrepancies among patient and clinician ratings of disease severity. This study investigated the level of agreement between patient- and clinician-reported disease severity ratings and explored demographic factors that may further explain discordance across three diseases (hidradenitis suppurativa [HS], rheumatoid arthritis [RA], and chronic plaque psoriasis [Ps]). METHODS: Patient and clinician global assessments of disease severity (encompassing: 0-10 numeric rating scales and seven- or five-point categorical scales) from five quantitative and qualitative studies were pooled within HS (n=2), RA (n=2), and Ps (n=1). When necessary, scales were collapsed (e.g., combining very mild and mild categories) for consistency across patient and clinician ratings. Statistical analyses included: cross-tabulations of patient and clinician severity ratings and calculation of intraclass correlation coefficients (ICCs; for continuous variables) or weighted kappa coefficients (κw; for categorical variables) to assess the level of patient-clinician agreement within each disease. These analyses were repeated among patient demographic subgroups (i.e., sex, race, level of education). RESULTS: Data from 190 HS (mean age=41.8, [standard deviation=13.1 years]; 65.3% female), 240 RA (mean age=61.2 [12.9]; 62.1% female), and 200 Ps (mean age=61.3 [13.2]; 50.0% female) patients were analyzed. Percentage of matched patient-clinician disease severity ratings ranged from 73.5% to 79.9% in HS, 61.0% to 80.3% in RA, and 57.8 to 78.0% in Ps, and the level of agreement ranged from 0.69 to 0.71, 0.61 to 0.79, and 0.43 to 0.75 in HS, RA, and Ps, respectively. Lower agreement levels were found in the following demographic subgroups: females (HS), non-Caucasians (HS), and patients with lower education levels (HS, RA, Ps). CONCLUSIONS: Overall, clinicians and patients report high levels of agreement, demonstrating some level of consistency in disease rating across the three researched diseases. Less agreement in demographic subpopulations indicate that sex, race, and education are potential factors in patient reported severity of disease.

PHP168: PREDICTORS OF ACTIVITY AND PARTICIPATION IN PEOPLE WITH MOTOR NEURONE DISEASE, MULTIPLE SCLEROSIS AND PARKINSON’S DISEASE.

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OBJECTIVES: To identify predictors of activity and participation in people with motor neurone disease (MND), multiple sclerosis (MS) and Parkinson’s disease (PD). METHODS: The Oxford Participation and Activities Questionnaire (Ox-PAQ) and Medical Outcomes Study 36-Item Short Form Survey (MOS SF-36) were administered by postal survey to 386 people with a confirmed diagnosis of MND, MS or PD. Recruitment of participants was undertaken via their relevant support organisations in the United Kingdom. Data analyses focused on stepwise regression analyses in order to identify predictors of activity and participation in the three conditions assessed. RESULTS: Three hundred and thirty four participants completed the survey, a response rate of 86.5%. The mean age was 60.06 years, the mean age at diagnosis 52.82 years and the mean disease duration 7.31 years. The sample comprised 162 males and 172 females. Regression analyses identified multiple predictors of activity and participation according to Ox-PAQ domain and disease group, the most prominent being social and physical functioning as measured by the MOS SF-36. CONCLUSIONS: Results indicate that the physical and social consequences of neurological illness are of greatest relevance to people experiencing the conditions assessed.
Whilst the largely inevitable physical implications of disease take hold, emphasis should be placed on the avoidance of social withdrawal and isolation, and the maintenance of social engagement should become a significant priority.

PHP169: PATIENT-REPORTED OUTCOMES IN LABELS AND PACKAGE LEAFLETS OF DRUGS APPROVED BY THE EUROPEAN MEDICINES AGENCY FROM 2007 TO 2017

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OBJECTIVES: The patient perspective is becoming increasingly important to prescribing decision-making. Both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have published guidance on the use and inclusion of patient-reported outcome (PRO) data in product labelling. The objective of this study was to investigate PRO claims cited in the Summaries of Product Characteristics (SmPCs) and package leaflets of products approved by the EMA over the past decade. METHODS: We reviewed the SmPCs and package leaflets of branded drugs (including orphan drugs and biosimilars) approved by the EMA from January 2007 to May 2017 in five disease areas defined using the following key criteria: diabetes, mental health, rheumatic diseases, psoriasis, and breast neoplasms. RESULTS: We identified 125 branded drugs approved in the time period studied: 54 for diabetes, 32 for mental health, 18 for rheumatic diseases, 13 for psoriasis, and 8 for breast neoplasms treatment. PRO data were cited in 3.7%, 56.3%, 77.6%, 69.2%, and 75.0% of SmPCs in each disease area, respectively. Package leaflets were typically devoid of PRO data: only 3 leaflets containing this information were identified, all in the rheumatic disease category. We did not observe an increase or decrease in PRO reporting over time. CONCLUSIONS: With respect to the EMA guidance, PRO data are still unavailable in many of the SmPCs and package leaflets of products for the treatment of diseases known to severely affect patient daily life, especially diabetes. Pharmaceutical companies should ensure that this information, if available, is included so that health care providers and decision makers are better equipped when making treatment decisions.

PHP170: REPELLENT AND LARVICIDAL ACTIVITY OF THAI MEDICINAL PLANTS AGAINST MOSQUITOES: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Thai Herbs are a fascinating and viable natural alternative to conventional chemical mosquito repellents and larvicides. This study aims to analyze available data on the efficacy and safety of Thai herbs for mosquito repellents and larvicides. METHODS: A systematic review and meta-analysis of clinical trials was conducted to evaluate the efficacy and safety of Thai herbs used as mosquito repellents and larvicides. MEDLINE, EMBASE, the Cochrane Controlled Trials Register were searched for relevant articles based on pre-defined inclusion criteria. Two reviewers independently extracted data from the selected articles. Data on efficacy and safety outcomes were collected. We calculated pooled mean protection time (mosquito repellent) and mean 50% lethal dose or concentration values; LD50 /LC50 (larvicidal), weighted mean difference and 95% confidence interval were reported. RESULTS: A total of 33 studies were included in this analysis. Overall analysis indicated that extracts from the herbs analyzed had significant activity both as repellents as well as larvicides. Among agents conferring protection against Anopheles dirus, the longest protection time was seen with C.longa (480 minutes) even in comparison to the market standard chemical repellent, N, N-Diethyl-meta-toluamide; DEET (360 minutes), and 15%DEET lotion (120 minutes). The larvicidal effect of herbs as measured by LD50 (except, C.Aurantifolia and Z.limonella) were 83.92, 800.33, and 40.169 mg/l, respectively. CONCLUSIONS: Extracts of all Thai herbs showed various larvicidal and repellent activities. C.longa showed the highest repellent activity against mosquitoes. All 5 of the Thai herbs (A.graveolens, C.aurantifolia, C.longa, O.basilicum, Z.limonella) showed larvicidal activity (LD50) superior to DEET.

PHP171: DO PEOPLE WITH PRIVATE HEALTH INSURANCE ATTACH A HIGHER VALUE TO HEALTH THAN THOSE WITHOUT INSURANCE? RESULTS FROM AN EQ-5D-5L VALUATION STUDY IN THE REPUBLIC OF IRELAND

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OBJECTIVES: Various studies have interpreted observed differences in healthcare use between those with and
Intraclass correlation between two evaluators were 3.76 and 4.01, respectively. Chronbach's alpha was 0.70 with inter-

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OBJECTIVES: The T

METHODS: The T-

RESULTS: Minor adaptations were done in the translation of the Finnish T-NOTECHS. Mean scores between two evaluators were 3.76 and 4.01, respectively. Chronbach's alpha was 0.70 with inter-item correlation of 0.54. Intraclass correlation coefficient was 0.54 (95% CI, 0.34-0.70) and coefficient of repeatability was 1.53 (95% CI,
**PHP174: QUANTIFYING THE RELATIONSHIP BETWEEN HYPERKALAEMIA AND OUTCOMES IN PATIENTS WITH HEART FAILURE OR CHRONIC KIDNEY DISEASE**

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**OBJECTIVES:** Hyperkalaemia (HK) is associated with increased risk of mortality. Renin-angiotensin-aldosterone system inhibitors (RAASi) can reduce mortality risk and slow disease progression in heart failure (HF) and chronic kidney disease (CKD); however, their use may be limited by their potential to cause HK. This study aimed to quantify the relationship between elevated serum potassium (K+) levels and risk of mortality and RAASi discontinuation in HF and CKD. **METHODS:** Poisson Generalized Estimating Equations, derived from time-updated serum K+ data in 23,541 HF and 144,388 CKD patients in Clinical Practice Research Datalink (01/01/2006–31/12/2015), were used to predict the incidence of all-cause mortality and RAASi discontinuation. Five-year event rates were estimated across a range of K+ levels, adjusting for demographics, comorbidities and concomitant medication. Results were reported for male (and female) CKD and HF patients of average age: 74 and 75 years, respectively. **RESULTS:** Expected five-year mortality rates in CKD patients prescribed RAASi were 0.114, 0.116, and 0.142 (0.079, 0.080, and 0.098) for K+ levels of 4.5, 5.5 and 6.5 mEq/L, respectively; equivalent mortality rates for HF patients were 0.196, 0.210, and 0.316 (0.152, 0.164, and 0.246). RAASi discontinuation rates were 0.326, 0.419, and 0.576 (0.278, 0.358, and 0.492) in CKD and 0.407, 0.473, and 0.674 (both genders) in HF, for K+ levels of 4.5, 5.5 and 6.5 mEq/L, respectively. Discontinuing RAASi was associated with increased mortality risk: 0.263, 0.269, and 0.329 (0.182, 0.186, and 0.228) in CKD and 0.652, 0.701, 1.055 (0.508, 0.546, and 0.821) in HF, for K+ levels of 4.5, 5.5 and 6.5 mEq/L, respectively. **CONCLUSIONS:** Based on real-world UK data, this study highlights the strong association between elevated K+ levels and increased incidence of RAASi discontinuation and mortality. The risk outputs from this study are fit for use within long-term cost-effectiveness models assessing the benefits of effective K+ management in CKD and HF.

**PHP175: WILLINGNESS-TO-PAY FOR LIFE-SAVING TREATMENTS IN THAILAND: A DISCRETE CHOICE EXPERIMENT**

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**OBJECTIVES:** Many countries currently use cost-effectiveness threshold to guide their decisions on the selection of new healthcare technologies. However, individual’s willingness-to-pay (WTP) is essential to justify these decisions, especially for life-saving treatments since they tend to be more expensive. This study aimed to examine WTP for life-saving treatments. **METHODS:** Dimensions and levels from EQ-5D-3L, and cost were used to develop a discrete choice experiment questionnaire. Each questionnaire was composed of five choice sets. Each choice set contained two alternatives with different levels across all dimensions and a reference alternative (death and cost=0). Four hundred and eighty five respondents were conveniently sampled from three provinces in Thailand. They were asked to imagine that they had a life-threatening disease for one year. If they did not get any treatment, they would die. They could choose only one alternative in each choice set. A multinomial logit model using effect codes was developed and used to calculate the WTP of each level change for each attribute. The WTP for saving life and getting back to current health state was calculated. **RESULTS:** A total of 459 respondents (approximately 94% of all sampled respondents) completed the questionnaire. The average utility score of their current health states was 0.826 ± 0.170. Intuitively, the respondents preferred better health states. They were willingness to pay 161,000 Baht, 153,000 Baht, 126,000 Baht, 114,000 Baht, and 80,000 Baht for having no problem in pain/discomfort, mobility, usual activities, self-care, and anxiety/depression, respectively. Their average WTP for saving life and getting back to current health state after having a treatment for one year was 1,250,000 Baht. **CONCLUSIONS:** Thai citizens might be willing to pay for life-saving treatments higher than the cost-effectiveness threshold (160,000 Baht per QALY) that the country guideline currently suggests. Policy makers can use this finding when they select life-saving treatments.

**PHP176: DEVELOPMENT OF A MORTALITY RISK PREDICTION TOOL FOR PATIENTS WITH HEART FAILURE OR CHRONIC KIDNEY DISEASE AT RISK OF HYPERKALAEMIA**

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OBJECTIVES: Hyperkalaemia (HK) is associated with increased risk of mortality. This study aimed to develop a risk prediction tool to assess the probability of mortality in patients with heart failure (HF) or chronic kidney disease (CKD) at risk of HK, based on relevant demographics and clinical risk factors. METHODS: Poisson Generalized Estimating Equations fitted to 23,541 HF and 144,388 CKD patients in Clinical Practice Research Datalink (Jan 2006–Dec 2015) were incorporated within an Excel-based tool to predict annual probabilities of mortality using demographic, comorbidity, concomitant medication and clinical measurement data. An illustration of the tool’s output is presented relative to a baseline probability for a male/female with CKD/HF, non-smoker, aged 60, eGFR 50 ml/min/1.73m², serum potassium (K+) 4.5 mEq/L, without diabetes or renin-angiotensin-aldosterone system inhibitor (RAASI) prescription. Results were expressed as percentage increase/decrease from baseline. RESULTS: The listed characteristics were all statistically significant predictors of mortality. Baseline annual mortality probability was 0.016 and 0.068 in males and 0.008 and 0.055 in females, with CKD and HF, respectively. RAASI use was associated with decreased probability of death compared to baseline in CKD (56.6%) and HF (69.3%). Older age, increased K+, diabetes, smoking and reductions in eGFR all increased estimated probability of death. The influence of eGFR was greater for CKD patients (36.4%–153% for 10–30 ml/min/1.73m² reduction) compared to HF (18.4%–65.2% for 10–30 ml/min/1.73m² reduction). While the impact of K+ was greater for HF: 7.2% and 58.4% for K+ 5.5 and 6.5 mEq/L, respectively, compared to 2.1% and 24.9% for CKD. CONCLUSIONS: Utilising real-world UK data, this evaluation of the impact of clinical risk factors on mortality risk in patients with CKD or HF serves as the structural framework for a broader tool to enhance the assessment of risk of outcomes in patients susceptible to HK.

PHP177: THE FIRST EQ-5D-5L VALUE SET IN CENTRAL AND EASTERN EUROPE

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OBJECTIVES: There is no EQ-5D-5L value set for any Central and Eastern European country. Our objective was to derive a tariff for the EQ-5D-5L in Poland. METHODS: Quota sampling was used to achieve a representative sample of the Polish population with regard to age, sex, education, geographical region, and the size of locality. The study design followed the EQ-VT protocol (v2.0). Fifteen trained professional interviewers performed computer-assisted face-to-face interviews between June and October 2016. Each respondent valued ten health states using composite time trade-off (cTTO) and completed seven discrete choice experiment (DCE) tasks. Quality control was performed according to EQ-VT rules. All the flagged interviews were removed. The hybrid model was estimated in Bayesian setting, with non-informative priors, using JAGS/R environment. RESULTS: Data from 1252 respondents (52.5% females, age 18 - 91 years) were available. In the estimation, we used: 11,480 TTO valuations and 8,764 DCE pairs. In TTO, in 10.7% experiments, the time was not traded, and eight respondents did not trade for any state. The average utility of 55555 state in TTO amounted to -0.433. In the final model, the estimated decrease of utility for level five amounts to: 0.341 (Mobility), 0.312 (Self-care), 0.237 (Usual Activities), 0.592 (Pain/Discomfort), and 0.249 (Anxiety/Depression). In the final value set we got u(22222) = 0.889, u(33333) = 0.832, u(44444) = 0.375, u(55555) = -0.731 (compare to u(33333) = -0.523 in the Polish EQ-5D-3L tariff). CONCLUSIONS: New value set is available and should be used in health technology assessment in Poland. It may be considered as a second best choice in other CEE countries, lacking their own directly measured or cross-walk value sets. The new tariff does not introduce revolutionary changes as compared to the previous EQ-5D-3L version but offers greater sensitivity to subtle health state changes thanks to five levels.

PHP178: THE ROLE OF DISABILITY ON EARLY RETIREMENT

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OBJECTIVES: To examine the role of disability on early retirement in Portugal. METHODS: We analyzed data from a nationwide epidemiological study performed between September 2011 and December 2013 (EpiReumaPt Study) consisting of a representative sample of the population with 10,661 surveyees. Data was self-reported and comprises sociodemographic and clinical variables (including major chronic diseases, such as cardiovascular, respiratory, gastrointestinal, mental disorders, neurological, rheumatic diseases and cancer). We analyzed those aged 50-64, near the official retirement age. Disability was measured according with the Health Assessment Questionnaire (HAQ). The association between disability and early retirement was estimated using multivariable logistic regression. RESULTS: About 30% (29.9%) of the Portuguese population aged between 50 and 64 was retired and had a mean HAQ score of 0.33 (95% CI: 0.31-0.36). Women self-reported worse HAQ scores (mean: 0.45 versus
men: 0.20, p<0.001), while those with at least one major chronic disease were more likely to have higher mean HAQ scores (0.38 vs. 0.11, p<0.001). Retirees presented worse disability compared with any other occupational status (mean HAQ average for retired: 0.44; unemployed: 0.34; and employed: 0.22). In fact, disability was significantly associated with early retirement (age- region- and sex-adjusted OR: 1.77; 95% CI: 1.39-2.27; p<0.001), while the relationship between morbidity and this occupational outcome is only significant when disability is high (OR: 1.97; 95% CI: 1.44-2.70; p=NS). On the other hand, those with low disability are more likely to be employed regardless of their self-reported morbidity (OR: 1.94; 95% CI: 1.50-2.51; p<0.001).

CONCLUSIONS: Disability is an important intermediate step in the causal chain between morbidity and early retirement and should be addressed in policies aiming to reduce premature work withdrawal. HAQ assessment could be a relevant tool to be applied regularly in the workplace for those at risk of early retirement, namely sick employees near the statutory retirement age.

PHP179: RELIABILITY AND VALIDITY OF TWO PROXY VERSIONS OF EQ-5D-5L IN JAPAN

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OBJECTIVES: It aims to examine two proxy versions of EQ-5D-5L in Japanese for their reliability and validity. METHODS: We compared various patient groups with use of EQ-5D-5L in Japanese version (Self-response version) and two proxy versions. In Proxy 1, a proxy will be asked how he/she would make an evaluation when evaluating a health condition for a subject. In Proxy 2, a proxy will be asked how it should be determined when a subject can communicate his/her own health condition. Proxy version evaluated an occupational therapist in charge. For the statistical processing, reliability and validity were calculated with Cronbach’s α coefficient and Pearson’s correlation coefficient respectively through using STATA14.0. RESULTS: Total 251 patients became the subjects. The breakdown of disorders was 101 patients for cardiac disorder, 75 patients for respiratory disorder, 41 patients for cerebral tumor, and 34 patients for cervical myelopathy. 159 patients were female (63.3%). The mean scores of EQ-5D-5L in Japanese version (Self-response) and two proxy versions. In Proxy 1, a proxy will be asked how he/she would make an evaluation when evaluating a health condition for a subject. In Proxy 2, a proxy will be asked how it should be determined when a subject can communicate his/her own health condition. Proxy version evaluated an occupational therapist in charge. For the statistical processing, reliability and validity were calculated with Cronbach’s α coefficient and Pearson’s correlation coefficient respectively through using STATA14.0. RESULTS: Total 251 patients became the subjects. The breakdown of disorders was 101 patients for cardiac disorder, 75 patients for respiratory disorder, 41 patients for cerebral tumor, and 34 patients for cervical myelopathy. 159 patients were female (63.3%). The mean scores of EQ-5D-5L were 0.739 (95%CI: 0.718-0.764) for Self-response, 0.735 (95%CI: 0.710-0.759) for Proxy 1, and 0.729 (95%CI: 0.705-0.754) for Proxy 2. α coefficient indicated 0.929 for Self-response/Proxy 1 and 0.956 for Self-response/Proxy 2. When verifying a coefficient with 3 scores by disorder, cardiac disorder (0.951), respiratory disorder (0.985), and cerebral tumor (0.912) indicated higher while cervical myelopathy (0.777) indicated lower. The correlation coefficient was 0.867 for Self-response/Proxy 1 and 0.952 for Self-response/Proxy 2. CONCLUSIONS: We successfully clarified the reliability and validity for two proxy versions of EQ-5D-5L in Japanese. It was concerned that Proxy 2 may possibly estimate a patient’s QOL to be lower and the reliability would become less depending on disorder. Thus, it is required to give careful attention to those results when using Proxy versions.

PHP180: ALLOWING RESPONDENTS TO SKIP ITEMS DURING ELECTRONIC COLLECTION OF PATIENT-REPORTED OUTCOME (PRO) DATA: DOES IT MATTER?


OBJECTIVES: The collection of electronic patient-reported outcome (ePRO) data in clinical trials presents an opportunity to minimize missing data by requiring subjects to respond to all items in order to complete the questionnaire. However, implementation of this data entry rule can have unintended consequences. The purpose of this report is to share considerations around requiring subjects to respond to items and provide data on the prevalence of skipped items in three therapeutic areas and ePRO modes. METHODS: Three quantitative pilot studies conducted by the PRO Consortium allowed participants to skip items on the draft questionnaires, one of three scenarios described by O'Donohoe et al. (2015) on considerations for requiring completion. Use of an “active skip” ensured that participants indicated they were choosing to skip an item, and that it was not missed accidentally. Data on skipped items were analysed from the Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ) on a tablet device, the Symptoms of Major Depressive Disorder Scale (SMDDS) on a web-based system, and the Asthma Daily Symptom Diary (ADSD) on a handheld device. RESULTS: Diverse samples were recruited for the NSCLC-SAQ (N=152), SMDDS (Wave 1=315; Wave 2=207), and ADSD (N=219) studies. No items were skipped on the NSCLC-SAQ, while rates of item-level skipping ranged from 0.09% to 2% of possible completions on the SMDDS and ADSD, respectively. Missing data appeared to be at random and did not indicate problems with the items skipped. CONCLUSIONS: Requiring completion of items may reduce missing data but can result in questionable data. Careful implementation of skipping rules and the use of well-designed questionnaires
assessing relevant and appropriate concepts for the context of use may reduce respondents’ desire to skip items when allowed to do so, as evidenced by the low rates of missing item-level data seen in three PRO Consortium studies.

**PHP181: KNOWLEDGE AND CONFIDENCE OF HEALTHCARE PROVIDERS WORKING AT HOSPITALS ABOUT APPROPRIATE PRESCRIBING FOR GERIATRICS**

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**OBJECTIVES:** To assess the knowledge of health care providers (HCPs) about inappropriate prescribing (IP) in geriatrics, and their confidence in prescribing for this population. **METHODS:** Six clinical vignettes were developed based on 2015 Beers criteria and the STOPP/START criteria version 2 to assess the knowledge. The confidence was investigated by asking the HCPs about their agreement on the following statement “I have confidence in my ability to recommend appropriate medications for the older patients”. The scale was validated by expert panel, piloted on 34 HCPs and then distributed to 123 physicians and clinical pharmacists working in general medical wards of two tertiary hospitals in Malaysia. **RESULTS:** The scale content validity index value of 0.95 and the Cronbach's Alpha value of 0.717 indicate good content validity and reliability, respectively. Of the 82 HCPs who completed the questionnaire, 35% were clinical pharmacists, 9.8% had ever undergone a training in geriatric medicine, and 70.8% stated that about 25% of their patients are elderly. Only 7.3% had ever used the STOPP/START or Beers criteria when prescribing for older patients, and 60% of the respondents had never heard of either criteria. The mean (SD) score in knowledge part was 3.65 (1.46) points out of 6 and only 27 HCPs (22.9%) scored high (≥5 points). The frequent incorrectly answered clinical vignette was that pertaining to long-term pain management in patients with cardiovascular comorbidities. Overall, only 34% of HCPs rated themselves as confident in prescribing for older patients and this was significantly associated with their knowledge score (p = 0.02). **CONCLUSIONS:** The study showed low confidence in prescribing for older patients coupled with inadequate knowledge about IP in more than half of the participants. Educational program regarding geriatric pharmacotherapy is needed to boost HCP’s knowledge and confidence in prescribing for older patients.

**PHP182: THE EFFECT OF CHRONIC DISEASES, FINANCIAL HARDSHIP AND PERSONALITY TYPES IN PATIENT’S MEDICATION ADHERENCE**

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**OBJECTIVES:** Medication adherence has been shown to be associated with the nature of the disease being treated and characteristics of the prescribed treatment. Non-adherence typically ranges between 30–50% of all patients. In addition, patients’ beliefs about health and illness and their behavioral expressions of their personality types may be important contributors to medication adherence. The objective of this study was to describe the associations between disease type, financial hardship and four personality temperaments (Traditionalists, Experiencers, Idealists, Conceptualizers) with self-reported medication adherence. **METHODS:** Data were collected from the 2015 National Consumer Survey of the Medication Experience and Pharmacists’ Roles, via an on-line, self-administered survey coordinated by Qualtrics Panels in the United State of America, between April 28, 2015, and June 22, 2015. Data were analyzed using IMB/SPSS version 24.0 software. Logistic regression analysis and descriptive statistics were used. **RESULTS:** Out of 26,173 responses, 12,195 were taking at least one prescription medication and were not a licensed health professional, making them eligible for this study. Of these, the highest proportion of non-adherence among those without financial hardship was shown in breathing problems disease (37%), and least was in cancer (19%). Among those with financial hardship, non-adherence increased significantly (listed from the highest increase to lowest) to 41% for cancer, 40% for heart disease, 48% for diabetes, 45% for arthritis, 50% for obesity, and 44% for stroke. Of the four personality types, Experiencers had the highest rate of non-adherence and Traditionalists were the lowest in all disease types regardless of financial hardship. Logistic regression models showed that disease type, financial hardship, and personality type all affected the likelihood of non-adherence. **CONCLUSIONS:** In addition to acknowledging disease and treatment characteristics, financial hardship and personality type are important considerations for improving adherence to medications.

**PHP183: WHY DO PEOPLE PARTICIPATE IN HEALTH-RELATED PREFERENCE STUDIES? A DISCRETE-CHOICE EXPERIMENT**

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OBJECTIVES: Patient and citizens are increasingly asked to participate in surveys about health to promote community centeredness. Ethical standards govern how one might interact with respondents, but there is a paucity of research asking what potential respondents want out of this type of research. We sought to document the preferences and motivations of potential respondents to survey research. METHODS: Respondents from a national panel completed a discrete-choice experiment comparing pairs of potential studies respondents could participate in at a local hospital. Studies were defined across six attributes (validity, relevance, bias, burden, time, and reimbursement) with three possible levels each. A D-efficient design resulted in three blocks of 12 tasks. A choice model was estimated using a continuous coded mixed logit and latent class analysis (LCA). After completing the survey respondents were asked which motivating factors they used to justify their choices from pre-defined list of factors that were identified through community engagement. RESULTS: 629 people participated in the survey. Participants valued validity (OR=2.4), relevance (OR=1.8), and minimizing bias (OR=1.7) the most. A 2-class LCA confirmed that the majority of participants (76%) valued quality indicators, but 24% of respondents strongly valued incentives such as increasing reimbursement (OR=3.4) or decreasing time (OR=1.3). While both groups had similar motivations, the quality-focused class was more likely to be motivated by “measuring real preference” (p<0.001) and “benefits to society” (p=0.009). CONCLUSIONS: Given the increase in studies focused on patient and community centeredness, the paucity of preference-based research focused on what patients and citizens want out of research is surprising. Understanding the motivations of respondents is not only important in designing future studies, but also in interpreting the results of existing studies.

PHP185: BREAKFAST CONSUMPTION AND ASSOCIATED FACTORS AMONG STUDENTS IN OLABISI ONABANJO UNIVERSITY, OGUN STATE, NIGERIA.

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OBJECTIVES: This study therefore assessed the pattern of breakfast consumption in undergraduate students and its associated factors. METHODS: A cross-sectional study was carried out among 302 students of allied health sciences in Olabisi Onabanjo University, Sagamu, Ogun State, selected via multi-stage sampling. Data was collected with the aid of a semi-structured, self-administered questionnaire and analyzed using SPSS 20.0. Relevant descriptive and inferential statistics were calculated. Participation was fully voluntary. RESULTS: The mean age of respondents was 20±2 years, 73.5% of the participants were females while 26.5% were males. Only 32.5% of the respondents consumed breakfast on a daily basis while 67.5% skipped breakfast. About 4% of the total respondents ate breakfast weekly. Majority (67.9%) of the individuals had a low Individual Dietary Diversity Score (IDDS). There was a significant relationship between breakfast consumption and academic performance of the students (p=0.000) as well as breakfast consumption and eating outside the home (p=0.004). Out of the breakfast skippers in this study (67.5%) majority of them skipped breakfast due to time constraints as well as financial constraints. CONCLUSIONS: Majority of the respondents had no knowledge about the importance of breakfast consumption. The pattern of breakfast consumption of the respondents was irregular and was majorly influenced by time constraints, financial constraints and fasting purposes. Keywords: Breakfast, undergraduates, associated factors.

PHP185: THE ASSOCIATION BETWEEN MULTIMORBIDITY, SOCIOECONOMIC FACTORS, AND MULTIMORBIDITY-RELATED EXCESS HEALTHCARE USE - RESULTS FROM THE 2014 NATIONAL HEALTH INTERVIEW SURVEY

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OBJECTIVES: In a context of increasing aging of the population and rising number of chronic diseases, it is crucial to better understand multimorbidity and its impact. We measured the association between multimorbidity and socioeconomic factors, self-reported health status, and functional impact. Additionally, we measured the excess healthcare use (HCRU) related to multimorbidity. METHODS: Our sample included all people aged above 15 years old from mainland Portugal (7,944 men and 10,260 women) who participated in the fifth Portuguese National Health Interview Survey, conducted in 2014. We considered the following chronic conditions: hypertension, diabetes, coronary disease, stroke or myocardial infarction in the previous year, arthrosis, chronic back or neck pain, chronic obstructive pulmonary disease, asthma, allergy, kidney disease, urinary incontinence, liver cirrhosis, and depression. Multimorbidity was measured by the presence of two or more of these self-reported conditions. Linear/logistic regression models were used to assess the association between number of chronic diseases/multimorbidity and relevant factors. RESULTS: Overall, 42% of participants reported multimorbidity. The likelihood of having multimorbidity increased with age (OR:1.30, 95%CI:1.27-1.33) and female gender (OR:1.90, 95%CI:1.69-2.14). The number of chronic conditions and multimorbidity were associated with lower educational level, lower income, worse self-rated health status, and lower functional capacity. In addition, participants with multimorbidity reported higher HCRU, namely general practice appointments (86.9% vs. 66.5%; p<0.0001), specialist appointments (58.6% vs.
40.5%; p<0.0001), and hospital admissions (6.1% vs. 3.1%; p<0.0001) in the previous 12 months, compared with those without multimorbidity. We observed a 25% increased risk of hospitalization per additional comorbidity (OR:1.25, 95%CI:1.20-1.29). **CONCLUSIONS:** Multimorbidity is associated with key socioeconomic factors, worse health status and reduced functional capacity. It also seems to generate greater healthcare consumption, particularly hospitalizations. Given the expected rise of this condition, health systems should prioritise patients with multimorbidity as well as those at higher risk, given the identified factors.

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**PHP186: THE COMPARISON AMONG DIFFERENT COUNTRIES’ EQ-5D-5L VALUE SETS APPLIED IN CHINESE GENERAL POPULATION**

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**OBJECTIVES:** EQ-5D-5L value sets have been estimated in several countries: China, Korea and Canada etc. The value sets can be used to generate utility in both general population and disease population. The object of this work is to study the difference of health utilities calculated by China and six other countries’ EQ-5D-5L value sets (Dutch, Spain, England, Uruguay, Korea and Canada) which are applied in Chinese general population, and to explore the cross-cultural adaptation of different EQ-5D-5L value sets. **METHODS:** In this study, the difference of health utilities among 7 countries’ EQ-5D-5L value sets applied in Chinese general population were analyzed. **RESULTS:** Among the 371 participants who were face-to-face interviewed in Nanjing, China, 241 have completed the EQ-5D-5L questionnaires. The mean health utility calculated by China value set is the second highest (0.963), while the highest and lowest is Uruguay (0.983) and Korea (0.935), respectively. In terms of the difference in mean utility regarding sex and samples with or without chronic diseases, conclusions are consistent. The variation of utility is biggest in Dutch (0.505~1), while Uruguay is the smallest one (0.800~1). When it comes to China (0.647~1), it just has a larger utility range than Dutch and Canada (0.620~1). **CONCLUSIONS:** The estimation of EQ-5D-5L value sets are based on local people’s health preference and affected by culture, social environment, as well as economic development. China value set of EQ-5D-5L is available now, it’s more appropriate to apply it in Chinese general population.

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**PHP187: PREFERENCES OF THE GENERAL PUBLIC FOR REIMBURSEMENT CRITERIA FOR EXPENSIVE DRUGS: A MULTI CRITERIA DECISION ANALYSIS FOR RITUXIMAB AND BEVACIZUMAB**

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**OBJECTIVES:** Policy makers increasingly have to make complex reimbursement decisions involving making trade-offs between multiple potentially conflicting criteria. This study aims to assess the general public’s preferences for reimbursement criteria for two expensive drugs by means of multi criteria decision analysis (MCDA). **METHODS:** MCDA was conducted for rituximab in rheumatoid arthritis (RA) and non-Hodgkin lymphoma (NHL) and bevacizumab in metastatic breast cancer (MBC) and non-small cell lung cancer (NSCLC). Criteria selection was based on a literature review and included health economic-related criteria (costs per patient per year, quality of life, budget impact, life prolongation and side-effects) and other criteria (availability of alternatives, disease severity, and disease rarity). Preferences were elicited using the swing weighting method. Respondents were recruited through social media and our personal network. Overall scores (0-1 scale) were calculated per alternative by multiplying standardized performance scores with standardized criteria preferences. **RESULTS:** Based on the respondent’s (n=143) criteria preferences, the reimbursement criterion quality of life ranked highest (0.81), followed by life prolongation (0.69), disease severity (0.68), availability of alternatives (0.67), and side-effects (0.59). Costs per patient per year (0.58), budget impact (0.49) and disease rarity (0.45) ranked lowest. Rituximab in RA and NHL attained the highest overall score (0.60 and 0.52 respectively) and bevacizumab in MBC and NSCLC the lowest (0.46 and 0.40 respectively). The overall score of rituximab in RA was mainly attributable to high performance scores for disease severity, side-effects, and costs per patient per year. **CONCLUSIONS:** MCDA can facilitate reimbursement decision making as it quantifies both an overall score of each alternative and the relative importance of multiple criteria. This study shows that disease burden and unmet need were valued more importantly than cost-criteria. This information may support policy makers in making trade-offs between potentially conflicting criteria in reimbursement decision making for expensive drugs.

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**PHP188: COMPARATIVE EFFECTIVENESS AND SAFETY OF MEDICAL ABORTION FOR SECOND-TRIMESTER PREGNANCY TERMINATION: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS**

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OBJECTIVES: Unsafe abortion is one of major causes of illness and death of pregnancy. Medications for second-trimester abortion had been investigated, but the optimal regimen had not been specifically compared. METHODS: We performed a systematic review and network meta-analysis by including randomized controlled trials (RCTs). The following databases were searched: Medline (PUBMED), EMBASE, Cochrane Central Register of Control Trials, CIINAHL (EBSCO), Web of science, WHO trial registry and ClinicalTrial.gov, up until Dec 31, 2015. Studies of medical abortions for second-trimester pregnancy were included. The primary outcome was success abortion within 24 hours. This study was registered with PROSPERO (CRD42015026888). RESULTS: We identified 1136 studies from searching, 56 randomized controlled trials were included. Regarding to the second-trimester pregnant 7636 patients, which had social or medical indication to terminate pregnancy were included in this analysis. Form network meta-analysis, that oral mifepristone then buccal misoprostol found the highest efficacy (RR 2.75, 95%CI 2.07-3.66, P <0.001, SUCRA 92.8%). For adverse event (severe bleeding), vaginal gemeprost showed the highest safety (RR 6.65, 95%CI 0.35-124.98, P =0.206, SUCRA 81.5%). Comparing efficacy and safety together, oral mifepristone 200 mg then buccal misoprostol 400 mcg every 3 hours had the highest efficacy and safety. CONCLUSIONS: Oral mifepristone 200 mg then buccal misoprostol 400 mcg every 3 hours was the best treatment option in medical abortion regimen for second-trimester pregnancy termination due to its most efficacy and safety profiles. Before clinical implication, further large randomized clinical trials are warranted.

PHP189: EVALUATING HEALTH IMPACT OF COMMON CHRONIC CONDITIONS ON QUALITY OF LIFE OF EQ-5D-3L IN OLDER CHINESE

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OBJECTIVES: This study aimed to estimate the loss of health-related quality of life (HRQOL) associated with common chronic conditions in older Chinese population. METHODS: Weitang Geriatric Diseases Study is a community-based health survey on 5,557 Chinese aged 60 years or older. The study population was measured with EQ-5D-3L for HRQOL assessment. We also assessed the coexisting chronic conditions of depression, cognitive dysfunction, stroke, heart disease, diabetes, hypertension, obesity, hyperlipidemia and visual impairment based on self-completion questionnaires, biomarkers and medical records. Ordinary Least Square regression was performed to model the relationship between the conditions and the EQ-5D-3L index scores. The robust standard error (RSE) estimator was adopted to calculate 95% confidence interval (CI) for parameter coefficients. RESULTS: The mean EQ-5D-3L representing overall HRQOL was 0.954 (standard deviation: 0.081) with 70% of participants reporting full health. After controlling for socio-demographic characteristics and comorbidities, depression, stroke, heart disease and cognitive dysfunction had significantly adverse impact on the EQ-5D index score. The respective coefficients (95% CI) of each condition were -0.191 (-0.233, -0.150), -0.052 (-0.086, -0.019), -0.019 (-0.029, -0.010), and -0.016 (-0.024, -0.008). CONCLUSIONS: Chronic conditions were found to contribute to HRQOL loss in older Chinese population. The utility and utility decrement estimated can be used for quality-adjusted life-year calculation.

PHP190: COMPRENDIUM OF METHODS FOR MEASURING PATIENT PREFERENCES IN MEDICAL TREATMENT

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OBJECTIVES: Patient preference studies are taking on an increasingly important role in the medical product lifecycle. While there are numerous industry, academic, regulatory and patient group efforts addressing standards, quality and proper application of preference studies, there is limited understanding of the range of methods to assess preferences and the trade-offs between them. To develop evidence-based recommendations to guide different stakeholders on how and when patient preference studies should be performed, we developed a comprehensive overview of patient preference exploration and elicitation methods. METHODS: We used a three-step approach to identify existing preference exploration (qualitative) and elicitation (quantitative) methods: 1) listing methods identified in previous preference method reviews; 2) conducting a systematic literature review on 4,572 unique papers identified through multiple scientific databases, using English full-text papers published between 1980 and 2016; and 3) having discussions with international experts (N=14) in the field of health preferences and/or medical decision making to validate the methods found. RESULTS: We identified 32 unique preference methods: 10 exploration and 22 elicitation methods. Consensus was reached among the experts interviewed to cluster exploration methods in three main groups: “Individual techniques”, “Group techniques” and methods that were both “Individual and Group techniques”. Elicitation methods were clustered in four groups: “Discrete Choice Based related techniques”, “Conjoint analysis related techniques”, “Iterative ranking related techniques”, and “Other related techniques”.

PHP191: EVALUATING THE EFFECT OF SUGAR-SWEETENED SOY DRINK ON DENTAL CARIES IN 6-8-YEAR-OLD CHINESE CHILDREN

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OBJECTIVES: Previous studies have shown that sugar-sweetened drinks can contribute to dental caries. Whether sugar-sweetened soymilk can reduce the occurrence of dental caries in Chinese children has not been evaluated. METHODS: In this randomized controlled trial, 48 children (12 boys and 36 girls) aged 6-8 years old were randomly divided into two groups. The intervention group consumed 350 ml of sugar-sweetened soymilk per day, while the control group consumed 350 ml of water per day for 6 months. The primary outcome was total decayed, missing or filled teeth (DMFT). RESULTS: The mean DMFT in the intervention group was 0.23, while it was 0.51 in the control group (P = 0.008). CONCLUSIONS: Consumption of sugar-sweetened soymilk can significantly reduce the occurrence of dental caries in Chinese children.
“Indifference Choice Based related techniques”, “Rating related techniques” and “Ranking related techniques”. **CONCLUSIONS:** This study identified 32 unique methods for exploring and measuring patient preferences, and reached consensus in clustering the methods. This compendium is a resource for researchers in the patient preference field and also serves as the basis to conduct additional studies that appraise the methods and determine which methods are most appropriate for measuring patient preferences in which phase of the medical product lifecycle to support patient-centric decision making.

**PHP191: MINIMALLY IMPORTANT DIFFERENCE: EMPIRICAL COMPARISON OF ESTIMATION METHODS USING ORTHOPAEDICS AND OTOLARYNGOLOGY**

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**OBJECTIVES:** The concept of minimally important difference (MID) is defined as the smallest change on a patient-reported outcome (PRO) questionnaire that a patient considers meaningful. There is currently little guidance on selecting the appropriate MID method or for interpreting MID results. In addition, studies rarely differentiate between effect-size-based (MIDE) estimates, which can be used for sample size determination, and observed-change-based (MIDC) estimates which can be used for interpreting changes in scores. This study compared MID estimation methods in two PROs to provide empirical evidence on the 1) efficiency of different MID estimation methods, 2) the difference between MIDE and MIDC estimates, and 3) the relative magnitude of MID estimates across different PROs. **METHODS:** This study was a retrospective analysis of observational data from patients undergoing elective surgery for chronic rhinosinusitis or end-stage ankle arthritis. The PROs investigated were the Sino-Nasal Outcome Test (SNOT-22) and the Ankle Osteoarthritis Scale (AOS). The study applied three distribution-based MID methods and three anchor-based MID methods. Bootstrap 95% confidence intervals were used to assess efficiency. **RESULTS:** 123 patients were included for the SNOT-22 and 238 patients were included for the AOS. MIDE estimates were much smaller in magnitude than MIDC estimates for both the SNOT-22 and AOS. MIDC estimates were similar for both instruments. The mean change method produced the widest confidence intervals for both the MIDE and MIDC. **CONCLUSIONS:** Because it produces unstable and inefficient estimates, the popular mean change method should be discontinued in favor of regression-based methods that use the entire study sample. This study found a two-fold difference between MIDE and MIDC estimates – therefore, studies should clearly differentiate between measurement objectives. Consistent with previous research, one-half standard deviation and the standard error of measurement most closely matched anchor-based methods for MIDE.

**PHP192: THE FRENCH COMPASSIONATE PROGRAM “TEMPORARY AUTHORIZATION FOR USE” AND THEREAFTER... HOW CAN IT AFFECT DRUG MARKET ACCESS?**

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**Objectives** “Temporary Authorization for Use” (ATU) is a French compassionate program allowing the use of drugs before their marketing authorization (MA). Only hospital pharmacies are allowed to deliver these drugs, even for outpatients. After the MA, the reimbursement is maintained during the HTA assessment and national agreements on reimbursement and price. This period, so-called “post-ATU” and that has been reframed in 2014, should not exceed 180 days as it sustains a “free pricing window” for pharmaceutical companies. The aim of this study is to assess the economic impact of the post-ATU period from the hospital perspective and to identify the determinants of its duration. **Methods** We included all drugs that have been through the post-ATU process since 2014. We censured data in May 2017. The financial impact was calculated for the 37 public hospitals of Paris (AP-HP), the largest university hospital in France. We conducted univariate analyses between potential explicative variables and wait time to obtain price and reimbursement. Drugs prices were based on APHP’s acquisition prices. **Results** 62 International Nonproprietary Name (INN) have been through the post-ATU period, among which 26 are still on the post-ATU list. In 2016, post-ATU expenditures have totaled €85.2 million for AP-HP (8.4% of APHP’s drug global budget). The post-ATU period has lasted 469 days in average (median: 446; min: 92; max: 1064). Only 1 INN has respected the regulatory deadlines. There is a significant correlation between increasing of post-ATU duration and orphan drugs status (p value = 0.01). There is no correlation with therapeutic areas, and surprisingly, no correlation with drug prices. **Conclusions** Post-ATU drugs represent an important financial burden for hospitals whereas these drugs are still under a derogation procedure. Results showed the difficulty to sustain innovation without create perverse effects as the duration found here is largely higher than usual delays of negotiation.

**PHP193: ESTIMATING THE REFERENCE ICER FOR AUSTRALIA AND PUBLIC PERCEPTIONS TOWARD ITS USE**
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OBJECTIVES: Economic evaluations are used to help determine whether new health technologies represent value for money. Under a fixed budget, an empirical estimate of the opportunity cost of funding decisions provides a reference value below which the Incremental Cost-Effectiveness Ratio (ICER) of a new technology can be considered value for money. A key barrier to adopting the estimated opportunity cost as a reference ICER in decision making is the perceived negative community response. METHODS: National data on healthcare spending and mortality outcomes are used to estimate the per capita mortality-related QALY gains using Instrumental Variable Two-Stage Least Squares regression. Population-level change in Health-Related Quality of Life (HRQoL) is estimated using a fixed effects model from a longitudinal, panel survey to generate per capita morbidity-related QALY gains. The reference ICER is estimated from the combined per capita mortality- and morbidity-related QALY gains. Community preferences for price reductions and willingness to accept potential consequences are sought using a nationally representative online survey. RESULTS: Results indicated that healthcare spending had a significant impact on mortality-related QALYs lost (β=-1.6, p<0.001), resulting in a per capita mortality-related QALY gain of 0.0013. There was a significant improvement in the annual time trend for population-level HRQoL (β=0.0026, p<0.001) generating a per capita morbidity-related QALY gain of 0.0066. The base case estimate of the reference ICER for Australia is less than AUD30,000 (95% CI AUD20,758, AUD37,667). Public preferences and willingness to accept potential consequences of using this estimate will be explored. CONCLUSIONS: There is no explicit use of a reference ICER in key decision making committees in Australia, though evidence suggests funding is less likely with an ICER greater than AUD45,000/QALY. The reference ICER estimated here suggests that for every QALY gained from a health technology with an ICER of AUD45,000/QALY, 0.5 QALYs are lost elsewhere in the healthcare system.

PHP194: PAYING FOR GENE THERAPIES: APPROACHING A SUSTAINABLE SOLUTION

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OBJECTIVES: 1. To develop a framework that captures pricing and reimbursement challenges faced by gene/cell therapies in the context of current healthcare pricing and reimbursement systems; 2. To identify alternate payment and funding models from within the biopharmaceutical industry, and from broader industries, that may overcome those challenges for gene/cell therapies; 3. To conduct a feasibility assessment of those alternate models for future gene/cell therapies in the context of current EU5 healthcare pricing and reimbursement systems. METHODS: To understand the challenges faced by gene/cell therapies, a targeted review of current pricing and reimbursement decisions for marketed gene/cell therapies was conducted, supplemented with expert interviews. Innovative pricing and funding models within the biopharmaceutical industry and across broader industries were identified by conducting a targeted review of materials available in the public domain. A feasibility analysis was conducted to explore in which countries these pricing and funding models might be feasible, and what, if any, healthcare system adaptations would be required. RESULTS: Six distinct challenges were identified and broadly segmented into those associated with payment and funding (e.g., one-off up-front payment required for curative therapies), and those associated with assessing value (e.g., uncertainty around long-term effect). Eight innovative pricing and funding models were identified and described: payment-by-results, partial or full capitation, amortisation, annuity, prize funding, reinsurance, and framework contracting. Payment-by-results and capitation models were found to offer the most feasible solutions for gene/cell therapy pricing and reimbursement in select European countries. Considerable legislative/policy changes were considered necessary for the successful implementation of other models in EU5. CONCLUSIONS: Existing pricing and funding models are insufficient to support a sustainable gene therapy business model. National or regional legislative change may be required to achieve a sustainable solution.

PHP195: VALUING HEALTH AT THE END OF LIFE: AN EXAMINATION OF FRAMING EFFECTS AND STUDY DESIGN CONSIDERATIONS

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OBJECTIVES: A number of recent studies have examined the extent of public support for an ‘end-of-life premium’ – that is, whether people place greater weight on a unit of health gain for end-of-life patients than on that for other types of patients. The objective of this study is to assess whether any observed preferences regarding an end-of-life premium are affected by framing effects and study design considerations, such as the perspective used to elicit preferences and whether or not visual aids and indifference options are included in the survey. METHODS: Preferences were elicited from a representative sample of the UK general public using an online survey (n=2401). Respondents were randomly allocated to one of six study arms, each of which applied a different framing. The study design was informed by the National Institute for Health and Care Excellence's supplementary policy appraising life-extending end-of-life treatments. The choice tasks involved asking respondents which of two
hypothetical patients they would prefer to treat, assuming there were enough funds to treat only one of them. Respondents were also asked a series of attitudinal questions examining their support for general health care priority setting policies. Comparisons between arms and between tasks were assessed using the Pearson’s chi-squared test. RESULTS: The overall results were not consistent with an end of life premium. Respondents’ choices were found to be sensitive to the choice of perspective, and to the inclusion of indifference options and (to a lesser extent) visual aids. However, in none of the study arms did a majority of respondents choose to prioritise the treatment of the end of life patient. CONCLUSIONS: The findings demonstrate the influence of framing effects and study design considerations in stated preference research. Researchers should seek to control for such effects when seeking to examine people's health care priority setting preferences.

PHP196: DO CHANGING ATTITUDES TO DEATH HAVE IMPLICATIONS FOR NATIONAL TARIFFS FOR HEALTH STATES? RESULTS FROM AN EXAMINATION OF ATTITUDES TO EUTHANASIA IN THE REPUBLIC OF IRELAND.

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OBJECTIVES: Many religions teach that life has intrinsic value regardless of the condition in which it is experienced. Those who adhere to such religions may be less likely to assign “worse than dead” values to health states or favour access to services such as euthanasia when quality of life is poor. Quantitative methods may be useful in understanding more precisely the role religious adherence and attitudes on access to euthanasia may have on the propensity to assign worse than dead values. METHODS: Using the EuroQol Valuation Technology (EQ-VT), EQ-5D-5L valuation tasks were administered to a sample of 153 residents of the Irish Republic in 2016. Individuals provided data on attitudes to physician provided euthanasia as well as how frequently they attended religious services. Each respondent provided 10 time trade-off valuations for health states drawn at random. Data were analysed using a recursive bivariate probit (RBP) in which endogeneity related to attitudes to euthanasia was identified and addressed in a model examining propensity to assign worse than dead values. RESULTS: 96% of respondents whose religion was identified were Roman Catholic. A Wald test revealed that attitudes to euthanasia were endogenous at p<0.01. RBP results revealed that those who favour access to euthanasia were 30 percentage points (p<0.01) more likely to assign worse than dead values than those who were not. Those who were older were also more likely to exhibit a higher propensity to assign worse than dead values. CONCLUSIONS: Religious adherence and attitudes to euthanasia are examples of social norms. These may influence the values assigned to health states. Societies undergoing social change may experience shifts in social norms that impact on values and the distribution of values assigned to health states in national tariffs. This will have implications for value sets and the frequency with which they require revision.

PHP197: A SYSTEMATIC REVIEW TO EVALUATE THE ASSOCIATION BETWEEN MEDICATION ADHERENCE AND PERSONALITY TRAITS

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OBJECTIVES: Medication adherence is a matter of concern for clinicians, healthcare systems, and payers. We empirically evaluated the association between prescription medication adherence and personality traits. METHODS: PsycINFO®, Embase®, MEDLINE®, and CINAHL were searched from database start to January 2017. Studies assessing impact of personality constructs on medication adherence in patients with chronic conditions (hypertension, heart failure, HIV, diabetes, asthma, dialysis, organ transplant, etc.) were included in the review. Screening and data extractions were conducted by two independent reviewers, and any discrepancies between reviewers were reconciled by a third independent reviewer. RESULTS: A total of 9980 individual references were identified through database searches. Personality was found to be associated with adherence across 47 included studies. Prospective observational cohort design was employed in 47% of the included studies. Self-report for measuring adherence was used in 63% of the studies. Neuroticism (16 studies), openness to experience (10 studies), hostility (5 studies), and extraversion (4 studies) were the most commonly investigated personality traits associated with non-adherence. Conscientiousness (17 studies), extraversion (13 studies), and agreeableness (12 studies) were most commonly reported personality traits associated with good adherence. In a random effects logistic regression analyses, neuroticism was associated with medication non-adherence (<80% of prescribed pills), with an increase in SD by 1 in neuroticism associated with a 4.2% (95% CI: 0.3, 6.1); p<0.05 increase in probability of non-adherence. Conscientiousness was positively related to adherence, indicating that individuals scoring high tended to be more adherent to treatment, β (SE) = 0.049 (0.018); p<0.01. CONCLUSIONS: Although a correlation was observed between personality traits and medication adherence, the results of the study should be interpreted with caution due to heterogeneity across the studies including study design, population, personality inventories, and statistical techniques.
OBJECTIVES: The PPEP is a national programme supported by Welsh Government, Welsh health boards and the NHS Wales Informatics Service, with the aim of providing an electronic platform for data collection across the country. The programme has been funded via the Welsh Government Efficiency through Technology Fund. Its purpose is to make patient-level data available during clinic consultations, and collated data to be analysed for clinical effectiveness assessment and benchmarking. METHODS: Patients are invited to submit PROMs at baseline and post-treatment. Tools are available for completion in English and Welsh, and are currently collected at home via a website or in-clinic via tablet computers. Collected data for all consenting patients include the EQ5D, co-morbidities, BMI, employment status and work productivity impairment, as well as lifestyle information such as smoking history, alcohol intake and exercise levels. Condition-specific tools are in use for 3 conditions, while a further 15 condition specific PROMs and a generic PREMs survey will be available imminently. The platform is currently being piloted in 4 of the 7 health boards in Wales with all consenting responses linked to clinical data. RESULTS: 2,263 generic PROMs have been collected by consenting patients at Cardiff & Vale University Health Board. Analysis confirmed that the 72.2% of responding patients who do not meet the national exercise guideline had worse health scores than those who do (p<0.01). Furthermore the 25.8% of patients with high blood pressure and the 60.7% who are overweight/obese also had worse generic health scores (p<0.01). CONCLUSIONS: Such data analyses will facilitate service improvements while informing patient and clinician decision making as part of the prudent healthcare agenda. The platform has allowed large dataset collection in a small space of time, with the programme continuing to capture datasets for chronic and acute conditions across Wales.
univariate association with mortality and principal components analysis within disease categories. To derive a weighted index from the adjusted regression coefficients, we applied a scoring rule where each additional point reflected risk associated with a 5-years age increase. We assessed the predictive performance of the computed index in the validation population, using discrimination and calibration measures. **RESULTS:** Adjusted Odds Ratios (95% confidence interval) for the fifteen selected conditions ranged from 1.35 [1.31-1.38] for Depression, 1.36 [1.32-1.40] for Rheumatic or connective tissue diseases, to 3.89 [3.72-4.07] for End-Stage Renal disease, 4.06 [4.01-4.11] for Cancer. Score values were monotonically related to mortality. The weighted index had a higher discrimination (c-statistic=0.825) than age and gender (c-statistic=0.761) or count of all-56 available morbidity variables (c-statistic=0.790). Within each score value, predicted probability was included in the 95% confidence interval of observed mortality proportion. **CONCLUSIONS:** We computed a performant score to study multimorbidity in the French context. Such predictive measures could be externally validated in large medico-administrative databases with routinely collected morbidity information.

**PHP201: THE PREVALENCE OF CHRONIC HEALTH CONDITIONS AND MULTIMORBIDITY IN THE PORTUGUESE POPULATION - RESULTS FROM THE 2014 NATIONAL HEALTH INTERVIEW SURVEY**

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**OBJECTIVES:** In a context of severe population aging, knowing the prevalence of chronic diseases and multimorbidity is crucial to evaluate healthcare needs, as these are the most costly health conditions. We measured the prevalence of self-reported chronic health conditions multimorbidity in the adult Portuguese population for the year 2014. **METHODS:** Our sample included all people aged above 15 years old from mainland Portugal (7,944 men and 10,260 women) who participated in the fifth Portuguese National Health Interview Survey, conducted in 2014. We considered the following chronic conditions: hypertension, diabetes, coronary disease, stroke or myocardial infarction in the previous year, arthrosis, chronic back or neck pain, chronic obstructive pulmonary disease, asthma, allergy, kidney disease, urinary incontinence, liver cirrhosis, and depression. Multimorbidity was measured either by the presence of two or more of these self-reported chronic conditions. **RESULTS:** Chronic back pain was the most prevalent self-reported condition (32.9%), followed by hypertension (25.3%), neck pain (24.1%), arthrosis (24.1), allergy (19.4%), depression (11.9%) and diabetes (9.3%). Multimorbidity affected 42% the population, was higher among women (49.7%), and increased sharply with age (age ≥ 65 yo: 78.8%) and decreasing education (high: 47.3%; low: 47.3%; and no education: 81.0%). **CONCLUSIONS:** Multimorbidity was commonly found in the Portuguese population, especially among women and low-educated people. The co-occurrence of chronic health conditions increased sharply with age. These findings highlight the relevance of the issue, in particular amongst the most vulnerable groups.

**PHP202: VARIATION IN OPIOID UTILIZATION BY PHYSICIAN SPECIALTY AND PAYER USING A LINKED CLAIMS-EMR DATABASE**

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**OBJECTIVES:** To describe variation in opioid utilization by provider specialty and payer among patients in the US. **METHODS:** The IBM® MarketScan® Explorys® Claims-EMR Data Set was used to identify patients with a new opioid claim (index date) in 2015. These data link patient-level claims found in the MarketScan Databases with data for the same patients in the IBM Explorys electronic medical records dataset. Six months of pre-index and 12 months of post-index continuous enrollment was required to establish a new opioid episode and to assess opioid use in the subsequent year. The primary outcome was the number of opioid prescription claims and associated days supply. Opioid use was stratified by initial provider specialty and payer type. **RESULTS:** A total of 176,282 patients met the study inclusion criteria (mean age 56.2 [SD=16.0]; 59.6% female). The mean days supply (DS) on the first opioid claim was 14.2 days [SD=16.7]. On average, patients received 4.9 [SD=5.4] opioid claims with total DS of 92.5 [SD=126.9]. Average number of opioid claims and total DS for the year was similar among family practitioners (4.8 claims, 88.7 DS) and emergency medicine doctors (4.8 claims, 80.3 DS). Higher number of claims and total DS was seen for patients who saw an oncologist (5.7 claims, 110.9 DS), orthopedist (5.6 claims, 108.3 DS), or surgeon (5.7 claims, 108.6 DS), while pain specialists had the highest rates (9.3 claims, 210.7 DS). Pediatricians (3.0 claims; 43.1 DS) and OB/GYN practitioners (3.4 claims; 51.9 DS) had similarly lower opioid utilization. Overall, opioid utilization was slightly higher among Medicare (5.7 claims, 125.2 DS) than privately insured (4.7 claims, 83.8 DS) or Medicaid (5.1 claims, 86.2 DS) patients. **CONCLUSIONS:** There was substantial variation by provider specialty and payer on top of higher than expected overall opioid utilization among patients starting a new opioid treatment episode in 2015.
MULTIPLE LINEAR REGRESSION was used not only to analyze the association multimorbidity with health status and identify conditions may have declined more rapidly in health status. In many case, activities of daily living (ADL) is associated with health status. OBJECTIVES: The generation and selection of items is key in the development of any quality of life instrument. Advances in technology over recent years has enabled a range of methodologies for item selection to become more accessible to instrument developers. The aim of this study is to provide a contemporary overview of methods for item selection recommended in guidelines and methods by instrument developers. METHODS: A focused review of key standards and guidelines was used to identify recommended methods and psychometric assessments. A systematic review of the literature was conducted to identify the methods used in empirical studies reporting development processes of descriptive systems and additional methods not included in the guidelines. The search was conducted using COSMIN’s precise search filter for measurement properties, restricted to include health related quality of life studies focusing on development of descriptive systems, and 553 abstracts were identified. Supplementary searches were conducted by reviewing bibliographies and citations of the included studies. RESULTS: Eleven guidance documents and 61 full text articles were included. Item generation involved three approaches: developing items de novo, identifying items from several existing measures or using a single measure to derive a short form measure. Item selection was determined using statistical analyses in datasets containing completed questionnaires. A staged approach was used to establish dimensions first, with exploratory factor analysis or principal component analysis, before finalising items in each dimension, using item response theory, Rasch or structural equation modelling. These measurement models established construct validity and in most cases further psychometric properties were assessed. CONCLUSIONS: It was common practice to establish dimensionality of the dataset before carrying out item selection. Few of the statistical methods identified are interchangeable in terms of purpose, but may generate very different instruments. The developers seldom explained why one statistical model was chosen over another.

OBJECTIVES: Screening is the use of different tests on a healthy person to detect diseases prior to developing symptoms. The aim of the study is to highlight the extent of adherence to screening practices among healthcare professionals working in a tertiary care center. METHODS: A cross-sectional study using self-administered questionnaire was conducted among physicians, nurses and pharmacists. The questionnaire consisted of demographics, past medical history, knowledge of screening tests, and medical screening questions, was distributed as a hard copy. Adherence was defined as 50% and above. Participants were selected at random, using stratified random sampling. Interval variables were reported in terms of mean and standard deviation. Categorical variables were reported in terms of count and percent. Analysis was done using SAS V9.4 RESULTS: 231 nurses, 129 physicians, and 19 pharmacists had filled the questionnaire. Physician’s age was 35.57±10.08, nurses’ 35.46±8.63, pharmacists’ age was 29.17±7.09 years. Diabetes screening was done by 65(52.85%) physicians, 100(49.02%) nurses, 11(61.11%) pharmacists (p=0.392). Breast cancer screening among females with positive mammogram (age ≥40 years) was among 73(57.03%) physicians, 115(50.66%) nurses, 11(57.89%) pharmacists. CONCLUSIONS: Awareness campaigns are needed for better understanding and adherence of recommended medical and cancer screening guidelines.

OBJECTIVES: As the population grow older, many people suffer from multimorbidity. OBJECTIVES: The generation and selection of items is key in the development of any quality of life instrument. As the population grow older, many people suffer from multimorbidity. OBJECTIVES: The generation and selection of items is key in the development of any quality of life instrument. Advances in technology over recent years has enabled a range of methodologies for item selection to become more accessible to instrument developers. The aim of this study is to provide a contemporary overview of methods for item selection recommended in guidelines and methods by instrument developers. METHODS: A focused review of key standards and guidelines was used to identify recommended methods and psychometric assessments. A systematic review of the literature was conducted to identify the methods used in empirical studies reporting development processes of descriptive systems and additional methods not included in the guidelines. The search was conducted using COSMIN’s precise search filter for measurement properties, restricted to include health related quality of life studies focusing on development of descriptive systems, and 553 abstracts were identified. Supplementary searches were conducted by reviewing bibliographies and citations of the included studies. RESULTS: Eleven guidance documents and 61 full text articles were included. Item generation involved three approaches: developing items de novo, identifying items from several existing measures or using a single measure to derive a short form measure. Item selection was determined using statistical analyses in datasets containing completed questionnaires. A staged approach was used to establish dimensions first, with exploratory factor analysis or principal component analysis, before finalising items in each dimension, using item response theory, Rasch or structural equation modelling. These measurement models established construct validity and in most cases further psychometric properties were assessed. CONCLUSIONS: It was common practice to establish dimensionality of the dataset before carrying out item selection. Few of the statistical methods identified are interchangeable in terms of purpose, but may generate very different instruments. The developers seldom explained why one statistical model was chosen over another.

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the mediating effect of ADL. **RESULTS:** Mediator analysis revealed that the indirect effect of multimorbidity on SRH through the proposed mediators was significant (b=0.112, p<0.001) with an explained variance of adj. R2 = 0.48. We found that functional health and physical limitations such as Activities of Daily Living partially mediate the association between multimorbidity and SRH. Firstly, multimorbidity was a powerful and important determinant of SRH. The effect of physical limitation, ADL, was also significant and remarkable factors about SRH. All analyze was performed with control variables such as SES, lifestyle. **CONCLUSIONS:** Self-rated health is a very individual index of general health. It is influenced by multiple chronic condition, functional and physical health. In an aging society, young people will not be sufficient to care for the elderly. Self-care will be a factor to improve the health status of the old people in the elderly society.

**PHP206: DISPUTE ISSUES ABOUT THE HEALING AND HEALTH PROMOTION OF CHILDREN**

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**OBJECTIVES:** Many parents ask the pediatrician, nurses and health visitors on the Internet forums about fever, not mandatory vaccinations, homeopathy, such as breastfeeding and moving development of the children. **METHODS:** We conducted a cross-sectional quantitative, descriptive survey and shared a questionnaire on a community page among parents with young children (n= 657) with convenience sampling in 2016. The data were analyzed with chi-square test, Mann-Whitney and Kruskal Wallis test. **RESULTS:** The participants 97.6% were female the average age was 32.69 year. The first-born children’s average age was 4.71 years. Highest percentage of the parents begin to calm the fever immediately (36.9%). Mostly, (86.9%) they didn’t agree with that fact they should damp the fever, only if the child is sick and don’t want to drink. The most popular antipyretic method was to give medicine (36%), and the cooling bath (22.4%), and only 3% of the parents use homeopathy in this case. Many parents reject the amber jewelry (81%). The 82.4% of the respondents given no mandatory vaccinations. The antipyretic attitudes influenced by the parent’s level of education (p<0.05) their knowledge level (p<0.05) and by the confidence in the doctors (p<0.05). In the groupup of those who are against the vaccination, there are more parents who use laying on of hands method for healing (p<0.05). The older ones (p<0.05) and the parents with higher level of education (p<0.005) agreed with the importance of the movement development and breastfeeding in higher rates. **CONCLUSIONS:** Our results draw attention to several current problem to the professionals. It would be important to start the education of the parents in time. The knowledge level and the trust in the doctors influenced the parents decisions. An unified, reliable and accessible source of information, or forum would be advisable, which help to serve the uncertain situations.

**PHP207: EQ-5D-5L POPULATION NORMS FOR MOSCOW (RUSSIA): INTERIM ANALYSIS**

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**OBJECTIVES:** To develop the EQ-5D-5L population norms for Moscow (Russia) based on a representative sample of city citizens. The aim of the interim analysis is to investigate feasibility of QoL measurement with the use of Russian version of EQ-5D-5L. **METHODS:** We used official Russian language paper and pencil version of EQ-5D-5L questionnaire provided by the EuroQol Group in the interview of Moscow adult population. To make our study representative, we used quota sampling, dividing Moscow into ten official administrative districts and using Russian Statistics Office (ROSSTAT) for the district, age and sex sampling. We collected data on: five EQ-5D-5L dimensions - mobility (MO), self-care (SC), usual activities (UA), pain/discomfort (PD), anxiety/depression (AD), subjective perception of quality of life (EQ VAS), respondents' education, salary, smoking status, use of the Internet, emotional problems, feeling calm and peaceful, type of settlement and geographical region of origin. **RESULTS:** From March to June 2017 we have interviewed 371 adult Muscovites (mean age 49.2 years; 57.7% females). Mean subjective perception of QoL measured by EQ VAS was 75.4 (SD 17.7). The dimension with the highest frequency of reported problems was PD 51.5%, followed by AD 46.1%, UA 35.3%, MO 31.5% and SC 11.1%. Any problems were more often in women (80.2%), than in men (67.1%). A group with unexpectedly high percentage or reported problems was 25-34 years age group. **CONCLUSIONS:** Interim analysis confirmed feasibility of QoL measurement with Russian version of the EQ-5D-5L. Preliminary results indicate some deviations from the typical picture of QoL limitations. We will continue collection of the data until the target sample of 1000 citizens. Interesting QoL trends in young population of Moscow will be investigated.

**PHP208: ASSOCIATION OF MULTIPLE CHRONIC CONDITIONS WITH HEALTH-RELATED QUALITY OF LIFE AND PHYSICAL FUNCTIONING**
OBJECTIVES: Multiple chronic conditions (MCC), defined as the co-occurrence of two or more chronic diseases, may adversely affect quality of life. This study aimed to determine the association of MCC with health-related quality of life (HRQoL) and physical functioning. METHODS: This retrospective cross-sectional study used 2011-2012 Medical Expenditure Panel Survey data, a nationally representative US survey of the civilian noninstitutionalized population of all ages in the US, and included adult patients (age ≥ 18 years). MCC was assessed based on the Center for Medicare and Medicaid Services’ list of 17 chronic conditions. Physical and mental HRQoL was measured using short form health survey (SF-12); physical functioning was measured using Activities of Daily Living (ADL) and instrumental ADL (IADL). Covariates included age, sex, body mass index, smoking status, education, and insurance. Multiple linear (for mental and physical HRQoL) and multivariable logistic (for ADL and IADL) regression models were constructed to determine the association of MCC with outcomes while adjusting for covariates. RESULTS: The study cohort included 47,087 patients: 51.9% (no MCC), 19.9% (1 MCC), 12.1% (2 MCC [dyads]), 8.4% (3 MCC [triads]), 4.5% (4 MCC) and 3.2% (5+ MCC). Patients with no MCC had mean physical HRQoL of 49.2 and mental HRQoL of 51.0. Two most frequent dyads were hypertension+hyperlipidemia (physical HRQoL: 40.9; mental HRQoL: 49.3) and hypertension+diabetes (physical HRQoL: 38.6; mental HRQoL: 48.1). Two most frequent triads were diabetes+hyperlipidemia+physical hyperlipidemia (physical HRQoL: 37.9; mental HRQoL: 48.1) and hypertension+hyperlipidemia+ischemic heart disease (physical HRQoL: 35.7; mental HRQoL: 48.1). Risk-adjusted regression models showed that each additional chronic condition reduced the physical HRQoL (β: -3.02) and the mental HRQoL (β: -1.76) and increased the odds of ADL (odds ratio [OR]: 1.66, 95% CI:1.57-1.74) and IADL (OR: 1.68, 95% CI:1.60-1.76). CONCLUSIONS: MCC adversely affects HRQoL and physical functioning, with significantly greater deterioration associated with increasing number of chronic conditions.
diseases. **CONCLUSIONS:** This study indicated that medical practitioners of all specialties still rely on more antibiotics use which needs strict regulations for antibiotics prescriptions especially when there is no need.

**PHP211: REPLICATING THE MEDICATION ADHERENCE REASONS SCALE (MAR-SCALE) FACTOR STRUCTURE IN PEOPLE USING DAILY ORALS FOR DEPRESSION, GASTROESOPHAGEAL REFLUX DISEASE, RHEUMATOID ARTHRITIS, AND EPILEPSY**

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**OBJECTIVES:** Determine whether the four-factor structure of the Medication Adherence Reasons Scale (MAR-Scale) is replicated in additional comorbid conditions. **METHODS:** Data were analyzed from participants re-contacted from the 2017 United States National Health and Wellness Survey, an Internet-based survey administered to demographically representative adults (≥18 years), who self-reported taking oral medication daily to treat one of four disparate conditions (depression: n=2,879; gastroesophageal reflux disease [GERD]: n=2,862; rheumatoid arthritis [RA]: n=1,589; and epilepsy: n=206) and who completed the MAR-Scale. The measure includes 19 items describing reasons for not taking a prescribed medication to treat a medical condition (e.g. not taking a medication because of side effects, trouble managing medications, missing medications because of a busy schedule). Participants respond to each item by reporting their adherence during the previous seven days. Four separate categorical confirmatory factor analyses (CCFA; one for each condition), along with a mean- and variance-adjusted least squares estimator, were used to ascertain whether participant responses fit a previously identified four-factor configuration: logistic issues, belief issues, forgetfulness issues, and long-term concerns. A CCFA fit the data well if the criteria for 2 global fit indices were exceeded; the root mean square error of approximation (RMSEA; <0.08) and the comparative fit index (CFI: >0.95). Additionally, all standardized factor loadings (FL) needed to be greater than 0.50 and significant (p<0.05), indicating a strong relationship between the item and the latent variable it is purported to measure. **RESULTS:** CCFAs for each patient group fit the data well. Across all models, the RMSEAs and CFAs exceeded prespecified criteria (RMSEA range: 0.038-0.073; CFI range: 0.960-0.973). Additionally, all FLs were strong (Range: 0.716-1.000) and significant (p<0.001). **CONCLUSIONS:** Replication of the MAR-Scale factor structure across different conditions is a critical step to ensuring MAR-Scale use can be extended appropriately to novel settings.

**PHP212: THE ATTITUDE OF PARENTS TO NON-MANDATORY VACCINATIONS**


**OBJECTIVES:** Nowadays, there are different kind of opinions about vaccination all over the world. This essential decision has to be made by parents. In our thesis we are going to investigate parents' attitude and hesitation in connection with optional vaccination in Hungary. **METHODS:** We made an online questionnaire cross-sectional survey in Hungary. Most of responses are from Pest county, Fejér county, Baranya county and Komárom-Esztergom county. The total numer of patients included into the study were 206. The questionnaire included a closed type and the socio-demographic questions moreover, it had special questions about vaccines. Parents could give their answers respondents from 1 to 4 Likert-scale, single or multiple multi-choice options. **RESULTS:** The most of parents chose the vaccine of against meningitis (72.3%), after that they chosen in equal numbers for the vaccine of against chicken pox (49.0%) and the vaccine of encephalitis caused by ticks (49.0%). Additionally, they chosen in 38.3% the vaccine of against meningitis (72.3%), after that they chosen in equal numbers for the vaccine of against chicken pox (56.3%). Then the next highest uncertainty in boost against rota virus (32.5%). Based on the results of the primary and most reliable source of gathering information on the parents of the child's personal family doctor. **CONCLUSIONS:** Our results draw attention to uncertainties of optional vaccines. It is important for professionals in-depth orientation, in responding adequately and empathetic behavior in case of issues related to vaccines.

**PHP213: KNOWLEDGE AND SATISFACTION OF HEALTH INSURANCE CLIENTS: CROSS-SECTIONAL STUDY OF A TERTIARY HOSPITAL SERVICES IN GHANA**

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**OBJECTIVES:** Knowledge and satisfaction of health services provide valuable feedback for improving quality of healthcare. This study assesses clients' knowledge and satisfaction with services under the National Health Insurance Scheme in a tertiary healthcare facility. **METHODS:** A cross-sectional exit interview was conducted at the
Korle-Bu Teaching Hospital in the Greater Accra region of Ghana. Respondents were classified into various knowledge and satisfaction groups based on the number of positive responses obtained for the knowledge and satisfaction measures on a 5-point Likert scale. Bivariate and multivariate analyses were conducted to identify associations between clients’ characteristics and their knowledge of NHIS and satisfaction with the services. RESULTS: Two hundred and four clients participated in the survey, representing 97% response rate. About 39% (79) had more knowledge of NHIS, 56% (115) were more satisfied with NHIS services, and 98% (200) were more satisfied with healthcare services. Postgraduate education (OR=23.53, 95% CI: 1.42-388.73), tertiary education (OR=13.93, 95% CI: 3.21-60.31), secondary education (OR=6.85, 95% CI: 1.94-24.10), and six or more years of enrollment (OR=5.09, 95% CI: 1.05-24.66) were significantly associated with more knowledge of NHIS. Similarly, more knowledge of NHIS (OR=3.79, 95% CI: 1.92-7.45) was significantly associated with more satisfaction with NHIS services. However, being an old patient was negatively associated with more knowledge of NHIS (OR=0.25, 95% CI: 0.08-0.73) and more satisfaction with NHIS services (OR=0.31, 95% CI: 0.11-0.87). CONCLUSIONS: Clients have less knowledge of the NHIS, are somewhat satisfied with NHIS services and more satisfied with healthcare provider services. More education and sensitization on the scheme targeting individuals with low level of education would be necessary to increase their knowledge and improve satisfaction.

PHP214: INFLUENCE OF DISEASE FAMILIARITY ON IMPLIED TIME PREFERENCES FOR SEIZURE FREQUENCY REDUCTION
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OBJECTIVES: To test the association between time preference rates and diagnosis of condition used in the scenario to elicit time preference rates. We hypothesised scenarios that are more familiar may lead to higher estimates, as they place a higher value on the future benefits of adherence. METHODS: Data from two empirical surveys that estimated time preference using a scenario of delays in starting antiepileptic medication and reduction in seizure frequency were compared for samples of: (i) hypertensive adult patients in England or Wales; and, (ii) UK patients with epilepsy. Time preference rates were elicited using a questionnaire containing 4-items to derive estimates for a 3-year and a 6-year delay. The same questionnaire was hosted within two independent online surveys. Patients were matched using propensity scoring based on, age, sex, and employment status. Associations between time preference rate and condition were assessed using an independent two-sample t-test with equal variances, using the propensity score matched sample for both the 3-year and the 6-year delay. RESULTS: 485/512 patients with hypertension and 310/311 patients with epilepsy were matched in the analysis. Mean annual time preference rates for the 3-year delay were significantly higher for patients with the condition (hypertension=0.21, 95% CI: 0.20, 0.22) than for patients not known to have the condition (hypertension=0.08, 95% CI: 0.05, 0.12). Similarly, mean time preference rates for the 6-year delay were significantly higher for patients with the condition (epilepsy=0.012, 95% CI: 0.011, 0.112) than for patients not known to have the condition (hypertension=0.04, 95% CI: 0.03, 0.06). Familiarity with condition explained 38.2% and 53.2% of the variability in time preference for the 3- and 6-year delay, respectively. CONCLUSIONS: Evidence on the association between experience of the condition described in the hypothetical scenario and estimated time preference rates suggests people with experience of condition have higher time preference.

PHP215: STAKEHOLDER PERSPECTIVES ON THE INTEGRATION OF PATIENT PREFERENCES IN THE MEDICAL PRODUCT LIFE CYCLE: A MULTIMETHOD APPROACH

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OBJECTIVES: This study aimed to explore stakeholders’ desires, expectations, concerns and requirements regarding the measurement and use of patient preferences throughout the medical product life cycle. METHODS: This study used a four-step multimethod approach. First, 16 exploratory interviews were conducted. Second, a literature review consulting scientifically published and other publicly available documents was performed. Third, 144 semi-structured interviews were conducted with stakeholders (patients, informal caregivers, patient representatives, physicians, regulators, reimbursement agency representatives, health technology assessment representatives, industry representatives, academics) from Sweden, Romania, Italy, the United Kingdom, the Netherlands, Germany, France and the United States. Fourth, 8 focus groups with different representatives from the same stakeholder groups were designed. RESULTS: The exploratory interviews with patient representatives (n=4), physicians (n=2), regulators (n=2), health technology assessment representatives (n=4), industry representatives (n=3) and academics (n=1) revealed a lack of consensus on the definition for patient
preferences. Interviewees agreed on the value of using patient preferences in all stages of the medical product life cycle. The literature review showed that the use of patient preferences to inform industry, marketing authorization, health technology assessment and reimbursement decision-making is desired by stakeholders. Stakeholders' requirements for measuring and using patient preferences are general, operational and quality requirements. Stakeholders expect that using patient preferences will lead to more meaningful results when used for industry decision-making and a higher legitimacy and public acceptance of marketing authorization and reimbursement decisions. Stakeholders are concerned about methodological and scientific aspects and the lack of guidance for measuring and using patient preferences. Results of the semi-structured interviews and focus groups will also be presented at the ISPOR congress. CONCLUSIONS: Although the use of patient preferences is desired by stakeholders, their concerns and requirements need to be addressed before patient preferences can be integrated throughout the medical product life cycle.

**PHP216: PATIENTS ACKNOWLEDGE ADAPTATION: THE CASE OF AMPUTEES**

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**OBJECTIVES:** Measurement of health states' QoL is at the base of resource allocation of health care expenditure. Currently, the public evaluates health states in a hypothetical scenario. However, studies confirm there are differences between the assessments of the public and the ones of the patients. Most research attributes the disparities to adaptation and scale of reference bias. The aim of this paper is to gauge the existence of adaptation based on a survey on amputees and controls, and draw attention to the methodological issues of measuring QoL in the presence of adaptation. **METHODS:** We test different hypothesis on QoL evaluations done by patients with acquired amputations, and the public. Our methodology consists of OLS estimations for proof of adaptation and Probit for determinants of gaps between amputees and peers and the public evaluations. **RESULTS:** We observe that patients adapt to health states whereas the public perception does not reflect this phenomenon; in our dataset, each additional month results in an increase of 8.53% in reported QoL. Amputees reported QoL values converge to those of healthy individuals after 2 years since event. Adaptation is the main determinant of the gap between patients' and the public' QoL evaluations. We also analyse the dynamics of the QoL evaluations of patients. Our main interest is the evaluations done by amputees on behalf of peers. While patients with shorter duration since event evaluate their own QoL higher than those of peers, the QoL reported converges over time, and thus patients themselves acknowledge adaptation. **CONCLUSIONS:** This later finding is relevant in moving forward and improving measurements of quality of life. This inference could be easily tested and replicated in patients with different conditions, such as diabetes or urology conditions, where adaptation has already been proven. If patients acknowledge themselves adaptation, their evaluations are more accurate compared to the public.

**PHP217: SURVEY OF NURSES’ KNOWLEDGE ABOUT SURGICAL WOUND CARE AND ITS COMPLICATIONS AND THE KNOWLEDGE OF WOUND DRESSINGS**

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**OBJECTIVES:** The rapid and extraordinary advances of medicine felt the impact in many areas of wound care consequently many treatment material and wound dressing appeared on the market. Thus we witness of a significant improvement in several areas of wound healing. Multicentre studies related to wound care made in the 20th century which are integral parts of today's wound care protocols. My research aims to assess the nurses' knowledge of the affected departments about management of surgical wounds, complications and phases of wound healing as well as intelligent dressings. **METHODS:** The quantitative and retrospective study was made between 1st of December, 2015 and 30th of January, 2016 with a non-randomly sampling of experts and self-made questionnaire. Main groups of the questionnaire are about sociodemographic, knowledge of surgical wounds, complications and dressings. The target group is the registered nurses from ear-nose-throat, traumatology, obstetrics and gynecology and general surgical departments of Kanizsai Dorottya Hospital in Nagykanizsa (n=85). Descriptive statistic and χ² test (p<0.05) was used in Microsoft Office Excel. **RESULTS:** There was no significant difference between the education of nurses and the knowledge about the wound dressing (p=0.07) however significance was among the daily nursing work and knowledge of intelligent dressings (p<0.01). No greater knowledge about phases of wound healing was observed among those who perform wound care in their daily work (p=0.14) but more knowledge about the order of wound care of primary healing wounds (p<0.01). The nurses’ knowledge about smart dressings was higher who received training before applying the bandage (p<0.01). **CONCLUSIONS:** General knowledge of nurses surveyed is deficient which need to be improved to ensure safe patient care. Information source must be available and accessible. Organization of training courses would be effective to broaden their professional knowledge.
PHP218: METODOLOGY TO ASSESS PRICING AND REIMBURSEMENT (P&R) POTENTIAL IN CENTRAL AND EUROPEAN (CEE) COUNTRIES

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OBJECTIVES: CEE region is characterised by its wide range of approaches to granting public funding for drugs – from a "no submission and no HTA" approach up to an extensive HTA with systematic review and economic evaluation. The aim is to create and test the methodological approach on assessment of P&R potential in CEE countries. The further goal is to identify countries with the highest reimbursement potential for a particular drug in the region. METHODS: The methodology approach on P&R potential assessment took into account: current management of disease, patient numbers, KOL mapping, patient pathways, guidelines and funding mechanisms, drug pricing and reimbursement processes, timelines, likelihood of achieving an average European list price and opportunities to supply drug on a Named Patient Programs basis. The necessary information was divided into six categories: epidemiology, price, probability of reimbursement, time, analytical effort, cost of application. For each category, a weight reflecting the importance and impact of parameters was assigned. The methodology has been tested on an orphan drug example in 15 CEE countries. RESULTS: The following CEE countries were pre-selected: Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Turkey and Ukraine. The greatest weights were incorporated to probability of public funding, epidemiology, price and time - 24%, 22%, 20% and 18% respectively, whereas cost of application and analytical effort were assessed as of lower importance: 10% and 6%. Turkey was assessed to have the highest P&R potential for tested drug. Poland and Slovakia were also found as important with attractive achievable price and similar moderate probability of reimbursement. CONCLUSIONS: Despite many differences among countries, using P&R potential overview method makes it possible to inform on strategic business decisions for which countries to prioritize for launch and for allocation of efforts to obtain public funding.

PHP219: PATIENTS ORIENTED ACCESS SCHEME: LEARNING FROM THE SUCCESS OF THE ISRAELI INNOVATIVE SOLUTION FOR THE ESCALATING DRUGS PRICES

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OBJECTIVES: To show market results of implementing patients oriented access scheme (POAS) method based on balanced risk sharing that allows an efficient process for inclusion of newly introduced pharmaceuticals into the public package and dealing with market failures that unable all players to reach their goals. METHODS: An ongoing analysis of MoH database to examine the influence of the POAS on the inclusion of pharmaceuticals into the public package and number of beneficiaries. RESULTS: The POAS method creates more opportunities for medicines to be publicly funded with mutual risk sharing. The size of the budget for new drugs under agreements increased form 7.5 million NIS in 2011 to 166 million NIS in 2016 (accounted for more the 50% of the budget); the number of potential patients treated under POAS agreements increased from 150 in 2011 to 22,000 in 2016. The most significant agreements were those which allowed Israel to be the one of the first countries which publicly funds the direct-acting antivars (DAAs) indicated for the treatment of chronic hepatitis C (CHC) drugs. CONCLUSIONS: The method seems to successfully facilitate patient access to the newest treatment under the constraints of public budget available by promoting the achievement of the goals of the various players. This study creates an opportunity for cross-national learning to face the challenge of pharmaceuticals spending.

PHP220: ACCESS GAP TO INNOVATIVE TREATMENTS IN ROMANIA

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OBJECTIVES: This research aims to illustrate how the current drug reimbursement legislation results in preventing access of innovative drugs from the HTA stage, due to rigid scorecard criteria and excessive focus on costs. METHODS: A critical appraisal of over 100 HTA reports issued after implementation of the HTA legislation 2014 in Romania was done, searching for the reasons which lead to unconditional, conditional reimbursement or negative reimbursement decision. An analysis of the impact of lack of NICE/IQWIG reports on the coverage with treatment for some oncology areas was performed, and a review of prescription protocols for some oncology areas: lung, breast, colorectal cancer. RESULTS: The current HTA scorecard criteria, according an important number of points to HAS, NICE, IQWIG reports and to direct costs budget impact, resulted in negative HTA decisions for 81 drugs, conditional reimbursement decision for 51 and unconditional reimbursement for 45. For many drugs reimbursed in Germany before 2011, the lack of IQWIG report caused negative decisions and for many oncology drugs negative NICE report caused a not reimbursement decision (14 drugs rejected). Also, in several therapeutic areas the current legislation blocks the access of several drugs for the same indication, leaving the patients without therapeutic alternatives. CONCLUSIONS: The HTA system, although slightly updated since 2014, applies rigid
criteria and is excessively focused on costs, raising a barrier for the innovative drugs, with serious consequences on therapies for serious illnesses. This prevents the negotiations between companies and the Payer, which could lead to flexible managed entry agreements.

**PHP221: APPLICABILITY OF THE EQ-5D-3L DESCRIPTIVE SYSTEM TO EXPLORE SUBJECTIVE FUTURE HEALTH EXPECTATIONS**

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**OBJECTIVES:** To assess the applicability of EQ-5D-3L for exploring long-term subjective health expectations (SHE) of patients with chronic diseases. **METHODS:** Current and expected health states for ages 60, 70, 80 and 90 were surveyed using the EQ-5D-3L descriptive system in patients with rheumatoid arthritis (RA; N=92), psoriasis (N=167), postmenopausal osteoporosis (OP; N=224) and age-related macular degeneration (AMD; N=122) in Hungary. The UK value set was used to calculate EQ-5D-3L index scores. Subjective life expectancy was recorded. Spearman rank correlations between SHE and patient characteristics were analysed. **RESULTS:** Patients mean (SD) age in RA, psoriasis, OP and AMD were 51.1 (11.9), 50.4 (12.5), 69.5 (8.9) and 75.2 (7.9) years, respectively. Complete responses on SHE for respective future ages were obtained from 99%/95%/92%/86% in RA, 93%/88%/72%/55% in psoriasis, 91%/85%/78%/70% in OP and 100%/94%/80%/56% in AMD. The proportion of patients expecting full health (11111 responses) for future ages was under 20%, with two exceptions (psoriasis for age 60: 24%; AMD for age 70: 28%) indicating an overall low ceiling effect. In all the four diseases patients expected sharp deterioration of health with age, the expected EQ-5D index scores for ages 60 and 90 were: RA 0.44, -0.02; psoriasis 0.56, -0.17; OP 0.42, -0.18; AMD 0.60, 0.24. Patients who believed to be alive at the age surveyed expected significantly higher EQ-5D-3L scores than those who did not (p<0.05). SHE showed moderate or weak positive correlation with current EQ-5D-3L index score and subjective life-expectancy. **CONCLUSIONS:** These first studies suggest that the EQ-5D-3L descriptive system is a feasible method to explore SHE in chronic diseases. Extending the survey to lower ages deserves consideration in diseases that affect mainly the younger population. It is strongly suggested, however, to explore in parallel the subjective life-expectancy as it influences the expected health status.

**PHP222: THE IMPACT OF PATIENT PREFERENCE STUDIES IN THE GERMAN HEALTHCARE SYSTEM**

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**OBJECTIVES:** Patients commonly have to deal with healthcare-related decisions based on their personal preferences. Preference studies could help informing on relevance of patient-related outcomes which are of paramount importance in the regulatory AMNOG process. IQWIG also already performed preference studies on the impact of adverse events of pharmaceuticals for the AMNOG process. Aim of this study was to assess the current impact of preference studies in the German healthcare context. **METHODS:** A systematic literature search was performed in PubMed and Scopus. Search terms comprised the different preference elicitation methods. The search included all studies conducted in/for Germany up to March 2017 with respect to the applied approach, year of publication, and indication. **RESULTS:** The search yielded n=511 hits (n=122 in PubMed, n=389 in Scopus, respectively) with n=94 publications being included and stratified by approach, publication year, and indication. Six categories of preference methods were determined: Analytic Hierarchy Process (AHP), Best-Worst-Scaling (BWS), Conjoint Analysis (CA), Contingent Valuation/Willingness to pay (WTP), Discrete Choice Experiment (DCE), and others. Most publications (64.9%) used DCEs, followed by AHP (11.7%) and CA (9.6%) with the first study dating back to 2001. Since 2011, numbers significantly increased with a peak in 2016 (24.5%). 80.9% of the preference studies were conducted for specific disease areas being led by psychological disorders (16.0%), metabolic disorders (10.6%), and infections (9.6%). **CONCLUSIONS:** Patient preference studies have become an important research area when considering the increasing number of patient preference studies in Germany over recent years. Out of the identified methods of preference elicitation, the DCE is the most commonly applied method in Germany. Patient preference studies were adapted over a wide range of diseases suggesting that an inclusion of such evidence in many cases might constitute a feasible option of identifying patient-relevant outcomes offering a separate component of value also during the regulatory AMNOG process.

**PHP223: INPATIENT MEDICATION ERRORS AND PHARMACIST INTERVENTION AT MINISTRY OF HEALTH PUBLIC HOSPITAL IN RIYADH, SAUDI ARABIA**

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**OBJECTIVES:** To explore the inpatient medication errors and pharmacist intervention at MOH public Hospital, Riyadh, Saudi Arabia. **METHODS:** It is a 9-month cross sectional study at 300-bed public hospital through pharmacist
response and prevents of inpatient medications errors in adults and pediatrics. The hospital had medication safety officer with medication safety committee. The medication errors documented in a form consisted of patient demographic information, the sources of medication errors, time of errors, type of medication errors, and description of mistakes. The Causes of errors, the recommendation to prevent the errors, and the outcome of medication errors by using National Coordinating Council (NCC) for Medication Error Reporting and Prevention (MERP) system. RESULTS: The pharmacist prevented 3,089 medication errors occurred within 805 patients. The number of medication errors prevented was (3.8 errors) per each prescription. The majority of patients were in the age of 18-65 (71%). The most errors prevented were near miss (93.3%) followed by (6.28%) errors reached to the patient without any harm. Patient-related errors (50.63%) and prescriber-related errors (46.46%) were the highest type errors occurred. The most package error occurred was the packaging container (77.13%) and syringe (3.41%). The highest percentages causes of medication errors were clinical information missing (83.74%) and miscommunication of drug order (80.9%). The most medications involved in medication errors were Intravenous Paracetamol and enoxaparin injection. CONCLUSIONS: The pharmacist had the very crucial role in preventing medication errors. In order, to prevents medication misadventures and improve patient outcome; the pharmacists provide the health care professional education about medication safety, and establish the intravenous medications guidelines at hospital practice

PHP224: CONDITIONS AND CONTEXTUAL FACTORS THAT INFLUENCE THE UTILITY AND APPLICATION OF PATIENT PREFERENCE STUDIES: A STUDY COMBINING LITERATURE AND FOCUS GROUPS

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OBJECTIVES: The aim of this study was to identify conditions and contextual factors that influence the utility and application of patient preference studies in decision making by Health Technology Assessment (HTA) bodies, regulators and industry, throughout the life cycle of medical products. In parallel, it was sought to identify the current applications of patient preferences in decision making. METHODS: The study design consisted of a literature review and focus groups. A systematic literature search was conducted in five scientific databases. In addition, other publicly available documents were consulted including documents of national and international health agencies and patient-centred initiatives. Focus groups were designed to include HTA representatives, regulators, industry representatives, patients, patient representatives, physicians and academics from the United Kingdom, Sweden, Romania and Italy. NVivo was chosen to analyse the results. RESULTS: A total of 742 publications were retrieved and 85 were included. The literature revealed conditions and contextual factors affecting the utility of patient preference studies related to the organization, study design, conduct and use of results of patient preference studies. In study design, question framing for example was found to be an influencer of the utility of patient preferences studies. Evidence was found on the possible applications of patient preferences in decision making, but limited evidence was found on their actual inclusion in decision making. Patient preferences were mostly found to be used to identify outcomes relevant to patients and to weigh outcomes. Results of the focus groups (n=8) will also be presented at the ISPOR congress. CONCLUSIONS: Patient preferences can be incorporated in decision making through different applications. However, many conditions and contextual factors have to be taken into account when designing and conducting a patient preference study in order to retrieve valuable results that can be used in evaluations.

PHP225: OVERVIEW OF INNOVATIVE MEDICINE SECTOR IN TURKEY

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OBJECTIVES: Investments in innovative medicines are prioritized and prompted by Turkish government. Turkish Biotechnology Strategy Document and Action Plan for 2015-2018 have been published. Main challenges and weakness are lack of infrastructure in terms of know how, facilities and human resource, not compatibility of regulations on intellectual property rights with the investment and manufacturing goals in long term and transferability of know how to Turkey. he aim of this study is to compare Turkey with EU countries in terms of access to innovative medicines. METHODS: A computer based search has been conducted for understanding Turkey’s innovative or biotechnology medicines policies. Web pages of Turkish Medicines and Medical Device Agency (TITCK) and European Medicine Agency (EMA) were used to check the marketing authorization of products. A policy enviroment report for biotechnology sector in Turkey has been conducted. Marketing authorization of innovative products were compared between TITCK and EMA from 2011 to 2016. RESULTS: Regulations on licensing are compatible with the EU regulations. No specific regulations regarding biotechnology (including biosimilars) and innovative medicines in
terms of pricing and market access is available for Turkey. General problems faced by originator drugs are also valid for biotechnological and innovative medicines as fixed exchange rate, cost containment measures and investment pressure. 59 innovative medicines have been granted marketing authorization by EMA between 2011 to 2016, while TİTÇK granted only 17. **CONCLUSIONS:** Depending on analysis, Turkey has not written rules or hurdles for biotechnology or innovative medicines. However, access to innovative medicines may take longer than EU countries. Detailed analysis is needed to understand the possible cause of the delayed process.

**PHP226: EVALUATION OF PATIENT- (PRO) AND OBSERVER-REPORTED OUTCOMES (OBSRO) MEASURES REGARDING ACCEPTABILITY AND PALATABILITY OF ELTROMBOPAG IN A PEDIATRIC POPULATION**

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**OBJECTIVES:** The development of clinical outcome assessments for pediatric populations poses unique challenges. Consideration must be given to age-related vocabulary and conceptual comprehension. When the patient is unable to respond themselves, valid and reliable proxy measures should be used. This study evaluated the use of modified patient-reported outcome (PRO) and observer-reported outcome (ObsRO) acceptability and palatability instruments for use in pediatric studies. **METHODS:** A review of existing acceptability and palatability instruments (of deferasirox), highlighted gaps in conceptual coverage and provided rationale for modification of the instruments, in accordance with criteria outlined in the European Medicines Agency guidance. Cognitive debriefing interviews were conducted with adolescents 12–18 years and parents of children 1–12 years with severe aplastic anemia or secondary thrombocytopenia. A “think-aloud” exercise was used, whereby respondents completed the questionnaire while speaking aloud their thoughts as they read each instruction and completed each item, to evaluate conceptual comprehension and relevance. **RESULTS:** All adolescents (n=5) and parents (n=6) demonstrated good understanding of the majority of items in the modified acceptability and palatability PRO and ObsRO instruments. Two items in the PRO instrument, related to administration and the shape of medication, were not clearly understood by adolescents (4/5 and 5/5 respondents, respectively). For consistency, suggested revisions to items in the PRO were also applied to corresponding items in the ObsRO instrument. Adolescents and adults were willing to complete the respective instruments once a week or as often as required. **CONCLUSIONS:** Drawn from the qualitative findings of this study informed key recommendations to enhance the content validity of the PRO and ObsRO instruments. Eight of 18 items in the PRO and 4 of 16 items in the ObsRO were revised. The finalized versions of the PRO and ObsRO instruments are deemed to be conceptually comprehensive based on this research, within the specific context of use.

**PHP227: TESTING THE BEACON TOOL WITH HEALTH ECONOMISTS AND CLINICIANS – IS THERE CONSISTENCY IN ITS APPLICATION?**


**Objectives** The BEACON tool was developed to help pharmaceutical companies align the data generated during a clinical development programme with the requirements of HTA bodies and payers. Whilst it has been used internally at Mundipharma International, it was decided to test it externally against four stylised product profiles to understand if they were scored consistently by different respondents and thus its potential value as an industry tool. **Methods** Four profiles were presented to a mix of Health Economists and Clinicians from UK, Germany, France, Italy, Spain and Switzerland. They were asked to score these profiles in national groups against the six criteria of the BEACON tool. They were asked to score the profiles on a scale of 1 to 4; 1: likely negative impact on market access; 2: risk of negative impact on market access; 3: payer acceptable but unlikely to drive access; 4: likely to support market access. **Results** Ten of the potential 120 data points were not completed, due to respondents being unsure of what score to give, or they were not completed. The lack of an active comparator (C) in the data package was consistently scored as potentially a negative impact on market access by all groups. Conversely, more clinical trials (N) consistently equated to potentially having a positive impact on market access. Outcomes (O) was also identified as impacting on market access, i.e. measuring the correct outcomes in trials. Trends in the other BEACON criteria (B, E, A) were less clear, but this could be due to the brief nature of the profiles used. **Conclusion** BEACON has the potential to be used to help pharmaceutical companies identify data weaknesses and gaps prior to HTA submissions during the development programme. Larger scale testing with more detailed profiles is needed to confirm this. Funded by Mundipharma International Limited

**PHP228: NATIONAL SURVEY OF MEDICATION SAFETY PRACTICE AT MINISTRY OF HEALTH HOSPITALS DURING MASS GATHERING (HAJJ-2016) IN SAUDI ARABIA**
CURRENT SITUATION AND DEVELOPMENT OF CHRONIC DISEASES IN CHINA

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[Objectives] General course of chronic disease is a long and slow process, including cardiovascular disease, cancer, diabetes and chronic respiratory diseases. Chronic diseases have now become the leading cause of death, especially the cerebrovascular disease, malignant tumor, etc. China has taken corresponding measures to cope with chronic disease, and higher requirements of prevention and control are put forward in the “13th year plan”. However, the situation is still grim. This study aims to analyze the current situation. [Methods] The study is mainly based on a comprehensive literature review, which covers both domestic and international data bases, such as “CNKI”, “Wanfang data”, Pubmed and so on. In addition, expert interviews are also conducted in order to have a better understanding of practical environment. [Results] We found that deaths caused by chronic disease has become the main cause of deaths, taking up 86.6% of total deaths and nearly 70% of the total burden of disease. In 2012, prevalence rate in adult population is 25.5% for hypertension and 9.7% for diabetes. According to Chinese cancer registration result in 2013, Chinese cancer incidence reached 235/100,000. Smoking, excessive drinking, lack of physical activity and unhealthy diet are main risk factors. The Chinese government issued a series of policies to deal with the problem. Mortality rate of lung cancer chronic obstructive pulmonary disease and strokes tended to decline after the implementation of related policies. [Conclusions] The study found that prevention and control of chronic disease must focus on early prevention, early treatment, advocating a healthy life, and whole monitoring. The cause needs a joint efforts and good cooperation of government and social parties.

SKIN-BASED TEMPERATURE MEASURING WITH DIFFERENT THERMOMETER TYPES

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[Objectives] Measuring correct temperatures, using correct techniques and equipment is crucial both in pediatric and adult care. Our goal is to compare measured values gained by mercurial, digital, infrared, tympanic and skin (forehead) thermometers to clarify relations between measured temperature and tools used. [Methods] The study was a quantitative, cross-sectional analysis. Data collection was done at the Sárvár St. László Town Hospital – Nursing and Rehabilitation Department in march, 2016. Non-randomized, purposive sampling method was used to select patients above 25 years of age into the sample group (N=50). Exclusion criteria were otitis externa/media, previous ear surgery, use of hearing aid, injury or deformity of the place of measuring. Data collection protocol included 3 measurements and data recording on a cumulative observation sheet. Using MS Excel and SPSS softwares, we have made paired T-test, correlation, ANOVA (p<0.05) besides descriptive statistical analysis. [Results] We found positive, strong correlation between results of mercurial and digital tools in axillary
temperatures. (p<0.05). Positive, moderate correlation between tympanic and axillary mercurial, forehead and axillary mercurial, and tympanic and oral mercurial thermometer results (p<0.05). We also found positive, strong correlation between oral digital and oral mercurial thermometer results. (p<0.05). **CONCLUSIONS:** Regarding the objectives of the study we can say that as well as tympanic thermometer, mercurial, digital and infrared thermometers are also reliable in the clinical practice.

**PHP231: ATTITUDE OF PHARMACY EDUCATORS TOWARDS COMPLEMENTARY AND ALTERNATIVE MEDICINES (CAM) EDUCATION IN PHARMACY CURRICULUM: A QUALITATIVE EXPLORATION**

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**OBJECTIVES:** Studies suggested that the use of CAM among healthy individuals and patients with different ailments is increasing day by day. Doctor’s and pharmacists plays an important role in guiding patients toward the rational use of CAM. Pharmacy educators’ perceptions is crucial to evaluate in order to propose guidelines to make changes in pharmacy curriculum regarding CAM. This study aimed to explore the perceptions of pharmacy educators towards CAM education in Pharmacy curriculum. **METHODS:** A qualitative research approach was adopted. Eleven pharmacy educators were purposively selected for this study. All participants were pharmacist working in academics for a minimum of five years. Participants were interviewed using a semi-structured interview guide. A saturation point was reached after the 10th interview, and no new information emerged with the subsequent interviews. All interviews were transcribed verbatim and analyzed by means of a standard content analysis framework. **RESULTS:** Content analysis of the interviews yields two major themes: i) perceived effectiveness of conventional therapies in pharmacy curriculum ii) cues to action for curriculum development. The finding suggested that pharmacy educators showed a positive perception towards including CAM education. Different methods were suggested such as elective courses on CAM, industrial attachments and recognition of different traditional practices in the clinical practice guidelines. **CONCLUSIONS:** An overall positive attitude was shown by the educators towards the traditional therapies education. A number of innovative ideas were suggested to improve awareness regarding CAM among pharmacy students.

**PHP232: PRACTICALITIES OF USING REAL-WORLD EVIDENCE (RWE) IN COMPARATIVE EFFECTIVENESS RESEARCH (CER): LEARNINGS FROM IMI-GETREAL**

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**OBJECTIVES:** The IMI-GetReal project aimed to explore incorporation of robust methods for real-world evidence (RWE) collection and synthesis in the medicines development process, both by pharmaceutical companies and healthcare decision makers. The focus was on the potential use of RWE, alone or in combination with randomized controlled trials (RCTs), to demonstrate effectiveness of new interventions. Seven case studies were conducted in multiple disease areas to examine methods for predicting drug effectiveness and the perspectives of different stakeholders on these methods. This study aimed to identify practical obstacles in accessing and using RWE and RCT data for effectiveness research conducted as part of these case studies. **METHODS:** Qualitative content analysis was conducted to identify and characterize key issues relating to accessing and analyzing study data from external sources, both RWE & RCTs. **RESULTS:** Accessing RWE from registries proved difficult due to multiple reasons, including: complex and non-transparent application procedures, resistance from registry owners to discuss applications and datasets not being research-ready within project timeframes. There were also issues with RWE eventually accessed, including a lack of individual participant data (IPD) and incomplete data. Where access to IPD from RCTs was obtainable, there were restrictions imposed on how it could be used. For example, it could not be used to target analysis on an individual product, but rather explore methodologies for data synthesis in a product-anonymized setting. This condition encouraged additional data sharing by other stakeholders. **CONCLUSIONS:** Despite the collaborative, multi-stakeholder nature of IMI-GetReal and proper disclosures with data owners, access to data proved challenging. Such barriers to data accessibility can delay
effectiveness research, restrict opportunities for the development of methods incorporating RWE and diminish the potential use of RWE in decision-making. Where data is intended to be used for this purpose, sufficient attention should be paid to these potential barriers.

**PHP233: LEADERSHIP IN NURSING**

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Health care reform taking place in the Kazakhstan includes, as an essential element, increasing the efficiency of nursing staff, and improved management of nursing service. Nurse Manager decides on important strategic issues, makes decisions under conditions of extreme instability, constant shortage of all types of resources. An essential criterion of the value of nurses as a Director; becomes its managerial ability, leadership qualities, communication skills, optimism, vision, and willingness to engage in their self-development. Methods of research. In the research process was applied analytical, mathematical, and statistical methods. The results of the study. The study involved 10 heads of nursing services, including one chief nurse and nine senior nurses. The majority of heads of nursing services is in the range 40-56 years. Practically all heads of nursing services (90%) have a qualifying category. 40% - the highest category, 40% is the first and 10% in the second and 10% have no qualification category. 70% of managers working in these positions for more than 10 years. In some cases, heads of nursing services indicate a lack of information, regulatory in nature and related to the latest achievements in medicine. In most cases, heads of nursing services possess leadership qualities and have a positive impact on colleagues and on the question: "Are You a leader in the team?" 80% of managers said Yes, 20% were undecided. The conclusion. The above analysis shows that the professional activities of nursing managers contain certain risks affecting the activities of the nursing services. One of the important tasks of management of nursing is "removing" the risks for the effective style of leadership (management) and improving the quality of medical care.

**PHP234: COMPETENCIES OF FORMAL CARERS REGARDING BASIC CLINICAL AND SOFT SKILLS IN THE PROVISION OF OUTPATIENT SERVICES AND PATIENTS' PERSPECTIVE: THE TWO SIDES OF THE SAME COIN**

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**OBJECTIVES:** To investigate formal carers' training needs from 4 European countries participating in the i-Care project (Greece, France, Italy and Cyprus), with regard to their basic and soft skills, by reporting self-competency evaluation, as well as the perspective of the patients regarding their own carers' competence. **METHODS:** The study sample was composed of formal caregivers (nurses, health care assistants and social workers) and patients from the 4 i-Care partner countries. Two questionnaires were developed, one to assess carers' training needs regarding basic and soft skills and one to be completed by the patients assessing their carers' needs. **RESULTS:** 166 carers (69% female) with a mean age of 41.6 years (SD=12.5) and 200 patients (55% female) with a mean age of 65 years, completed the questionnaires. Carers identified themselves as more sufficiently skilled in preventing pressure ulcers (p=0.006), first aid (p=0.001) and caregiver’s health and safety skills (p=0.001), when compared to patients' perspective. Additionally, carers identified themselves as skilled (scores higher than 4 in a 5-point Likert scale) in the majority of soft skills, while patients considered their carers as moderately skilled in all items of basic skills and insufficiently skilled in basic physiotherapy exercises and preventing pressure ulcers. On the other hand, patients cared for by formal carers considered their carers to be insufficiently skilled in relation to managing patients' feelings of isolation and loneliness (p<0.001), communication skills (p=0.020) and managing their own grief reactions (p=0.022). **CONCLUSIONS:** There is a clear gap between formal carers' self-perception of competence and patients' perspective. Carers' training should be designed according to the level of competency in each item of skills. Yet, patients' perspective should be also considered in order to ensure that patients' needs are met and expectations regarding their carers' training are taken under consideration.

**PHP235: COMMUNITY PHARMACISTS' INTEREST IN AND ATTITUDE TO PHARMACY PRACTICE RESEARCH IN ETHIOPIA: A CROSS-SECTIONAL STUDY**
OBJECTIVES: Aimed to assess the community pharmacists' interest and attitude towards pharmacy practice-research in Ethiopia. METHODS: A cross-sectional survey was conducted among community pharmacists in eight major cities in Ethiopia. A validated 25-item self-administered questionnaire covering interest and attitude related to pharmacy practice-research was distributed. Responses were analysed using descriptive and inferential statistics. RESULTS: A total of 389 community pharmacists responded to the survey (response rate: 88.4%). Most of community pharmacists showed a high level of interest and positive attitude in being involved in all aspects of pharmacy practice-research. The median summary score for interest and attitude were 38 (IQR 20–40) (range possible 10–50) and 30 (IQR 18–39), respectively. Sixty-seven percent of the respondents thought about being involved in research, felt research is important for their career (57.6%), confident to conduct the research (56.2%), and agreed that research is a part of pharmacy practice (48.5%). However, only forty-six percent agreed that they underwent research training. A multivariate analysis showed that females were more interested in pharmacy practice research than males [AOR: 1.50, 95% CI: 0.99±2.27; p<0.05]. CONCLUSIONS: Community pharmacists showed high interest towards several areas of research competencies and demonstrated positive attitude towards pharmacy practice-research. Our findings suggest that providing research training to community pharmacists may contribute in undertaking research activities and build the research capacity in Ethiopia.

PHP236: KNOWLEDGE AND ATTITUDES IDENTIFYING VICTIMS OF HUMAN TRAFFICKING IN THE US: A CROSS-SECTIONAL STUDY

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OBJECTIVES: Human trafficking is today’s modern form of slavery and the second largest criminal activity in the world. Trafficking typically originates in disadvantaged areas with high levels of poverty, lack of opportunities and high crime rates but can also exist in communities of any socioeconomic class. The objective of this study was to assess the knowledge and attitudes about identifying victims of human trafficking among US pharmacy students. METHODS: This was a cross-sectional study. A survey was distributed amongst first, second, and third year pharmacy school students in a private university in the US. The questionnaire comprised of 17 questions that were divided into four components: general questions about human trafficking (7), types of human trafficking (4), human trafficking and health (5), and attitude about human trafficking (1). Descriptive analyses were conducted using SPSS version 21. RESULTS: A total of 219 pharmacy school students participated in the survey. 69.4% participants were females and 30.6% participants were males. Study participants had poor knowledge about the age group (13.24%), race (2.28%), and warning signs (14.16%) of victims of human trafficking respectively. Only 7.31% of participants had accurate knowledge about the disease conditions associated with human trafficking. Approximately 77% participants agreed that 911 should be called upon encountering a human trafficking victim in the pharmacy. 53% participants felt that upon encountering a human trafficking victim, they would inquire about the availability of a friend for emotional support. CONCLUSIONS: Pharmacy students had a positive attitude about treating victims of human trafficking, even though they had poor knowledge about victims of human trafficking. This study stresses the need for implementing education about human trafficking in the pharmacy curricula to raise awareness about this serious issue, both in the US and across the globe.

PHP237: ASSESSMENT OF KNOWLEDGE AND PERCEIVED PRACTICES OF ANTIMICROBIAL STEWARDSHIP AMONG MALAYSIAN FUTURE HEALTHCARE PROFESSIONALS

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OBJECTIVES: The antimicrobial stewardship is currently not mandatory as part of the undergraduate healthcare educational programs. Better understanding of current levels of knowledge and perceived practices can facilitate more effective educational interventions for future healthcare professionals. Therefore, this study was conducted to assess the levels of knowledge and perceived practices of Malaysian final year undergraduate healthcare students towards the antimicrobial stewardship. METHODS: This cross-sectional study was conducted from January to April, 2017, using a self-administered questionnaire in the State of Selangor, Malaysia. The questionnaire consisted of three parts: socio-demographic characteristics of respondents (5 items), knowledge (8 items), and perceived practice (8 items) towards antimicrobial stewardship. A convenience sampling approach was used to recruit undergraduate final year students from the faculties of pharmacy, medicine, dentistry, and nursing in MAHSA University, Malaysia. The descriptive (numbers, and percentages) and inferential (Spearman's correlation coefficients, and Chi-square test)
statistical analyses were conducted by using Statistical Package for the Social Sciences (SPSS), version 23. **RESULTS:** Post-oral consent, a total of 180 undergraduate final year healthcare students completed the questionnaire, giving an overall response rate of 81.4%. The majority (n=107, 59.4%) of the respondents showed good levels of knowledge and (n=122, 67.8%) perceived practices. There was a statistically significant moderately positive correlation between the overall knowledge and attitude score of the enrolled students (r=0.450, p=0.001). No statistically significant association was found between the categories of socio-demographic characteristics and perceived practices; whereas, students’ age (p<0.040) and nationality (p<0.025) categories showed the statistically significant associations across the levels of knowledge enrolled students. **CONCLUSIONS:** The enrolled students possessed good levels of knowledge and perceived practices regarding antimicrobial stewardship. Continuous efforts focusing the principles and practices of appropriate use of antibiotics and antimicrobial stewardship are essentials to sustain these good levels of knowledge and practices for future healthcare providers.

**HEALTH CARE USE & POLICY STUDIES - Health Technology Assessment Programs**

**PHP238: THE ROLE OF PATIENT-REPORTED OUTCOMES AND PATIENT ENGAGEMENT IN HEALTH TECHNOLOGY ASSESSMENTS AND REIMBURSEMENT DECISION MAKING IN 10 COUNTRIES**

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**OBJECTIVES:** We evaluated the role of patient-reported outcome (PRO) data and patient testimonial evidence (e.g. patient advocacy) in reimbursement decisions in 10 countries. **METHODS:** Websites of national/regional health technology assessment (HTA) agencies for the UK (England, Wales, Scotland), Spain, France, Germany, Italy, Canada, Japan, and Brazil were searched for decision documents that included PRO data and/or evidence of patient involvement in a pre-specified list of treatments for three diseases (diabetes, obesity, and haemophilia). HTA guidance for formal patient involvement processes was also identified and national clinical guidelines were reviewed for information regarding patient involvement. Data were compared to identify common themes and inter-country differences. **RESULTS:** In total, 155 HTA decisions were reviewed for PRO data and patient involvement. Only 28% (44) reported use of PRO data in decision making. PRO data were referenced more frequently in HTA decisions from countries that use a cost-utility and/or cost-effectiveness approach to economic evaluation (UK, Canada, and Italy), for which detailed guidance on PRO data expectations exists. Reasons for PRO data not being included were: poor trial design (e.g. no head-to-head data or data from open-label studies), limited generalisability to the population, and lack of clinically or statistically significant differences between interventions. Processes for patient involvement were identified with substantial inter-country variability, from formal patient submissions/consultations and committee involvement (UK, Canada) to limited/unclear patient involvement (France, Japan). Clinical guidelines were largely clinically-led, although patients were formally involved in guideline development in the UK, Spain, and Italy. **CONCLUSIONS:** Patient involvement had limited influence on HTA decision making in the diseases evaluated, suggesting that formal processes for patient involvement are not fully maximised. PRO data influenced few decisions, potentially due to being insufficiently robust or compelling. Valid, reliable, responsive PROs in well-designed comparative clinical studies are needed to generate data for reimbursement decision making.

**PHP239: THE USE OF REAL WORLD DATA FOR NICE DECISION-MAKING: A REVIEW OF SUBMISSIONS TO THREE TREATMENT EFFECTIVENESS EVALUATION PROGRAMMES IN 2015 AND 2016**

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**OBJECTIVES:** Randomised controlled trials (RCTs) are traditionally the ‘gold-standard’ data source for National Institute for Care and Health Excellence (NICE) evidence appraisals, although real world data (RWD) is gradually being accepted alongside RCTs or sometimes as a distinct evidence source. Guidance regarding the appropriate use of RWD is limited and varies across programmes. This audit aimed to quantify the extent to which RWD was considered in submissions and reviews for three NICE evaluation programmes in the previous two years. **METHODS:** A systematic review of NICE guidance published by the NICE Technology Appraisal (TA), Diagnostic Assessment (DA) and Medical Technologies Evaluation (MTE) programmes in 2015-16 was conducted in May 2017. Key information, including a description of evidence considered, committee comments and recommendations made was extracted and recorded in an electronic database. References to RWD (i.e. data generated from non-comparative, observational studies) were noted. **RESULTS:** In 2015-16, 91 TA, 9 DA and 9 MTE submissions were appraised by NICE. Of TA evidence submissions, 10% (9/91) included RWD, compared with 67% (6/9) DA and 89% (8/9) MTE submissions. The reviewing committee identified aspects of real-world study methods or reporting requiring improvement for 56% (5/9) TA, 50% (3/6) DA and 44% (4/9) MTE appraisals involving RWD: key areas of focus included sample size, generalisability to wider population, and potential confounders. Guidance included specific recommendations for further RWD collection for 5% TA, 100% DA and 56% MTE.
submissions. **CONCLUSIONS**: The relatively low proportion of RWD in TA submissions suggests a slower uptake for medicine appraisals compared with diagnostics and other technologies. Nevertheless, the thorough evaluations of real-world evidence by NICE, and trend towards specific recommendations for further RWD, indicate increasing prominence of RWD for NICE decision-making. Detailed guidance and collaboration across NICE programmes is needed to enable robust design and consistent critique of real-world studies.

**PHP240: WHEN THE OUTCOME OF AN APPRAISAL IS NOT NICE: A REVIEW OF NICE APPEALS**

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**OBJECTIVES**: The National Institute for Health and Care Excellence (NICE) provides stakeholders to health technology appraisals the option to appeal the decision. We conducted an analysis of past appeals to review the appraisal appeal process by time, therapeutic area, number and type of appellants, grounds of the appeal, and success of the appeal. **METHODS**: Appeals starting from the year 2000 were identified on the NICE website. Appeal decision documents were reviewed to obtain date of appeal, therapeutic area, number of appellants, type of appellant, grounds of the appeal, and outcome of the appeal (ie, whether it was dismissed or upheld). Results were tabulated in an Excel spreadsheet and descriptive statistics were compiled. **RESULTS**: A total of 87 past appeals were identified and appeal decisions were available for 75 of the appeals. The annual number of appeals peaked between 2006 and 2008. The most common therapeutic areas of appeals were oncology (39%), rheumatology (16%), and endocrinology (12%). There were a mean of 2.4 appellants per appeal. Manufacturers were the most common appellant (47%), followed by professional group (22%), patient group (22%), clinical (5%), and other (3%). The most frequent ground for an appeal was unreasonable evidence (92%), followed by failure to be fair (64%), and exceeded powers (23%). Forty-two (56%) of the appeal decisions were dismissed on all grounds, while the remaining 33 (44%) were upheld on one or more grounds. Failure to be fair was the most common ground for upholding the appeal (38%), followed by unreasonable evidence (34%), and exceeded powers (7%). **CONCLUSIONS**: Manufacturers are the most common appellant in NICE appeals, with unreasonable evidence being the most common ground for the appeal. However, failure to be fair is the ground for appeal most likely to be upheld.

**PHP241: HOW DO NICE EVIDENCE REVIEW GROUPS PERCEIVE SINGLE TECHNOLOGY APPRAISALS PRESENTING LIMITED EVIDENCE OF COMPARATIVE TREATMENT EFFICACY?**

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**OBJECTIVES**: When determining relative treatment effects, synthesising data from several high-quality randomised controlled trials (RCTs) using conventional (network) meta-analysis (NMA) or indirect treatment comparison (ITC) techniques is recommended. This review aimed to determine how Evidence Review Groups (ERGs) perceived National Institute for Health and Care Excellence (NICE) single technology appraisals (STAs) in the absence of these established methods. **METHODS**: STA manufacturer submissions from 2015 onwards, excluding terminated appraisals and reappraisals, were screened in June 2017. Submissions that did not conduct any conventional comparisons were eligible for inclusion. The rationale for not using conventional methodology, the use of non-conventional techniques and the corresponding ERG critiques were reviewed. **RESULTS**: Of the 72 submissions screened, 24 were ultimately included. In just under half of the included submissions, the primary reason for not conducting a meta-analysis was reported to be that only a single relevant RCT was identified, whilst the primary reason cited for not conducting an ITC or NMA in almost a third of the submissions was between-study heterogeneity. The ERGs concluded that conventional comparisons could have been conducted for five submissions, and performed their own meta-analysis in one case. Only six submissions used non-conventional methods to perform a comparison, including naïve comparisons only (n=2), adjusted comparison methods (n=3) and meta-analysis using single-arm trial data (n=1). The ERGs were largely receptive of these non-conventional methods and acknowledged the data limitations; all six submissions were recommended. Ultimately, 22 of the included submissions received a positive recommendation from NICE. **CONCLUSIONS**: A third of the STA submissions reviewed did not include a conventional comparison, usually due to limited data availability or between-study heterogeneity. However, ERGs were generally receptive if a robust search strategy and full exploration of the evidence had been undertaken, and the majority of submissions lacking conventional comparisons were ultimately recommended.

**PHP242: INDIRECT COMPARISONS PRESENTED IN GERMAN BENEFIT ASSESSMENTS – STATUS QUO AND QUO VADIS?**

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**OBJECTIVES**: German benefit assessments on drugs evaluate added benefit against the appropriate comparator,
which is determined by G-BA. If a direct comparison between new drug and comparator is not available, an indirect comparison may be submitted by the manufacturer. This is evaluated during assessment by IQWiG/G-BA. The aim of this study is to provide a comprehensive overview on how indirect comparisons were evaluated in German benefit assessments until today. METHODS: All documents were retrieved from the G-BA homepage. Cut-off date for inclusion was September 1st 2016 (poster will include an update). The following sources had to be available: Dossier module 4 (manufacturers), benefit assessment (IQWiG, if applicable), G-BA decision/rationale (G-BA). Extraction included indirect comparisons submitted by manufacturers and added benefit claimed, IQWiG/G-BA evaluation of indirect comparison and added benefit. RESULTS: 202 benefit assessments were reviewed. Of these, 41 assessments contained 51 indirect comparisons. Manufacturers rated extent and probability of the added benefit higher than IQWiG/G-BA. Extent was rated “considerable” in 17 cases and probability was rated as “hint” in 16 cases, only 3 indirect comparisons were not used to support added benefit. IQWiG declined 40 indirect comparisons and accepted only 6. In 45 assessments added benefit was rated “not proven”. G-BA declined 38 comparisons, accepted 5 fully and 3 partially. Added benefit was rated “not proven” for 43 assessments. IQWiG/G-BA declined mainly due to inadequate methods, study populations or comparators. Only one assessment (Empagliflozin, start March 1st 2016) succeeded with an added benefit based on a partially accepted indirect comparison. CONCLUSIONS: Evaluations of indirect comparisons by manufacturers and IQWiG/G-BA differ considerably. So far indirect comparisons are no promising tool for achieving added benefit. However, being successful is at least possible. Developing and applying sound methods is key, as well as a strict interpretation of study populations and comparators.

PHP243: A COMPARATIVE REVIEW OF VALUE ASSESSMENT FRAMEWORKS IN GERMANY, FRANCE, ENGLAND, AUSTRALIA, AND SOUTH KOREA: AN INDUSTRY PERSPECTIVE

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OBJECTIVES: Many countries utilize Value Assessment Frameworks (VAF) or Health Technology Assessments (HTA) to inform market access and reimbursement for innovative medicines. We sought to characterize the absolute and relative strengths, challenges, and limitations of five well-established VAFs from the perspective of the biopharmaceutical industry, and to determine if each VAF’s stated objectives aligned with observed reimbursement outcomes. METHODS: For each country’s VAF, we first reviewed published documentation (government websites, peer-reviewed literature) to capture stated principles and procedures of assessment, appraisal, and pricing. We then qualitatively ranked the VAFs on scales of: transparency (regarding data requirements, published assessment outcomes, translation of value into price); flexibility (in comparator selection and consideration of non-RCT data); stakeholder engagement (influence of patients, industry, and clinicians in the assessment process); access to innovative medicines. Initial rankings were refined based on double-blinded interviews with 40 executives from biopharmaceutical companies, country trade association representatives, and HTA thought leaders. Finally, we conducted a precedent analysis of reimbursement outcomes for 12 recently launched innovative medicines that had been reviewed by multiple VAFs and represented a range of therapeutic areas. RESULTS: England rated highest relative to other VAFs on stakeholder engagement and flexibility of comparator and data requirements, while Germany fared best on patient access to innovative medicines across therapeutic areas. France, South Korea, and Australia were more likely to delay access to rare disease and oncology therapies. Though more opaque in how assessments translated to reimbursement, interviewees noted a preference for the “added clinical benefit” VAFs in France and Germany, compared with ICER-based VAFs. CONCLUSIONS: The innovative biopharmaceutical industry recognizes relative advantages and drawbacks of established VAFs, and its assessments are supported by empiric reimbursement outcomes across therapeutic areas. Countries interested in attracting multinational pharmaceutical investment and products should understand the nuances and lessons of established systems before imposing new VAF processes.

PHP244: EARLY SCIENTIFIC ADVICE AT CADTH – OPTIONS AND RECOMMENDATIONS FOR FUTURE DEVELOPMENT

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OBJECTIVES: Early Scientific Advice at CADTH was developed in response to a perceived need by innovators and modeled after similar programs internationally. It was developed with the principles that advice on early drug development plans will help produce a more complete package of evidence for reimbursement, and with the goals of reducing uncertainty for payers and providing more timely access for patients. The purpose of this qualitative study was to gauge industry stakeholder awareness of the initiative, and what changes within the scope or mandate of the program may make it more useful and accessible. METHODS: Semi-structured interviews were conducted with
representatives of pharmaceutical companies. Interviews were conducted by a consultant via telephone and written notes were sent back to each participant with instructions to review for accuracy and make modifications as necessary. Comments were aggregated into themes. **RESULTS:** Among 26 companies contacted, 16 completed an interview. The interview sample consisted of 4 small companies (≤ 10,000 employees globally), 6 large US-based companies, and 6 large non-US-based companies. Two of the interviewees were global representatives. Most interviewees were aware of the CADTH Scientific Advice program. Major themes that emerged with regards to suggested improvements to the program included the following: expand the scope of the program to include advice after initiation of Phase III trials; provide advice on real-world evidence study designs; allow for disclosure of advice received at the time of submission for reimbursement review; provide quick access to smaller requests for advice; offer parallel advice with a regulator or with other HTA agencies. **CONCLUSIONS:**: The findings from this study will help inform improvements to the Scientific Advice program at CADTH. They may also inform other HTA agencies with similar existing programs as well as those developing Scientific Advice programs currently.

**PHP245: HOW WILL PROPOSED CHANGES TO THE NICE HIGHLY SPECIALISED TECHNOLOGY EVALUATION PROCESS IMPACT PATIENT ACCESS TO INNOVATIVE DRUGS FOR RARE DISEASES?**


**OBJECTIVES:** Health technology assessments of ultra-orphan drugs (ultra-ODs) for very rare conditions are faced with several unique challenges. In recognition of this, in 2016–17 the National Institute for Health and Care Excellence (NICE) proposed new initiatives to its Highly Specialised Technology (HST) programme, including introduction of a cost-per-QALY threshold. The objective of this study was to evaluate HST evaluations in the context of the proposed changes and the potential impact they may have on patient access to ultra-ODs in England and Wales. **METHODS:** All publicly available HST evaluations published between its inception in April 2013 and June 2017 were reviewed, alongside guidance relating to the proposed changes. **RESULTS:** Six HST evaluations had been conducted by NICE and seven were in development. Five received positive reimbursement decisions with a cost per treatment/year of £125,000–£394,680. One (sebelipase alfa) was not recommended based on the prohibitively expensive cost (£491,992 per treatment/year), in the context of uncertainties around the long-term benefits. All positive recommendations have conditions attached, including a patient access scheme (eculizumab, ataluren, migalastat), managed access scheme (ataluren, elosulfase alfa), and use within expert centres (eculizumab). The proposed changes to the HST programme include implementing a cost-effectiveness threshold for ultra-ODs of £100,000–£300,000 per QALY, using a QALY weighting based on the number of additional QALYs a medicine offers. Under the proposed changes those ultra-ODs with a positive recommendation would be unlikely to significantly raise the £100,000 threshold, and therefore may not receive a positive recommendation without a patient access scheme or managed access scheme to improve cost-effectiveness. **CONCLUSIONS:** The introduction of a cost-effectiveness threshold increases clarity about decisions regarding which ultra-ODs are routinely funded, but could make patient access more difficult as they may be less likely to be recommended by NICE.

**PHP246: REVIEWING THE EFFECTIVENESS OF UK DRUG HORIZON SCANNING EFFORTS & THE PRODUCTION OF NICE COMMENTARY ALONG THERAPEUTIC SPECIALTIES**

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**OBJECTIVES:** The National Institute for Health Research Innovation Observatory is responsible for notifying the National Institute for Health & Clinical Excellence (NICE) of new drugs & indications prior to market authorisation (MA). This constitutes the first step in NICE’s topic selection, and the desired notification period is 600 days for new drugs, 450 for new indications. This research aims to explore the success of previous horizon scanning at meeting notification requirements as well as the speed at which NICE commentary was produced. **METHODS:** All publicly available NIHR horizon briefs between 2006 and Q1 2017 were collated and segmented by specialty area. Of the resulting 1060 briefings, 223 were examined across 5 distinct specialties. The product, briefed indication, and notification date were identified, and the pertaining MA status within the United Kingdom and availability of NICE commentary were determined for each product & briefed indication. Resulting notification & commentary time periods were compared across product, specialty and label groups. **RESULTS:** 114/223 of the examined products were authorised (or likely soon to be authorised) in the UK for their briefed indications. The average notification period across all specialties was ~790 days for new drugs (85/114) and ~640 days for new indications (29/114). For all relevant drugs with NICE commentary (99/114), the average period between MA and commentary was ~500 days. Clear differences in average notification & commentary periods were seen between specialties (e.g. 20/21 Infectious Disease products had quicker-than-average commentary periods). **CONCLUSIONS:** For both new drugs & indications, the average notification period was significantly better than required, but differences between products & specialties indicate that improvements across groups can be made. Likewise, differences in average commentary...
periods also suggest that efficiencies might be gleaned from certain specialty areas, though the precise cause of these differences (beyond the mere impact of the specialty group) would require further elucidation.

**PHP247: WHEN THE PRICE IS RIGHT: WHEN, IN PRACTICE, ARE CONFIDENTIAL DISCOUNTS INTRODUCED IN THE NICE PROCESS?**

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**OBJECTIVES:** Manufacturers often submit a patient access scheme (PAS) to increase their cost-effectiveness during appraisals by the National Institute for Health and Care Excellence (NICE). We reviewed all NICE technology appraisals (TAs) since October 2007 to determine whether a PAS was submitted, and explore the timings of PAS introduction. **METHODS:** Using the NICE website, all TAs between October 2007 and May 2017 were reviewed, including those with a “not recommended” decision from NICE. The timing of the PAS submission for each TA was allocated to one of four categories: initially submitted/no change, initially submitted/changed during process, introduced after submission, no submission of PAS. **RESULTS:** 285 appraisals were published during this timeframe, with 228 recommended. Of these, 125/228 (55%) were contingent on a PAS. A simple discount, which can be changed during the submission process, was introduced in 88/125 (70%) of accepted TAs with PAS, whereas complex PASs which cannot be changed during the process occurred in 37/125 (30%). Of simple PASs, 39/88 (44%) were categorised as initially submitted/no change and 19/88 (22%) initially submitted/changed during process. In 30/88 (34%), a PAS was introduced after submission. Of all recommended TAs with PAS, 49/125 (39%) were introduced or changed after submission, when manufacturers could better estimate the likely outcome of the PAS. **CONCLUSIONS:** Some appraisals reveal implicit price flexibility from the manufacturer during the appraisal process. Flexibility could be a commercial advantage over manufacturers with inflexible PASs (e.g. complex PASs) where a discount is offered prior to the appraisal. It may be preferable for a manufacturer to submit a simple PAS upfront; once the submission has been appraised, there is more certainty of the likely outcome, and the PAS can be adjusted.

**PHP248: EARLY HTA ADVICE IN EUROPEAN COUNTRIES: SCOPE AND ASSOCIATED COSTS**

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**OBJECTIVES:** This research aimed to understand early Health Technology Assessment (HTA) advice opportunities in European countries: to characterise the scope of advice offered (e.g. formal vs. informal, written vs. oral, separate HTA advice or joint with regulatory scientific advice), the early advice process, and costs associated with advice. **METHODS:** A structured literature search was conducted incorporating National HTA websites, HTA conference websites and PubMed. The country scope included fifteen European countries: Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Spain, Sweden, and United Kingdom. **RESULTS:** Formal national early HTA advice (separate from regulatory advice and with the official description of the process and application form) is offered in Germany, United Kingdom, France and Italy. Sweden, Norway and Belgium have a procedure allowing manufacturers to obtain answers to HTA-related questions while applied for national early scientific regulatory advice. The majority of countries participate in multi-stakeholder programs: parallel EMA-HTA scientific advice procedures, the EUnetHTA early dialogue and Shaping European Early Dialogues projects. Most agencies recommend that early advice is sought between phase II and phase III of clinical development. Consultation times vary from 6-8 weeks in Norway to 18 weeks in France and United Kingdom. Advice is usually provided through hearings (teleconferences and face-to-face meetings) and some agencies like G-BA (Germany), AIFA (Italy), HAS (France), TLV (Sweden) and NICE (UK) provide a written report. There is no fee in Sweden, Belgium and Norway, while in all other countries it varies from €2,000 - €50,000. In France the early dialogue is free of charge, however, the advice is given only for innovative products. **CONCLUSIONS:** The scope of HTA early advice varies significantly across geographies as do the costs and consultation times for advice.

**PHP249: ACCEPTANCE OF POPULATION-ADJUSTED INDIRECT TREATMENT COMPARISON METHODS IN NICE ASSESSMENTS**

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**OBJECTIVES:** Guidelines for applying methods for population-adjusted ITC, e.g. matching adjusted indirect comparisons (MAIC) and simulated treatment comparisons (STC), in submissions to NICE were published in December 2016. These methods overcome issues like disjointed evidence networks and heterogeneity in network meta-analyses (NMA), and can produce comparative evidence where it may otherwise be impossible. Previous
research found 4 NICE appraisals using MAIC published between 2010 and 2016 [Thom et al 2016]. The objective of this study was to review recent submissions to NICE to determine the use and acceptability by the payer of the population-adjusted ITC methodology. METHODS: All manufacturer submissions, evidence review group reports and NICE committee feedback documents published between 01JAN2017 and 25JUN2017 were reviewed and information on methods for performing ITCs was extracted. RESULTS: In total, 37 single technology appraisals (STA) were identified. Ten did not include any ITC, 19 included standard NMA, four included a naïve comparison and seven included MAIC; some appraisals included more than one method. The STC method was not applied in any of the appraisals. All seven STAs using MAIC were in oncology. Four were recommended, two were restricted and one received a preliminary negative recommendation. The method was used to address a disconnected network in three STAs and to adjust for trial population heterogeneity in the remaining four. In all cases, the method was accepted for decision-making although several limitations were highlighted, such as lack of rationale for the choice of method, limited justification for the choice of matching variables, limited possibility of matching outcome definitions or inclusion/exclusion criteria between studies. CONCLUSIONS: Despite the short timeframe, our research demonstrates that the use of population-adjusted ITCs has been increasing in NICE STAs, with 19% of STAs including MAIC. The method has been generally accepted, although considered equivalent to observational evidence and its underlying assumptions subjected to close scrutiny.

PHP250: COMPARISON OF THE REIMBURSEMENT DECISIONS OF PHARMACEUTICALS IN HUNGARY, ROMANIA AND TURKEY

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OBJECTIVES: In countries with strong financial constraints healthcare decision-makers often restrict patient access to new medicines. In addition, manufacturers may delay their lunch due to undesired nature of these markets. We aimed to compare the reimbursed status of newly registered pharmaceuticals in three selected countries. METHODS: Drugs registered in 2015 by EMA were listed and published national databases about drug reimbursement were reviewed. In Hungary, the National Health Insurance Fund Administration publishes a regularly updated list of drugs that applied for reimbursement. In Romania, the process of access to innovative medicines is organized in 3 steps: first the drug is registered based on EMA procedure, second the dossier is filed at MoH with the Romanian price, and finally, it can be sold, but not yet reimbursed by the public payers. Process of reimbursement decisions are lack of transparency. In Turkey, Turkish Medicines and Medical Devices Agency (TMMDA) responsible for registration and pricing process of drugs and Social Security Institution (SSI) takes reimbursement submissions and decisions. SSI only publishes positive decisions. RESULTS: 82 registered products were reviewed in the national databases. In Hungary, 17 of the reviewed products were on the public reimbursement list, 3 received negative reimbursement decisions and 10 are awaiting for decision about their reimbursement application. In Romania, only 5 of the listed products are on the positive reimbursement list. In Turkey 63, of the listed products are not on the reimbursement list but 8 of them can be reimbursed upon approval of TMMDA by patient case (this case products imported from abroad) and 19 received positive reimbursement decision. CONCLUSIONS: We found similarities among Hungary and Turkey in the number of reimbursed drugs and more than half of the reimbursed products (10) were same in the two countries. Romania, however faces serious constrains in terms of patient access to newly approved drugs.

PHP251: INITIATIVES THAT IMPACT PRICING AND REIMBURSEMENT OF ORPHAN (AND ULTRA ORPHAN) DRUGS: REVIEW OF EUROPEAN TRENDS

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OBJECTIVES: There is significant variation in HTA initiatives implemented for orphan drugs across Europe which has a direct impact on pricing and reimbursement (P&R). We reviewed these initiatives to understand the differences influencing HTA decisions on orphan drugs in European markets. METHODS: The HTA and P&R pathways in France, Germany, Spain, Italy and UK were reviewed through the relevant organisation websites, with 10 qualitative 1:1 interviews conducted with national and regional experts representing the EUS to provide details on funding routes, evidence requirements, and pricing negotiations. RESULTS: Some European markets have implemented formal processes to support the assessment of orphan drugs. In the UK a drug is labelled as a highly specialised technology if the treatment population is below <1 in 50,000 and NICE then assesses the effectiveness, safety, and broad cost comparisons rather than utilising cost-effectiveness criteria. In Germany orphan drugs are automatically granted ‘additional benefit’ following marketing authorisation; however, the extent of the benefit is still assessed by
the G-BA. Alternatively, some markets (including Italy and France) have not introduced orphan-specific initiatives to date and subsequently orphan drugs are reviewed through the usual P&R pathways, but may be subject to a tailored procedure. Expectations are less stringent regarding clinical or economic evidence and there is greater flexibility for the trial design and the number of patients to enrol due to the small patient population. Furthermore, markets have variable economic thresholds for orphan drugs. In the UK, for example, highly specialised technologies are now being assessed against a maximum threshold of £300,000 per QALY. **CONCLUSIONS:** There is a common trend across Europe to streamline HTA processes for orphan drugs. Some markets have implemented formal processes, whereas other markets unofficially adjust evidence requirements. Nuances between markets need to be understood by orphan drugs' manufacturers in order to achieve optimal P&R.

**PHP252: THE COST-EFFECTIVENESS OF MANUFACTURER FEES FOR HTAS: ARE THEY PROMOTING OR HINDERING INNOVATION?**


**OBJECTIVES:** Due to rising costs and aging populations, countries with public health systems are increasingly utilising Health Technology Assessments (HTAs) to determine pricing and reimbursement of new treatments. This research evaluates the fees charged to industry for HTAs in countries with obligate cost-utility HTA bodies (UK, Canada and Australia) relative to their respective market size. **METHODS:** HTA appraisal fees were identified from publicly available websites from the HTA bodies: National Institute for Health and Care Excellence (NICE), Canadian Agency for Drugs and Technologies in Health (CADTH), and Pharmaceutical Benefits Advisory Committee (PBAC) and annual national market size were sourced from the UK National Health Service, Canadian Institute for Health Information, and the Pharmaceutical Benefit Scheme. **RESULTS:** HTA bodies are increasingly requiring partial funding from industry. NICE is proposing to charge £142,000 (£160,727) for a single technology appraisal where the annual national pharmaceutical market is £16 billion (£18.1 billion), which provides an Appraisal Cost to Market Size (ACMS) ratio of 112,676. CADTH charges CNS$72,000 (€48,374) for a Schedule A submission with a market of CNS$8.8 billion (€5.9 billion). PBAC charges AUS$131,407 (€88,377) for a Major Lodgment with a market of AUS$10.8 billion (€7.3 billion). ACMS ratios for Canada and Australia were 122,222 and 82,187, respectively. **CONCLUSIONS:** In order to be publically funded in the UK, Canada and Australia, therapies need to receive positive appraisals by HTA bodies which require financial contributions from manufacturers. These contributions bear little relation to the market size and cumulatively exceed €290,000 (even assuming no need for resubmissions). By adopting charging/cost recovery models, HTA bodies may be able to reinvest the proceeds to increase the efficiency and capacity of appraisals, expediting patient access. However, these fees may be burdensome especially for SMEs with promising therapies for orphan/rare diseases, and they may thus have the potential to deter and delay their submissions.

**PHP253: DO NICE APPEALS MAKE A DIFFERENCE? IMPACT OF APPEALS ON APPRAISAL OUTCOMES**

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**OBJECTIVES:** The National Institute for Health and Care Excellence (NICE) provides stakeholders to health technology appraisals the option to appeal the decision. We conducted an analysis of past appeals to assess the impact of the appeal on the appraisal outcomes. **METHODS:** Appeals starting from the year 2000 were identified on the NICE website. Appeal decision documents were obtained and reviewed to identify whether the appeal was upheld or dismissed. Appeals that were dismissed were reviewed to identify whether the appeal made any impact on the final appraisal determination (FAD) or resulted in any other changes. Appeals that were upheld were reviewed to identify the appeal panel recommendation and, if pre and post appeal documents were available, the impact on the recommended NICE guidance. **RESULTS:** A total of 87 past appeals were identified and appeal decisions were available for 75 of the appeals. Forty-two (56%) of the appeal decisions were dismissed on all grounds, with the remaining 33 (44%) upheld on one or more grounds. Among the dismissed appeals, 40% had no impact on the decision, 48% resulted in minor amendments to the FAD, and 12% had some other outcome (eg, comment on the process). Among the upheld appeals, 82% were remitted to the NICE appraisal committee for revisions, 9% resulted in guidance executive revisions, 6% resulted in appeal panel observations or comments, and 3% led to reappraisal. Among the upheld appeals, with pre/post documents available, 14% resulted in no change in the FAD, 33% in a minor change, 14% in a major change, and 37% in a reversal of the decision recommendation. **CONCLUSIONS:** NICE appeals can have a significant impact on the decision with nearly one-quarter of all filed appeals resulting in major revisions or a change in the recommendation. In addition, even the majority of dismissed appeals resulted in amendments to the FAD.

**PHP254: CONFIRMATORY VERSUS EXPLORATORY ENDPOINT ANALYSIS: DECISION-MAKING UNDER UNCERTAINTY ON THE BASIS OF EVIDENCE AVAILABLE FROM MARKET AUTHORIZATION AND EARLY
BENEFIT ASSESSMENT IN GERMANY

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OBJECTIVES: To compare the use and importance of confirmatory endpoints in German early benefit assessment (EBA) versus market authorization (MA) for oncology drugs with both evaluations relying on the same evidence. The EBA of pharmaceuticals in Germany and their preceding MA pursue different objectives resulting in divergent decision-making strategies. This is reflected inter alia by the inclusion of varying confirmatory endpoints within the evaluation of oncology drugs. METHODS: Identification of endpoints is based on a specifically developed guide. Data from completed assessments up to July 2015 are used to estimate the impact of explorative endpoints in comparison to confirmatory endpoints on MA and EBA by contrasting the benefit-risk ratio of EMA and the benefit-harm balance of the HTA jurisdiction. Agreement between MA and EBA is examined by Cohen’s kappa (k). RESULTS: 21 of 41 assessments were considered in the analysis. Procedurally, neither MA nor EBA are confirmatory because they also include explorative endpoints. However, in terms of quality of endpoints, MA is more confirmatory than EBA because it includes a higher proportion of primary endpoints. The latter implies a primary endpoint to be relevant for the benefit-harm balance in only 67% of cases (0.078). Explorative mortality endpoints reached the highest agreement regarding the mutual relevance for the risk-benefit ratio and the benefit-harm balance (0.000). For explorative morbidity endpoints (-0.600), quality of life (-0.600) and side effects (-0.949) no agreement is ascertainable. CONCLUSIONS: The comparability of the two evaluation processes based on endpoints is only possible with some limitations when using the evidence contributed by clinical trials. To warrant a broader confirmatory basis for decisions supported by HTA, closer inter-institutional cooperation of approval authorities and national HTA jurisdictions would be favorable. A reduction of the uncertainty surrounding decisions can be achieved by means of joint advice for manufacturers regarding endpoint definition and hierarchy.

PHP255: ASSESSING CRITERIA FOR NICE RECOMMENDATION WITH THE HST PROGRAMME


OBJECTIVES: This work aims to review the criteria by which the Highly Specialised Technology (HST) programme assesses treatments for rare conditions unlikely to meet standard clinical and cost-effectiveness criteria due to the limited patient population. METHODS: Review of all technologies with final evaluation determinations (FEDs) undergoing HST by June 2017, to assess the importance of budget impact, cost per patient, QALY gains, cost-effectiveness, innovation, unmet need, and other factors associated with NICE recommendation. RESULTS: Of the seven treatments with FEDs by June 2017, eculizumab-α and ataluren were recommended with managed access agreements (MAAs); elosulfase-α and migalastat were recommended without MAAs; asfotase-α was recommended for a subpopulation with an MA; and sebelipase-α was provisionally not recommended. These outcomes did not reflect data quality; eculizumab offered only single-arm, non-randomised data, while sebelipase-α was supported by RCTs. Recommendations were also unlikely to reflect clinical impact, as incremental QALYs gained with sebelipase-α (6.64) were higher than for migalastat (0.34-0.98). Additionally, babies presenting lysosomal acid lipase deficiency did not survive longer than 12 months without sebelipase-α, suggesting substantial unmet need. Cost-effectiveness was not reported, but the annual treatment cost (from list price) appears significant. Sebelipase-α had the greatest reported annual cost per patient of £491,992 (for an 11-year-old child), compared with £211,000-£340,000 for eculizumab and £394,680 for elosulfase-α. The annual budget impact, based on list prices, was also highest for sebelipase-α (5-year net: £59 million). However, the £13.4 million impact for the subgroups not recommended for asfotase-α was less than the £17.3 million for elosulfase-α, indicating the decision was made partially on efficacy grounds. CONCLUSIONS: The results suggest HST recommendations do not directly reflect treatment efficacy, which is frequently associated with substantial uncertainty. Annual treatment cost and budget impact appear more important factors, although these will be modified by confidential patient access schemes.

PHP256: MARKET ACCESS OF ADVANCED THERAPY MEDICINAL PRODUCT (ATMP) IN EUROPE: LESSONS LEARNT AND KEY CONSIDERATIONS FOR FUTURE SUCCESS

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OBJECTIVES: Although an increasing number of ATMPs are entering the market, the driving factors for successful commercialisation are unclear. This research aims to evaluate the eight ATMPs approved by the European Medicines Agency (EMA) to date and identify key success factors and barriers that impact market access of ATMPs in Europe. METHODS: We analysed health technology assessment (HTA) reports to understand reimbursement decisions of ATMPs in France, Italy, Germany, and the UK. We reviewed academic and news articles for updates.
and interviewed payers where clarification was needed. RESULTS: Eight ATMPs have been approved by the EMA. The first four ATMPs, ChondroCect, Glybera, Provenge and MACI, have already withdrawn from market due to commercial reasons. One key hurdle was country-level HTA, as the clinical benefits of the four ATMPs were not recognised despite being innovative technologies. Without recognition of the clinical value, it is challenging to justify the high price tags (e.g. Glybera received a non-quantifiable added clinical benefit rating in Germany, and at approximately €1 million per patient, its uptake has been low). In contrast, the four ATMPs approved by the EMA more recently (between 2015-2016) show more promising futures. The clinical benefits of Holoclar, Imlygic and Strimvelis have been recognised and reimbursement granted in at least one country in Europe. One key contributing success factor was the use of managed entry agreements to mitigate financial/outcome risks for payers and better support value for money. Other factors include the adoption of a private-public partnership model to effectively engage different stakeholders and the abilities to build infrastructure necessary for delivery of ATMPs. CONCLUSIONS: ATMPs approved by the EMA in the last two years have been more successful at gaining reimbursement in Europe. Success is driven by a combination of demonstrating clinical benefits and addressing payer clinical/financial concerns, as well as maturity in environment/infrastructure.

**PHP257: AMNOG DOSSIERS AS A CHALLENGE FOR PHARMACEUTICAL COMPANIES: IS THERE A CORRELATION BETWEEN VOLUMES AND ADDED MEDICAL BENEFIT?**

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**OBJECTIVES:** Since the enactment of AMNOG in Germany in 2011, 238 dossiers have been submitted to G-BA. A dossier is mandatory for pharmaceutical companies in order to be able to realize a price higher than the price of the appropriate comparator defined by G-BA in the price negotiation, given an added medical benefit is granted. However, the efforts and resources to assemble an AMNOG dossier are extensive and, oftentimes, underestimated by companies. One major challenge are the extensive mandatory data requirements that go beyond respective requirements posed by EMA or FDA. **METHODS:** Volume (number of pages) of Modules 1-4 was used as a proxy for efforts and resources to write an AMNOG dossier. Module 4 contains clinical data on which added medical benefit is assessed. Hence, volume of module 4 was compared to the respective added medical benefit to conclude on possible correlation. **RESULTS:** 38% of the dossiers were in field of oncology, followed by metabolic diseases (19%). The annual number of dossiers is increasing from 23 (2012) to 71 (2016). Mean number of pages was 820, with a maximum of 3,465. For non-orphan drugs, there seems to be an inverse trend between the volume of module 4/total dossier and added medical benefit: major (530/736 pages), considerable (638/838), minor (688/905) and no added medical benefit (747/970); non-quantifiable (549/722). In orphan drugs however, added medical benefit correlated with volume of module 4/total dossier: considerable (654/868), minor (383/524); non-quantifiable (275/422). **CONCLUSIONS:** For non-orphan drugs, uncertainty in regard with the presumed added medical value seems to translate into greater volume of the dossiers. The inverse effect in orphan drugs might be attributable to the fact that more comprehensive clinical data might facilitate emphasizing the clinical value of drugs thus leading to a higher rating.

**PHP258: UTILIZATION AND EVALUATION OF DELPHI PANELS IN GERMAN AMNOG ASSESSMENTS**

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**OBJECTIVES:** Expert advice and/or opinion can be a valuable source of information, especially if reliable evidence is not available. A Delphi Panel (DelP) is a structured approach, utilizing the expertise of experts to provide evidence in a consensus-driven approach. In accordance with the rules of procedure by the German Federal Joint Committee (G-BA) during the Benefit Assessment (AMNOG), expert advice achieved by consensus, in principle, is accepted within value dossiers. Aim of this study was to examine how DelPs are integrated in German AMNOG assessments and how they are evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG) and the G-BA. **METHODS:** Available AMNOG dossiers up until June 2017 were evaluated with respect to the integration of DelPs, size of the panel, acceptance and evaluation by IQWiG and G-BA, as well as decision on added benefit. Descriptive statistics were applied and the assessment of respective DelPs by IQWiG was analyzed. **RESULTS:** In total, n=251 AMNOG dossiers were included. Overall, DelPs were utilized in 4.4% (n=11) of all dossiers. Results of DelPs were incorporated in Module 3 (n=8) (epidemiology, cost, disease burden) and Module 4 (n=3) (clinical data). DelPs were used to address evidence needs in oncologic disorders (n=5), metabolic diseases (n=3), mental disorders (n=2), and diseases of the musculoskeletal system (n=1). On average 10.8 experts were included in the exercise. IQWiG, in the majority of cases, was basically positive, criticism focused on number of experts in two dossiers, as well as lacking discussion of limitations and transfer of results to target populations. In four dossiers IQWiG was not able to validate the indicated findings. **CONCLUSIONS:** DelPs are rarely used within the German AMNOG process. As the acceptance seems reasonable, the application of DelPs offers a viable option to address or minimize evidence gaps in an AMNOG assessment.
**PHP259: 12 MONTH REVIEW OF NICE AND SMC RECOMMENDATIONS FOR NEW TECHNOLOGIES**

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**OBJECTIVES:** Technology appraisals over the past 12 months were compared between NICE and the SMC to look for evidence of discrepancies and differences in approach to technology appraisal. **METHODS:** Using the NICE and SMC websites, published technology appraisals were examined between June 2016 and June 2017 on the NICE website. Given that the SMC typically issues guidance sooner than NICE, the corresponding SMC verdict was then compared with the NICE verdict from this timeframe. Guidance was categorised as: terminated, rejected, restricted, recommended (with patient access scheme), or recommended. SMC appraisals could also have been superseded by subsequent NICE multiple technology appraisal recommendations. **RESULTS:** In the 12 months prior to 13th June 2017 NICE updated 62 technology appraisals, seven of which were terminated. In total, seventeen discrepancies between NICE and SMC appraisals were identified. Removing terminated appraisals from either body, as well as SMC guidance which was superseded, there were 15 areas of discrepancy. These included: five restrictions by NICE which were accepted by the SMC, one restriction by NICE which was rejected by the SMC, and three acceptances by NICE which were rejected or restricted by the SMC. SMC guidance typically came several months before the NICE guidance, and discrepancies were not limited to a single disease area. **CONCLUSIONS:** NICE and the SMC generally agree on their reported recommendations for new technologies, given the costs of the drugs and the local epidemiology of disease are relatively similar between England and Scotland in most cases. However, discrepancies reflect the difference in approach taken by the SMC and NICE, and are not specific to a single disease area. This study furthers the discussion in favour of bespoke SMC submissions.

**PHP260: COMPARATIVE ANALYSIS OF THE DEVELOPMENT OF THE BULGARIAN AND THE ROMANIAN HTA SYSTEM**

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**OBJECTIVES:** Until 2012 there has been a lack of predictability and transparency of the Romanian process on drugs inclusion in the reimbursement list which is quite similar to the situation in Bulgaria until 2015. A new scorecard HTA process was implemented in 2014 in Romania. In this study we are analyzing and comparing the characteristics of HTA process in Romania implemented since 2014 and since 2016 (Bulgaria). **METHODS:** A critical appraisal of HTA Score Card was done based on the legislation, published articles and reports in Romania. HTA legislation and guidelines in Bulgaria have been reviewed and analysed while considering the reasons behind its introduction and analysing the HTA process as a whole. **RESULTS:** By December 2015, more than 200 HTA dossiers were evaluated and the scorecard HTA results were reflected in three processes of the drug reimbursement list update. The HTA scorecard in Romania is based on six criteria: France and Germany HTA decision, the number of EC reimbursement countries, the local real-world data and a budget impact. For medicinal product inclusion in the PDL in Bulgaria the HTA assessment should be more than 75% of all indicators (965 point) of the Score Cards and also the negative HTA assessments from HAS, NICE and GBA are directly transferred. The submitted 34 INN (71% ) out of 48 INNs were HTA assessed in 2016. **CONCLUSIONS:** A step-by-step process for applying of HTA in decision making reimbursement process of medicines is set up in both surveyed countries. Although the HTA system in Romania makes no direct evaluation of the value of drugs, authorities consider it to be effective, being designed only to favor cost-saving drugs and to promote high discounts. Where in Bulgaria the HTA process is also still controversial because the UK, France and Germany HTA evaluations are directly transferred and not locally assessed.

**PHP261: ASSESSMENT OF PUBLIC OPINION REGARDING THE ETHICS OF NICE CDF, HST, AND END-OF-LIFE CRITERIA FOR DRUG REIMBURSEMENT**


**OBJECTIVES:** NICE have never fully ascribed to utilitarianism (producing maximum QALYs on a fixed budget) or egalitarianism (providing adequate healthcare for people with all maladies) for drug appraisals. End-of-life treatments may add value (uncaptured by QALYs) through giving individuals time to make arrangements for death, making the policy arguably utilitarian. The Cancer Drugs Fund (CDF) places value on cancer treatments, which is arguably egalitarian if they are neglected, or possibly political. The recent introduction of Highly Specialised Technologies (HST) reduces national QALYs gained in favour of treating rare diseases, suggesting an egalitarian shift. This review assesses the public support for such policies. **METHODS:** Global review of public opinion on ethical drug reimbursement. Databases included PubMed, Embase, ISPOR, OHE, EconLit, NICE, and HTAi. Search terms
Combined “ethic” and “util” with “health care”, “end-of-life”, “NICE”, “CDF”, “HST”, “orphan”, and “HTA”. RESULTS: Eighteen relevant sources were identified. In one, 20 out of 27 citizen’s council members agreed paying premium prices for ultra-orphan treatments was sometimes or always necessary. Similarly, a larger study of 568 individuals showed 56% of respondents and 41% of medical decision makers favoured equity in healthcare over maximising utility. Another survey of 1,547 individuals splitting expenditure between common diseases and costly rare ones found 42.3% favoured an even split, with 23.5% favouring rare diseases, which decreased to 10.5% if costs were equal. Consistently, a study of 4,118 individuals found that while most respondents did not prioritise disease rarity, cancer, or end-of-life, there was a tendency across these factors to favour the more expensive option. CONCLUSIONS: Despite a paucity of data, public opinion does not necessarily support NICE’s CDF, HST, and end-of-life. While some studies showed additional value applied to disease rarity, this might simply reflect willingness to pay more for treatments that cost more, regardless of disease prevalence.

PHP262: A COMPARISON OF HEALTH TECHNOLOGY ASSESSMENT (HTA) REQUIREMENTS FOR SYSTEMATIC LITERATURE REVIEWS (SLRs)

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OBJECTIVES: An SLR provides comprehensive, high-quality synthesis of published evidence, and is a fundamental component of regulatory submissions for many HTA agencies. While there is a broad consensus among HTA bodies that an SLR is essential to identify relevant data, specific guidance on data sources, methodology, required outcomes, and reporting of the SLR varies considerably between HTA agencies. This study aimed to review and compare requirements for SLRs from several prominent HTA organizations. METHODS: Searches of 5 leading HTA agency websites were performed to identify guidelines or requirements for the conduct of SLRs used in product submissions. Available relevant guidance was extracted and compared between HTA bodies. RESULTS: All HTA agency websites included information regarding the type of literature review required to provide evidence for the proposed intervention (Table 1). With the exception of AMCP and CADTH, all other agencies reviewed (AMNOG, NICE, and PBAC) require an SLR evaluating clinical data and explicitly mention inclusion of comparator data and the potential need for indirect treatment comparisons. All 3 of these agencies mandate detailed documentation of SLR methodology. AMNOG restricts the SLR to head-to-head evidence against an agency-specified comparator; AMNOG and PBAC further specify data sources for the review. CADTH does not require an SLR, but requests documentation of search strategies. While all of the included organizations require background information on the intended patient population, none requests an SLR on epidemiological evidence. Economic data are required by AMOP, CADTH, and NICE, although only NICE dictates an SLR of economic evidence. CONCLUSIONS: The most stringent guidelines for SLR methodology were seen in Europe (UK and Germany) and Australia. North American HTAs’ guidance for the
THE USE OF MCDA IN HTA DECISION MAKING IN BULGARIA

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OBJECTIVES: Multi-Criteria Decision Analysis (MCDA) is used in HTA to make decisions, based on more than one criterion. Being incorporated in December 2015 in Bulgaria, MCDA delivers complex HTA decisions where while cost-effectiveness remains the dominant consideration. The decision making process is based on a list of criteria, including but not limiting to the cost per a QALY gained, to be measured, scored and weighted. METHODS: Legislative review and analysis of the new methodological Score List (SL) for inclusion of the new INN in the Positive Drug List (PDL) in Bulgaria. Retrospective, descriptive study, examining all new approved INN by the pricing and reimbursement competent authority and by the HTA Commission in Bulgaria. RESULTS: Adopting a solution with a reimbursement recommendation in the SL with points was introduced in 2016. For inclusion of the medicinal product in the PDL after HTA assessment is at more than 75% of the maximum number of MDC points (965). Between MDC 50% (643) and 75% (965) the decision for admission is under certain conditions, and below 50% (643) the MDCA is negative. Based on that SL in 2016 n=30 INN received a positive HTA assessment MDCA points between 50-75%. Out of them 40% INN were included in the reimbursement system of the country and n=18 INN with more than 60% MCDA (positive HTA assessment) were not listed for reimbursement. CONCLUSIONS: The MCD is a reliable method and the approach is well formulated, consistent and replicable, but nevertheless all INN with a positive HTA assessment were not included for reimbursement in 2016, which is an indication that the MCDA need a further validated approach.

EXTRAPOLATION OF ADULT DATA FOR PEDIATRIC DRUG BENEFIT ASSESSMENT IN THE AMNOG DOSSIER IN THE LIGHT OF THE NEW AMVSG

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OBJECTIVES: Extrapolation of efficacy results from adults to a pediatric population is used in EMA pediatric drug approval to decrease the number of pediatric studies and maximize the use of adult data. Little is known about the applicability of such extrapolation in the process of the German benefit assessment of pharmaceuticals (AMNOG) to claim an additional benefit for a pediatric drug. This research gives an overview of the type of extrapolation of adult data to pediatric populations in the course of the New German Medicines Supply Reinforcement Act (AMVSG) and its impact on the final grading of the additional benefit. METHODS: To understand the use of extrapolation in the German benefit assessment in alignment with the updated Ordinance for the Benefit Assessment of Pharmaceuticals (AM-NutzenV), and to investigate the requirements for acknowledgement of extrapolation, a research of published AMNOG dossiers since 2011 was performed. Benefit assessments of pediatric applications with involvement of extrapolation are described. Qualitative analysis will outline the requirements for its acknowledgment by IQWiG/G-BA. RESULTS: Similarity between adult and pediatric population in terms of the disease, the drug effect and clinical endpoints are indispensable requirements for consideration of extrapolation in the benefit assessment. Nonetheless, consideration of the similarity concept in the dossier not inevitably affects the final additional benefit. CONCLUSIONS: Based on our research, extrapolation of adult efficacy data to a pediatric population for the benefit assessment is feasible but requires careful consideration of a stringent methodical approach in accordance with the requirements of the updated AM-NutzenV. Comprehensive representation of the triumvirate of similarity exert a major impact on the consideration of extrapolation by IQWiG/G-BA. In conclusion, despite its statistical weakness, extrapolation can act as a powerful tool to substantiate the body of evidence generated with often small pediatric study populations.

DEFining Criteria Weights by AHP in Health Technology Assessment

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OBJECTIVES: Multi Criteria Decision Making (MCDM) is claimed to be the aid for Health Technology Assessment (HTA) based decision making. Transparent commitment of multi-disciplinary stakeholders is essential to attain public confidence in healthcare decision making. In current deliberative process commitment of stakeholders is not transparent. This research aims to propose a prioritization approach for MCDM applications in HTA by Analytic
Hierarchy Process (AHP). METHODS: Domains defined in HTA Core Model® of EUnetHTA are selected as nine criteria for MCDM application in HTA. The commitment of decision makers in prioritization of nine criteria is provided by using Saaty rating scale. The decision making group consists of nephrologists, pharmacologists, and health economists in HTA study on “The Role of Peritoneal Dialysis” by Turkish Ministry of Health are asked to define the relative importance of criteria by pairwise comparisons via an online survey. The weights of criteria are determined by applying AHP to survey results. RESULTS: The weights for HTA Core Model® domains by AHP are found to be 0.049 for Health problem and its current use of the technology, 0.036 for Description and technical characteristics of technology, 0.198 for Safety, 0.224 Clinical effectiveness, 0.073 for Costs and economic evaluation, 0.117 for Ethical analysis, 0.077 for Organizational aspects, 0.102 for Social aspects, and 0.132 for Legal aspects. The consistency ratio is 0.0302. CONCLUSIONS: The decision making process in any healthcare systems is a complex set of pragmatic interactions among many stakeholders. With the proposed model stakeholder participation in criteria prioritization is provided. Clinical effectiveness domain is found to have the highest weight followed by Safety. Cost and economic evaluation domain assigned to have lower weight. This shows that decision makers in this specific survey gives more importance on treatment effectiveness, patient safety, and societal aspects while deciding on best treatment alternative in dialysis.

PHP267: COMPARISON OF EARLY SCIENTIFIC ADVICE PROCESSES IN UK, FRANCE AND GERMANY (HTA ONLY): TIPS AND TRICKS

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OBJECTIVES: There are more than 20 health technology assessment (HTA) scientific advice (SA) processes available to provide SA to drug and device manufacturers. The aim of this study is to compare the three most widely used single early SA processes offered by National Institute for Health and Care Excellence (NICE, UK), Haute Autorité de Santé (HAS, France) and Der Gemeinsame Bundesausschuss (G-BA, Germany). METHODS: This overview and suggestions are based on review of NICE, HAS and G-BA SA processes and requirements as well as authors’ expertise. Authors reviewed the SA processes, timelines, template availability, and role of each participating party. RESULTS: SA timelines vary from 2 to 5 months and costs range from nothing up to £50,000. While the HAS process costs nothing, the G-BA process is quicker. It is highly advised to start the process as early as possible to obtain the most benefit. The advice is not legally binding for any of the processes, however, the received guidance provides valuable insights on the choice of comparators, endpoints, study design and health economics. NICE and HAS provide briefing book templates, while G-BA provides a request form. Questions included in the briefing book may cover a range of topics to help companies de-risk their clinical development programmes. NICE and HAS evaluate cost-effectiveness, while G-BA only discusses clinical benefit. Only NICE involves patient representatives in the SA process. SA is country and payer specific and helps to build relationships between all parties. CONCLUSIONS: In addition to aiding in the optimisation of clinical development programmes to generate evidence that is most relevant to HTA bodies, regulators, payers and patients, HTA SA dialogue can provide insights into country specific issues. Furthermore, the SA process helps to align the company’s position and involve all internal stakeholders at an early stage.

PHP268: RETROSPECTIVE ANALYSIS OF THE CEEESP EFFICIENCY OPINIONS AND ELIGIBILITY CRITERIA FOR ASSESSMENT SINCE ITS CREATION

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OBJECTIVES: Health economics is playing a greater role in pharmaceuticals pricing in France since the 2012 Social Security Funding Law established the Commission for Economic Evaluation and Public Health (CEESP), which sits within the Haute Autorité de Sante (HAS). Two criteria define the eligibility for a CEESP assessment: (1) improvement of the Medical Benefit (ASMR) or improvement of the Benefit (ASA) claimed by the company (ASMR or ASA I, II, or III); and (2) significant impact of the product on the health insurance budget (turnover > €20m). Both criteria have to be met. This study aims to discuss retrospectively the relevance of the CEESP assessment which is based on the ASMR claimed by the company as opposed to the ASMR granted by the Transparency Committee (TC). METHODS: Secondary research was performed to analyse eligibility opinions since the first CEESP assessment in 2014, until December 2015. ASMR and ASA scores were retrieved from TC opinions. For each case, the study questioned the rationale for a CEESP assessment as detailed by the manufacturer in the submission dossier, in light of the actual ASMR granted by the TC in parallel. RESULTS: 44 out of 163 pharmaceuticals have been declared eligible for a CEESP assessment. Among all the medicines declared eligible for an assessment 29 have been granted an ASMR IV, V or “not reimbursed”. CONCLUSIONS: The CEESP assessment is meant to inform the price negotiation with the pricing committee (CEPS). The decision to conduct a CEESP assessment is based on
the ASMR claimed by the manufacturer. However, the TC may eventually grant the drug a lower ASMR, meaning that the CEESP assessment that was conducted was not justified. This has an economic impact on the overall HAS budget as CEESP is potentially assessing drugs unnecessarily.

**PHP269: QUALITY ASSURED USE OF PHARMACEUTICALS: DOES GERMAN GBA FOLLOW EMA?**

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**OBJECTIVES:** After receiving the EMA approval for Europe, it is mandatory for pharmaceuticals in Germany to complete the AMNOG process to receive reimbursement. Finally the responsible G-BA (joint federal committee) publishes a decision not only on the added benefit of the drug, but also on any specific requirements for the quality assured use. These requirements may differ from the EPAR and SmPC specifications for quality assured use of the drug. **METHODS:** For all 110 AMNOG applications started and finished between January 2015 and June 2017 we compared the specifications of the AMNOG decision for quality assured use with the respective EPAR and SmPC documents. We categorized differences and determined its relative amounts. **RESULTS:** The G-BA decisions were clustered into three groups: [A] Complete agreement with the EPAR/SmPC documents (52%), [B] Concretization of the EPAR/SmPC requirements (41%) and [C] divergent requirements by G-BA (7%). In cases of category [B] the G-BA named the type of specialized physicians indicated by the EMA phrasing “...a physician experienced with…”. All products of category [C] receiving divergent specifications (7%, n=8) were orphan drugs and two of them had an oncologic indication while the others were for metabolic diseases. While EPAR and SmPC mentioned "health care professionals" or had no specific assignation, the G-BA assigned the application of the drug to specific disciplines. The G-BA gives no explicit reasons for this decision, but the orphan drug status appears to be an important driver. **CONCLUSIONS:** In case of rare diseases German Health authorities request supervision by a specialized and experienced physician, also in cases where the EMA does not. This should be taken into concern when the market entry of an orphan drug is projected, especially for critical indications like cancer or severe neurologic and metabolic diseases.

**PHP270: RELATIVE VALUE OF EVIDEM MCDA FRAMEWORK FOR REFLECTIVE DRUG EVALUATION AMONG THERAPEUTIC POSITIONING REPORT EVALUATORS FROM THE SPANISH AGENCY OF MEDICINES**

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**OBJECTIVES:** To assess the value of applying reflective MCDA to the generation of drug Therapeutic Positioning Reports (TPR) in Spain. **METHODS:** TPR are evaluation reports performed by the AEMPS to support P&R in Spain. AEMPS healthcare professionals involved in the generation of TPR participated in two MCDA sessions using the EVIDEM (v 4.0) framework. TPR currently considers the assessment of “comparative effectiveness”, “safety”, “criteria of use” and “follow-up” for the drug under assessment. In each session, the EVIDEM criteria were presented and weighted using a direct rating scale (1: low relative importance; 5: high relative importance). An example of the assessment of a biological drug in psoriasis was used to rate the evidence matrix and numbers were used to establish a reflective discussion among participants. **RESULTS:** A total of 15 AEMPS representatives participated in the session. Using a direct rating scale, the criteria considered most important (>4.0 points) were: “comparative effectiveness” (4.5), “disease severity” (4.5), “comparative safety / tolerability” (4.3), “type of therapeutic benefit” (4.1), “unmet needs” (4.1) and “quality of evidence” (4.0). The criteria considered less important (<3.0) were “comparative cost consequences” (2.9), “size of affected population” (2.9) and “expert consensus / clinical practice guidelines” (2.8). The scores assigned to each criterion regarding the comparative drug assessment were discussed to understand the value contribution of each criteria to the overall drug value. **CONCLUSIONS:** The relative importance assigned by participants to the priority criteria used in TPR (comparative effectiveness and safety) was highly consistent. Additional criteria not included explicitly in TPR, such as, “disease severity”, “quality of evidence” and “unmet needs” were also classified as very relevant. In general, reflective MCDA was considered as a positive methodology which could add transparent reasoning behind evaluators’ discussions during TPR generation.

**PHP271: MAINTAINING THE BELT AND ROAD – THE IMPACT OF ‘BREXIT’ ON UK MARKET ACCESS**


**OBJECTIVES:** Most new innovative medicines access European markets through the European Medicines Agency (EMA) centralised authorisation procedure. Post-Brexit, a new UK national regulatory process will be required. This research explores possible UK regulatory access scenarios post-Brexit and discusses their market access implications. **METHODS:** Publically available resources from the EMA, Swissmedic, NoMA, MHRA, BAG, EAK, HOD
were screened for information on regulatory approval process(es). All NICE and SMC single technology appraisal guidelines were screened and the outcome and date extracted (01/01/2011 to 31/05/2017). **RESULTS:** Norway is not in the EU but is in the EEA and is a full member of CHMP and participates in the centralised authorisation process. Switzerland is an independent country within Europe with a separate regulatory process, but has a customs-union with Liechtenstein, which is in the EEA, where precedence has been set on recognition of Swiss Marketing Authorisations. NICE and the SMC conduct HTAs for reimbursement of new therapies in the UK. However, 11% and 14% of their appraisals have been non-submissions, and recommendations have been at an average delay of 17.1 and 10.5 months, respectively. Whilst the UK is 7th largest market in the World, the top 20 list includes 5 other EU countries. **CONCLUSIONS:** Post-Brexit, UK regulatory approval could follow a model of rapid targeted assessment and approval of EMA-authorised products, parallel work-sharing of UK-EMA hybrid application, and/or mutual recognition agreements. These could substantially impact market access; although the UK is a large market, many companies already choose not to submit to NICE/SMC due to the difficulties in securing positive reimbursement recommendations. The prospect of an additional access hurdle formed by a separate UK-specific regulatory process may further deter some companies. Negotiations need to minimise the potential disruption to current approval and HTA recommendation timeframes to ensure that life-saving medicines are available in the UK.

**HEALTH CARE USE & POLICY STUDIES - Population Health**

**PHP272: POSITIVE EXTERNALITIES OF AUSTERITY? THE CASE OF SMOKING CESSATION DURING THE FINANCIAL CRISIS IN GREECE.**

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**OBJECTIVES:** Austerity measures imposed on Greece have led to increasing unemployment and decreasing income affecting lifestyle behaviours such as tobacco consumption especially for the socioeconomically disadvantaged population. The aim of the present study was to investigate the factors associated with quitting smoking and quitting smoking during the crisis in Greece. **METHODS:** Data were extracted from the 2016 “Health and Welfare” national survey conducted by the Hellenic National School of Public Health. The sample consisted of 2,002 adults. In order to investigate the determinants of quitting smoking and quitting smoking during the crisis, two binary logistic regression models were constructed. Quitting smoking was dichotomized as “ex-smokers” versus “smokers” while quitting smoking during the crisis as “quitted smoking during the crisis” (2010 to 2016) versus “quitted before the crisis” (up to 2009). Independent variables included socio-economic factors, factors relating to health and health behaviors, as well as to the economic crisis and a health services support factor. As a scale indicator (Cronbach’s α=0.76), economic distress, quantified the perceived impact of crisis on each individual in relation to household financial hardship. **RESULTS:** Overall, 36.9% of the sample were smokers, 16.0% ex-smokers and 47.1% non-smokers. Of all ex-smokers, 43.9% quitted smoking during the crisis. Factors associated with quitting smoking were age (95% CI: 1.02, 1.06), occupational status: unemployed (95% CI: 1.42, 4.82) and pensioner (95% CI: 1.00, 3.25), economic distress score (95% CI: 0.53, 0.92) and number of cigarettes (95% CI: 1.04, 1.07) A statistically significant influence of age (95% CI: 0.93, 0.96) and economic distress score (95% CI: 1.08, 2.49) was found for quitters during the crisis. **CONCLUSIONS:** While economic distress is negatively associated with quitting smoking, it is positively associated with quitting during the crisis, rendering smoking cessation a positive by-product of the crisis.

**HEALTH CARE USE & POLICY STUDIES - Prescribing Behavior & Treatment Guidelines**

**PHP274: DEVELOPMENT OF PHARMACOECONOMIC GUIDELINES IN UKRAINE: METHODOLOGICAL ISSUES AND POLICY IMPLICATIONS**

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**OBJECTIVES:** Pharmacoeconomic (PE) guidelines are used as standards for preparation of studies to be included in applications for reimbursement, procurement of drugs, guides for conducting a study, or templates for evaluating the economic study reports. Submission guidelines can provide a list of the official requirements of a health care decision-making body in a country concerning pharmaceutical reimbursement submissions with an economic evaluation section. This study aimed to set up a framework for the development of a methodological guideline PE for health technology assessment (HTA) reports submitted to the Expert Committee on selection and use of essential medicines due to current legislation in Ukraine in 2017. **METHODS:** In 2017 a literature review was conducted on
several submission guidelines (England&Wales, Finland, Poland, Scotland, Spain, Israel, Thailand, Australia), the EUnetHTA Core Model and other methodological guidelines. Based on these documents and taking into account the local setting a preliminary country-specific PE guideline for Ukraine was developed by a research team of experts. **RESULTS:** The initial version of the PE guideline as part of a submission guideline includes the following sections: research question, perspective of analysis, time horizon, methods of analysis, cost assessment, health outcomes assessment, modelling, discounting, sensitivity analysis, budget impact analysis, limitations and discussions, presentation of results and final conclusions. The feasibility of the guideline will be tested and discussed with various stakeholders in a structured and transparent way. **CONCLUSIONS:** The implemented submission guideline with an economic evaluation section will facilitate the appraisal of medicines based on objective and transparent information which will allow decision-makers and pharmaceutical companies to justify the reimbursement of new medicines based on cost-effectiveness and budget impact analysis.

**PHP275: IMPLEMENTABILITY EVALUATION OF ANTIBIOTICS FOR ABDOMINAL TRAUMA GUIDELINE USING THE GUIDELINE IMPLEMENTABILITY APPRAISAL (GLIA) TOOL**

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**OBJECTIVES:** A number of clinical practice guidelines (CPGs) developed in South Korea. However, implementation of the guidelines has not been successful. Therefore, we need to identify intrinsic barriers of individual recommendation and information about extrinsic barriers in domestic situation. This study aims to identify intrinsic and extrinsic barriers of implementation for draft recommendations developed in Korea before publishing final recommendation statement. **METHODS:** Four clinicians and 4 methodologists were apprised the 10 draft recommendations about using antibiotics for abdominal trauma patients to identify intrinsic barriers for implementation. And survey was conducted to identify extrinsic barriers expected in domestic situation for about 60 members of the Korean Society of Acute Care Surgery who are the target users of the guideline. **RESULTS:** Of the nine domains of GLIA, ‘flexibility’ and ‘novelty/innovation’ domains were appraised as ‘N’. It means that they do not meet the criteria and could be considered as barrier. For other domains, overall appraisal was ‘Y’. Matter of compensation, incentive and insurance were felt as one of the major obstacle. The most expected barriers when implementing the recommendations about using antibiotics for abdominal trauma were environment aspects including matter of resources and difficulty in cooperation among departments. **CONCLUSIONS:** Though the contents of GLIA are valuable, there is need to develop domestic instrument which can be used more easily and the more studies about appropriate strategies in domestic situation should also be carried out.

**PHP276: A COMPARISON OF SYSTEMIC PEDIATRIC FLUOROQUINOLONE USE IN SOUTH KOREA**

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**OBJECTIVES:** The age restriction of fluoroquinolone use in South Korea was implemented in December 2009. This study aims to quantify nationwide fluoroquinolone use in pediatric patients and to assess the effect both continuous and immediate fluoroquinolone use in children and adolescents. **METHODS:** The Korean Health Insurance Review and Assessment Service data was obtained to analyze fluoroquinolone prescribing practice in pediatric patients younger than 18 years. The time periods were separated: Pre-drug utilization review: 2007 to 2009, Post-drug utilization review: 2010 to 2015. We analyzed the annual prescription rate of fluoroquinolone per 100,000 person-years. In order to predict the prescription pattern if an age restriction had not occurred, an autoregressive model was selected. **RESULTS:** The systemic fluoroquinolone was administered to the children during the study period. The 297,054 children of the total 505,859 received ciprofloxacin and the other 208,805 received levofloxacin during the study period. After age restriction, the mean annual ciprofloxacin prescription rate decreased from 840 to 21 per 100,000 person-years (relative reduction: 97.5%) and levofloxacin prescription rate decreased from 598 to 11 per 100,000 person-years (relative reduction: 98.2%). The prescription in the outpatient setting decreased more substantially than in the inpatient setting for both drugs. While the proportion of fluoroquinolone use increased at other medical facilities, hospital, general hospital and tertiary hospital, those used at clinics declined significantly after regulatory action. **CONCLUSIONS:** Regulatory measure under the national drug utilization review program was effective in controlling the inappropriate and excessive use of fluoroquinolone in children. The Age restriction made an immediate and huge decrease in fluoroquinolone prescriptions guiding to more sensible and selective prescription behavior. Similar regulatory interventions to control the inappropriate and excessive use of certain medicines could be tried in other countries, states or institutions.
**PHP278: EVALUATING PHYSICIANS’ PERCEPTION OF LIMITATIONS AND OBSTACLES AGAINST THE EFFECTIVENESS OF “AUDIT AND FEEDBACK” AND “PRINTED EDUCATIONAL MATERIALS” INTERVENTIONS ON PRESCRIBING BEHAVIOR: A QUALITATIVE STUDY**

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**OBJECTIVES:** Different interventions including “audit and feedback” (A&F) and “printed educational materials” (PEM) are being employed both in Iran and the world in general to improve physicians’ prescribing behavior. While several interventional studies have assessed effectiveness of these interventions, only few studies have investigated the views of physicians and other stakeholders about these interventions. The purpose of this study was to evaluate prescribers’ views about the limitations and obstacles of using A&F and PEM interventions effectively. **METHODS:** The current qualitative study was performed using a semi-structured one to one and group interviews in the 2013-2014 period. 18 general practitioners, pediatricians and infection specialists from Tehran and Yazd were interviewed and twelve physicians and pharmacists attended the focus group discussion meeting. The interviews and the meeting were recorded, transcribed and encoded. For analysis of the content, the framework method was employed. **RESULTS:** The resulting data in this study include six themes and 25 sub-themes. Awareness of the behavior-changing intervention, the effect of intervention in changing the behavior, A&F format and content, the underlying factors affecting drug prescribing behavior, the way PEM are delivered, and preferred intervention in promoting rational drug prescribing are the themes derived from this study. **CONCLUSIONS:** The study demonstrated limited awareness of different interventions for improving prescribing behavior. Moreover, the doctors suggested different modifications in the format and delivery of feedbacks and PEMS. They also noted the multi-dimensionality of prescribing behavior, and hence highlighting the need to attend other concerns such as patients’ expectations, the perceived low quality of generic medicines in Iran, and the presence of financial issues between doctors and patients. Improving the effectiveness of such interventions requires careful attention to the interrelationships between doctors, pharmacists and patients.

**PHP279: THE FIRST FIVE MONTHS OF NATIONAL PRESCRIPTION MONITORING IN FINLAND**

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**OBJECTIVES:** Electronic prescription is mandatory in Finland since 1 January, 2017. A physician or a dentist can issue a written (paper) or a telephone prescription under exceptional circumstances set by law, and the reason for issuing must be given. Because of the administrative nationwide change it was the first time possible to measure prescription volume in Finland. **METHODS:** Written and telephone prescriptions were typed in to the national Prescription Centre at the 815 pharmacies. Electronic prescriptions were sent to the Prescription Centre from
PHP280: CREATING ORDER IN CHAOS - THE IMPACT OF BREXIT ON THE REGULATORY ENVIRONMENT IN EUROPE AND THE UNITED KINGDOM


OBJECTIVES: In March 2017, the UK government invoked Article 50 of the Treaty on the European Union (EU) to withdraw from the EU ('Brexit') by April 2019. This research evaluates Brexit's potential impact on EU regulatory access by examining existing marketing authorisations (MAs), MHRA’s role in EMA decision-making and parallel imports. METHODS: Publically available EFPIA, EMA and MHRA data were screened up to December 2016, for the number of centrally authorised MAs, MHRA rapporteurships, and parallel imports. RESULTS: 966 medicines are currently authorised by the EMA (including generics and biosimilars), for which MAs will require independent approval, or for mutual recognition agreements to be put in place to avoid shortage of supply post-Brexit. Existing MAs approved through the decentralised process, where the UK is not the reference member state, will have similar requirements for national approval. The MHRA currently leads Europe in number of rapporteurships (Rapp/Co-Rapp) appointments for centralised procedures, with 136 appointed (2013-2016, 16% of all rapporteurships), Sweden in second place had 84 appointed (10% of all rapporteurships) during this period. The value of parallel imports is estimated to account for 7.5%-9.0% of UK annual pharmaceutical sales (2012-2014) equating to €1.2-€1.5 billion. The likely import tariffs and lack of parallel imports for wholesalers could significantly impact pricing. Conversely, medicines manufactured in the UK may be subject to export tariffs. CONCLUSIONS: Brexit has the potential to enormously impact the pharmaceutical industry and medicines regulation, not just in the UK but also in Europe, given the central role that the MHRA plays within the EMA. The outcome of negotiations between the EU and UK government in this regard will be crucial, and a number of scenarios, including the Norway- and Switzerland-models have been suggested. Finding a solution that appropriately incentivises access whilst maintaining standards and minimising disruption will likely be very challenging.

PHP281: PRICING REGULATION IN GREECE - ANALYZING THE PRICE BULLETIN OF DECEMBER 2016

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OBJECTIVES: Pricing regulation in Greece provides that generics are priced at 65% of the reference off-patent's price, while off-patents are priced at the minimum between a decrease of 50% of their latest on-patent price and the average of the three lowest originator prices in the EU. The purpose of this study is to assess the impact of the pricing regulation for generics in Greece. METHODS: Official pricing data from the December 2016 price bulletin were used to stratify the generalised active substances per pricing regulation category. RESULTS: 325 active substances with generics in circulation were identified, of which 19% were priced at 65% of the average of the three lowest originator prices in EU, while 15% were priced below that level. Another 49% had ex-factory prices equal to or lower than 4.15€ (net ex-factory prices after obligatory paybacks ≤2.90€), 15% were subject to a price decrease of 10% and 2% were excluded from re-pricing due to reasons related with market equity. CONCLUSIONS: The current pricing system in Greece, in which price increases are not allowed, drives generic prices to a downward pricing spiral, while generic penetration remains at the comparatively low level of 25% in volume. By continuously correlating generic prices with the prices of their respective reference product a significant portion (15%) is priced lower than the provisions of the 65% of the average price of the three lowest prices in EU. Moreover, half of the substances are marketed with extremely low net prices, equal or lower to 2.90€ after deducting the obligatory paybacks of approximately 30% in 2016. The above, combined with the lack of demand-side measures to foster the use of generics, question the medium/long-term viability of generics. In that light, correlation of pricing with market penetration, poses as a more appropriate approach ensuring sustainability of generics.
PHP282: CHARACTERISTICS AND APPROVALS OF REGULATORY SUBMISSIONS BASED ON NON-RANDOMIZED STUDIES IN THE UNITED STATES AND EUROPE

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OBJECTIVES: Regulatory approval for most medications is based on evidence from randomized controlled trials involving comparisons against standards of care or placebo. However, under some circumstances, approval is based on non-randomized designs involving comparisons against external controls or specific standards. This is particularly evident in diseases: that are rare, with high unmet need, without approved therapies, and/or where placebo is considered unethical. The objective of this review was to characterize regulatory submissions based on non-randomized trials using comparisons with external controls in Europe and the United States. METHODS: We identified therapeutic products through systematic searches of: European Medicines Agency (EMA) databases of conditional approvals, exceptional circumstances, or orphan drug designations; Food and Drug Administration (FDA) inventories of orphan or accelerated approval designations; and clinicaltrials.gov, EMBASE and MEDLINE. Products were included if reviewed between 2004 and 2016, the primary evidence base was non-randomized trial(s), and the indication was for rare or haematologic cancers, stem cell transplantation, haematologic conditions, or rare metabolic conditions. RESULTS: We identified 34 eligible drugs submitted to EMA or FDA and extracted detailed data for 17 that represented the range of non-randomized comparisons with external controls. Of these, three submissions involved matching external controls to the trial population using individual patient-level data (IPD). Ten regulatory summaries referred to external controls without IPD and four did not reference external controls. Among the 17 products, six were refused by at least one regulator or withdrawn after initial review; one was initially refused, but later approved. Where reported, regulators tended to acknowledge the limitations of the evidence; however, for approved products, these limitations were outweighed by the magnitude of the product’s estimated benefit. CONCLUSIONS: Comparisons with external controls have well-documented risks of confounding and bias; however, when the drug’s benefit outweighed the limitations of the evidence, FDA and EMA regulators were willing to grant approval.

PHP283: THE SUCCESS OF EU OMP LEGISLATION: AN EMPIRICAL ANALYSIS

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OBJECTIVES: In 1999, the EU enacted legislation to foster the introduction of new Orphan Medicinal Products (OMP) into the market. To date only partial evaluations of the success of this legislation have been made, so this analysis investigates the outcomes of the OMP legislation from a broader perspective. METHODS: Based on EMA’s OMP approval list, a review was conducted on the commercialisation rate. Public information (5 years) allowed the analysis of 17 companies (segmented as OMP focused, portfolio biotech and broad portfolio companies). RESULTS: The EU OMP legislation has attracted a large number of companies and an increasing number of OMP designations have been achieved, despite this the commercialisation rate is still very poor (8.1% of designated OMPs). The financial structure of the companies shows that without external support it is very difficult for Small to Medium Enterprises (SMEs) to successfully launch new OMPs in the market. For emerging companies, the increased cost of capital (statistical difference in debt/equity rate) paired with the higher requirements on R&D expenditure (statistical difference in R&D/Revenue) is still a limiting factor for success. Only a few companies are in process or have transitioned from SMEs to successful portfolio biotech companies. A new highly innovative market is being created, however if this emerging market is to be sustainable and competitive, OMP legislation and health systems need to continue to incentivise companies to move from R&D driven SMEs to sustainable biotech companies. CONCLUSIONS: OMP legislation has led to some improvement in Rare Disease research, despite this the rate of commercialised drugs is not optimal. There are still important economic hurdles that hinder SMEs to commercialise OMP designated products. The OMP legislation has been successful, but to sustain the developing marketplace more companies should be able to achieve successful commercialisation to develop into portfolio biotech companies.


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OBJECTIVES: According to the law, the State Institute for Drug Control (SUKL) should decide the maximum price,
amount, and conditions of reimbursement of a new drug within 165 days in line with the Transparency Directive. In reality, this deadline is often exceeded, especially in case of innovative drugs. We analyzed whether the duration of the administrative procedure is related to methodological accuracy and reviewability of pharmacoeconomic analyses submitted by marketing authorization holder (MAH) and their results. METHODS: Ten administrative procedures, which assessed innovative not interchangeable drugs decided in 2016 were analyzed. In two cases, no cost utility analysis was submitted due to the character of the new intervention. The duration from the SUKL’s first written assessment (WA) to its final decision (Duration) was recorded. The relation between Duration and ICER and budget impact of CUA and BIA as well as the occurrence of objections to the published methodological rules raised by SUKL in WA were analyzed and considered. RESULTS: No relation between results of CUA and BIA and Duration was observed. Methodological concerns were expressed in WA in two cases; the average Duration was 320 days then. In cases where no methodological concerns arose in WA, the average Duration was 115 days. In three cases, SUKL addressed some methodological questions to MAH already before WA was published. If they were explained successfully by MAH, the average Duration was 171 days. CONCLUSIONS: The average Duration observed was 166 days. Methodological errors identified in WA prolonged the Duration almost two-times whereas timely and effective communication between SUKL and MAH led almost to the compliance with the Directive. When ICER and budget impact meet the threshold by the decision-making practice, their exact values do not influence Duration. On the other hand, not even the cost-saving result means a fast track.

HEALTH CARE USE & POLICY STUDIES - Risk Sharing/Performance-Based Agreements

PHP285: THE USE OF SCIENTIFIC EVIDENCE TO SUPPORT JUDICIAL DECISIONS

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OBJECTIVES: Seeking the Judiciary is an alternative to get access to medicines in Brazil. In attempt to regulate this process, the National Justice Council published in 2010 the Recommendation n. 31 advising the Courts of Justice (CJ) to sign technical support agreements in order to instatiate the judicial decisions through Technical Notes (TN) and Quick Technical Responses (QTR) wording. This study analyzed the conformity between the TN and QTR recommendations and the judicial decisions related to lawsuits against Minas Gerais State, Brazil, from 2014 to 2016. At the end, the financial resource that would be saved if magistrates had denied all technically not advised medicines was estimated. METHODS: The TN and QTR from Minas Gerais CJ’s website were analyzed: 124 TN and their respective lawsuits involving 156 medicines; 341 QTR and their legal actions encompassing 810 drugs. The annual purchase price of medicines not advised by the TN and QTR was estimated. RESULTS: For TN: 20% conformity between favorable to the drug dispensation judicial decision and TN; 3% of TN were in favor of it, but judicial decision was against it; 21% agreement between unfavorable to the drug dispensation judicial decision and TN. In 56% of the cases, the magistrate approved the medicine request despite the TN recommendation against it. For QTR: 38% conformity between favorable to the drug dispensation judicial decision and QTR; 14% agreement between unfavorable to the drug dispensation judicial decision and QTR. In 48% of the cases, the QTR were against it, but the judge approved the drug request. The estimated cost to purchase the not technically advised medicines was USD 1359245.89. CONCLUSIONS: The conformity between judicial decisions and TN and QTR recommendations was low. It’s necessary to evaluate if the use of technical advises is the way to solve the “Health Judicialization” in Brazil.

PHP286: COVERAGE EVIDENCE DEVELOPMENT IN THE COURSE OF THE DRUG REEVALUATION IN KOREA

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OBJECTIVES: Along with the governmental pharmaceutical reform in Korea (2007), conditionally temporary reimbursement was applied to undergo Coverage Evidence Development (CED) in 2011 for 88 drugs which pose uncertainty. Recently the last appraisal has finished as of June, 2017. This study aims to look back the journey of CED in the course of the drug reevaluation in Korea. METHODS: Through policy documents, HIRA’s public and internal data and press release information, we outlined the whole process of Coverage Evidence Development in the drug reevaluation – introduction, implementation, evaluation and decision making - and described the outcome, lessons and the challenges in practice. RESULTS: During the reevaluation, the delisting or the price-cut was extensively done. Having in difficulty where binomial decision, the Managed Entry was considered and the Committee suggested CED for the 10 active gradients 156 drugs (2011) which were gastrointestinal drugs. Prospective phase III non-inferiority RCTs were designed and the protocols were approved (2011). Of trials for 8 substances, 7 substances were terminated and released peer reviewed publication (2012~2013). HIRA and the Committee reevaluated whether reimbursable (2014) for 7 substances 88 drugs, 87 drugs came to be remained to reimbursable (the last one ongoing). In case of no termination, it was delisted and payback. Although CED was well accepted in the beginning, some clinical trial was discontinued or went a controversial lawsuit in the late. CONCLUSIONS: As a result of CED,
six substances have produced clinical evidence resolving/reducing uncertainty. It was valuable but resource-consuming decision so that it can be improved by real world evidence and registry use. Recently in Korea, off-label use for cancer drugs (2011), Conditional Treatment Risk Sharing scheme (2013), coverage for use within clinical research (2016) has been introduced. Lessons from this CED case will be helpful for those quasi-situations.

**PHP287: ADVANCED THERAPY MEDICINAL PRODUCTS – TRANSFORMATIONAL PATIENT BENEFITS BUT DESTINED FOR COMMERCIAL FAILURE?**

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**OBJECTIVES:** Advanced therapy medicinal products (ATMPs) encompass gene therapies, cell therapies, and tissue-engineered products. The first ATMP (ChondroCelect®) was approved by the European Commission (EC) in 2009. These therapies offer potentially transformational/curative patient benefits in severe diseases of very high unmet need. In April 2017, Glybera®, the first EC-approved gene therapy (in 2012) and most expensive drug (>€1 million/patient), announced they would not seek marketing authorisation renewal once it expires in November 2017 for commercial reasons, emphasising the significant reimbursement challenges that such therapies may face. This research investigates the commercial success of all ATMPs marketed to date. **METHODS:** EC-approved ATMPs were identified from the EMA website and a targeted review of relevant company press releases were undertaken to extract commercial information (up to 5th May 2017) **RESULTS:** Eight ATMPs have received EC marketing authorisation. Half (ChondroCelect®, Glybera®, MACI®, Provenge®) have been withdrawn by their manufacturers, all for commercial reasons after an average of 3.5 years on the market (range: 1-7 years). These also represent the first four approved ATMPs. Four others (Holoclar®, Imligic®, Strimvelis®, Zalmoxis®) have been EC-approved since 2015/6 with very limited information on their commercial success to date. GSK did announce that Strimvelis® was reimbursed for its first patient in March 2017, despite being EC-approved since May 2016 under a full “money-back guarantee” performance-based reimbursement scheme. **CONCLUSIONS:** The first four EC-approved ATMPs have all been withdrawn from market for commercial reasons. This emphasizes the magnitude of the commercial challenges faced by ATMPs including complex and costly regulatory and manufacturing processes, small patient populations with limited clinical data, and the need for high upfront investment for a course of therapy that may only be a single treatment. Innovative payment models such as annuities/leasing and/or performance-based reimbursement may need to be explored to ensure patient access and commercial returns.

**PHP288: DEVELOPING A MULTI-CRITERIA FRAMEWORK FOR INNOVATION AND BIOLOGIC DRUGS ASSESSMENT DECISION MAKING IN EGYPT**

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**OBJECTIVES:** Given the unmet medical needs, the search is optimal for achieving the balance between satisfaction of patient need, offering the fair price to the company and the best utilization of health care resources. This is even tougher for Egypt. Our analysis demonstrates that firstly, currently adopted reference and ceiling ration criteria was the key driver of the economic evaluation and pricing decisions and no other factors were considered. Second, Many of Innovative and biologic drugs according to current ICER are not cost-effective, due to high cost per QALY or when the benefits not captured by the QALY. Third, there is absence of the sufficient data about how the new drug will be used in practice. We aim to develop a local MCDA framework for evaluation and selection of innovation and biologic drugs. Provide practice guidelines for its application in pricing and reimbursement decisions. **METHODS:** Mapping out the proposed MCDA framework were based on a mixed approach: literature review, local document analysis, interviews with stakeholders. Firstly a systematic literature review was conducted to elicit the criteria to be used in the decision making process. Subsequently, the ‘importance’ of the core set of criteria was elicited with different stakeholder including policy makers, payers, professionals, academia, representatives of patients and pharma industry. Finally, validation the MCDA list. **RESULTS:** Based on our findings we suggest that the main criteria that can be the core of MCDA models for the assessment in our local setting are Health benefits and outcomes, Disease description, innovation level, the evidence provided and the socio-economic impact. **CONCLUSIONS:** MCDA is believed to be helpful tool to integrate different aspects into health-care decision. Also to demonstrate true drug benefit and enhance patient access where there is huge unmet need: by 1- Adapting different P&R outcomes compared to the standard process now. 2- Including wider societal perspectives.

**PHP289: IMPLEMENTING MANAGED ENTRY AGREEMENTS IN PRACTICE: THE DUTCH REALITY CHECK**

OBJECTIVES: In 2006, the National Healthcare Institute (ZIN) initiated conditional financing (CF) of expensive hospital drugs as an example of conditional reimbursement schemes (CRS). CF is a 4-year procedure encompassing initial HTA assessment (T=0) followed by additional data collection via outcomes research (separately assessing appropriate use & cost effectiveness in routine practice) and re-assessment (T=4). This study aims to retrospectively evaluate the CF framework, focusing on Health Technology Assessment (HTA) procedures. METHODS: All dossiers for drugs that underwent the full CF procedure were reviewed. Using a standardised data extraction form, 2 researchers independently extracted information on procedural, methodological and decision-making aspects from HTA reports of drugs selected for CF. RESULTS: 49 drugs were nominated for CF, of which 44 underwent T=0 assessments and 12 underwent the full procedure including T=4 assessments. The procedure extended beyond 4 years for 11/12 drugs. Particular components of HTA reports (e.g. value of information analyses) were missing from retrieved documents, contrary to guidelines. Outcomes research studies conducted between T=0 and T=4 provided insufficient scientific data for 5/12 drugs. After re-assessment, continuation of reimbursement was advised for 10/12 drugs, with 6 drugs necessitating yet additional conditions for evidence generation. Notably, advice to discontinue reimbursement for 2/12 drugs has not yet been implemented in Dutch healthcare practice. CONCLUSIONS: Theoretically, CF provides a valuable option for enabling quick but conditional access to medicines in the Netherlands. However, procedural, methodological and decision-making considerations related to scheme design and implementation may affect its value in decision-making practice. Shortcomings and learnings identified should inform recommendations for the development of future managed entry agreements worldwide.

PHP290: IDENTIFICATION OF ASSESSMENT AND FUNDING MODELS APPLICABLE TO COMPANION DIAGNOSTICS IN UK, FRANCE AND GERMANY


OBJECTIVES: European Medicines Agency (EMA) defines companion diagnostics (CDx) as a “device which is essential for the safe and effective use of a corresponding medicinal product”, frequently used to identify patients likely to gain benefits or be at risk from the corresponding medical product. Pharmaceutical companies frequently participate in the development and marketing of CDx products. The research aim is to identify and compare assessment and funding models for CDx in the United Kingdom (UK), France and Germany (EU3). METHODS: EMA guidelines and EU3 national recommendations on CDx were reviewed to identify assessment pathways. Funding models were then evaluated, followed by comparison of EU3 CDx funding based on a basket of products. The research findings were used to develop a typology of the various access models, specific to CDx in EU3. RESULTS: No common assessment has yet been defined by the EMA. However, a framework defining limits of CDx within in-vitro diagnostics (IVDs) is available, classifying them as “at least a class C” i.e. as high risk (on a scale from A, lowest risk to D, highest risk for patients). To be launched in EU3, any CDx needs to go through national health technology assessment (HTA) after receiving a European conformity (CE) mark. The clinical utility needs to be demonstrated in France; while a more pragmatic approach is used in the UK (clinical studies results or systematic literature review can be accepted as evidence). Funding variations between patient settings exist; for instance in Germany inclusion in the Einheitlicher Bemessungsmassstab (EBM) list and diagnosis-related groups (DRGs) are required to achieve outpatient and inpatient reimbursement respectively. CONCLUSIONS: Three different assessment models of CDx were identified in EU3. Each model can lead to a national health insurance funding for use with or without the targeted-drug, to identify relevant patients.

PHP291: ANALYSIS OF DRUG UTILISATION DATA SOURCES TO ENABLE NATIONWIDE VALUE-BASED PRICING OF MEDICINES ACROSS HEALTHCARE SYSTEMS IN EUROPE

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OBJECTIVES: The pharmaceutical industry is moving from volume-based pricing towards value-based pricing (VBP). Availability of nationwide, high quality drug utilisation data is critical to enable this transition. Here we present an analysis of existing drug utilisation data sources and their availability in different healthcare systems across Europe. METHODS: National healthcare landscapes (Hospital information systems, electronic health records, registries, e-prescription systems) were assessed in the context of VBP. Appropriate data sources and flow of resources (money and services) were analysed and mapped and then validated through interviews. Commonalities were identified to characterise functional archetypes. RESULTS: With regards to drug utilization data availability, three main archetypes could be identified across the various healthcare systems. While the quality and completeness of drug utilisation data varies widely, our findings show that the minimal data required to enable VBP exists in all healthcare systems. CONCLUSIONS: Lack of data is often seen as the rate-limiting step in the adoption of VBP.
analysis shows that existing drug utilisation data are 'fit for purpose' to enable VBP in Europe. Data and resource flow necessary to enable VBP can be reduced to three common archetypes, thus providing for a scalable platform and clear path to move from volume to value-based pricing.

**PHP292: THE IMPACT OF MANAGED ENTRY AGREEMENTS ON DRUG TIME TO MARKET IN ITALY**

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**OBJECTIVES:** Managed Entry Agreements (MEAs) aim to share the risk of uncertainties of new drugs, whose clinical effectiveness and economic impact are still unknown. MEAs are differentiated in outcome-based and non-outcome-based agreements. The main purpose of this research is to analyze the impact of MEAs on the drug time to market (TTM), from the EMA approval to the regional patient access. **METHODS:** A desk research was conducted on institutional websites, integrating different sources (EMA; AIFA; Italian Official Journal). The sample included 23 branded drugs belonging to different therapeutic areas, commercialized in Italy from 2011 to 2016. The analysis focused on products with a negotiated MEA (12 drugs with outcome-based MEA and 11 with non-outcome-based MEA). The dates of first regional dispensation were obtained through the QuintilesIMS Hospital database, which gathers data on hospital and local healthcare unit distribution. **RESULTS:** Negotiated MEAs were mainly observed for oncologic, innovative and orphan drugs. The analysis of all drugs with MEAs showed a National TTM of 14.1 months and a regional TTM of 6.1 months. The sub-analysis for different types of MEA evidenced an increase in TTM both at National (16.4 months) and at regional level (7.2 months) for drugs with outcome-based MEAs. On the contrary, non-outcome-based MEAs seemed to reduce the TTM especially at National level (11.5 months). **CONCLUSIONS:** MEAs have become a fundamental step toward a successful drug access to the Italian Pharmaceutical Market, to evaluate drug effectiveness and to ensure prescriptions are appropriate according to the drug label. Financial agreements (outcome-based MEAs) guarantee a faster drug access; hence, non-outcome-based MEAs require a more flexible administrative framework, in order to achieve successful agreements and to reduce TTM with faster patient access to drugs.

**PHP293: THE EFFECT OF VALUE BASED INSURANCE DESIGNS ON COSTS: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** Value based insurance designs (VBID) provide monetary incentives by cost-sharing techniques designed to increase adherence to high value health care. This might have two opposite effects on costs. On the one hand adherence might increase costs through increased utilization. On the other hand adherence might increase health and therefore decrease costs. The aim of this systematic review was to evaluate the VBID effect on different costs. **METHODS:** A systematic review of the literature is done on Embase, Medline and EconLit to identify studies that empirically analyzed the VBID effect on costs. Effects on medical, pharmaceutical and total costs are evaluated from different perspectives. Differences in incentives and their potential effect on outcomes, as well as risks of bias are considered. **RESULTS:** In total 16 records were included in this review. In carrot designs, pharmaceutical costs mostly increased from the insurer’s perspective and decreased from the patient's perspective. The opposite was observed in carrot plus stick designs. From a combined perspective pharmaceutical costs were mostly increasing. Effects on medical costs from the insurer’s and the patient’s perspective were mixed. From a combined perspective savings in medical costs were often observed. Effects on total health care costs were mostly not significant. Overall risk of bias of included studies seems to be reasonable, but only one randomized controlled trial was identified and selection bias cannot be ruled out. **CONCLUSIONS:** It seems like VBID could be advantageous from the patient’s perspective and cost neutral from a combined perspective. Differences in effects seem to be partly explained by the incentives of VBID and by the severity of disease.

**PHP294: REIMBURSED DRUGS WITH ALTERNATIVE PAYMENT MODEL IN TURKEY**

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**OBJECTIVES:** Products with alternative payment model submission in Turkey, are evaluated by Alternative Reimbursement Committee. This committee had been founded in 2015, however has started its studies in 2016. The committee has been executing evaluations on financial-based models so far, yet, it has been declared that performance-based model implementation will also be evaluated henceforth. The purpose of this study is to analyze the products entering Turkish pharmaceutical market and reimbursed with alternative payment model in last two years. **METHODS:** The study was undertaken from the Turkish health care payer perspective (SSI). An Excel sheet was formed to calculate the results and graphics. Resource utilization data were obtained from Social Security Institution web site and RxMediapharma. **RESULTS:** With alternative payment model submission, 15 products in
2016, and 15 products in the first half of 2017, all in all 30 products in total got reimbursement via Alternative Reimbursement Committee decision. 10 of these evaluated by payer invitation – Established/innovative products not available on the market- whereas 20 of them by companies’ initiative. Average evaluation period for products that were previously supplied via International Pharmacy is 286 days, while first time applications take on an average of 399 days. Products reimbursed according to ATC code, respectively are; Anti-neoplastic and Immuno-modulating, Anti-infective for systemic use, Musculo-skeletal System, Alimentary Tract and Metabolism. These products licenced to the companies, respectively: Gen Pharmaceuticals, Abbvie, Gilead, BMS, Takeda, mostly taking share of Hepatitis C, Multiple Sclerosis, Malignant Melanoma therapeutic markets. **CONCLUSIONS:** Alternative reimbursement submissions are in favour of payer related to budget constraints, whilst companies prefer to accelerate reimbursement process in Turkey.

**PHP295: LESSONS LEARNED WITH MANAGED ENTRY AGREEMENTS IN PORTUGAL**

**Gonçalves L, Caldeira S, Teixeira M, INFARMED, I.P., Lisbon, Portugal**

**OBJECTIVES:** Since a long time ago, Portugal has been concerned with the adoption of instruments that better enable to manage the total health expenditure on medicines. The Managed Entry Agreements (MEA) have proved to be a good mechanism for managing it as well as the uncertainty around the clinical evidence, eligible patient population, cost-effectiveness and budget cap. Now, it is time to rethink on what has been done in this matter in recent years. **METHODS:** The study considered the MEAs approved between 2005 and 2016 in inpatient and outpatient settings by National Health Service (NHS) and monitored by INFARMED, I.P. The analysis focused on the following: - To classify the MEAs according to the European Taxonomy defined by Ferrario & Kanavos (2013); - To characterize the MEAs (describing the main objectives, instruments, benefits, possible disadvantages, the criteria underlying its implementation); - To build a SWOT analysis of what MEAs represents for portuguese NHS; - To describe utilization variability among Therapeutic Areas. **RESULTS:** Portugal have focused mostly on financial schemes MEA and more recently implemented the performance-based MEA. In the period 2005-2016, were celebrated more than 160 MEAs, of which approximately 62% and 38% occurred in the inpatient and outpatient setting, respectively. Around 50% of the MEAs were celebrated in three years (2014 – 2016). The MEAs instrument most used is the price-volume agreement (PVA), followed up by outcome-guarantee and coverage with evidence development (CED) agreements. **CONCLUSIONS:** The variety of MEAs were increasingly used in Portugal to manage aspects of uncertainty associated with the introduction of medicines in the NHS. Therefore, MEAs represent a valuable strategic tool for overcoming these challenges and ensuring the sustainability of portuguese NHS.

**HEALTH CARE USE & POLICY STUDIES - Conceptual Papers**

**PHP296: ASSESSMENT AND COMPARISON OF NATIONAL AND INTERNATIONAL REGULATIONS ON REGISTRATION OF BIOSIMILARS**

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**Objective:** The objective of this study was to assess and compare the requirements in the guidelines published by EMA, FDA and TMMDA (Turkish Medicines and Medical Devices Agency) on biosimilars’ registration. **Methods:** Guidelines officially published by EMA, FDA and TMMDA were evaluated, and comparison was made in aspects namely classification and legal status of the guidelines, selection of the reference product and extrapolation of the clinical data between different indications. **Results:** EMA has 3 main guideline groups (overarching guidelines, product specific guidelines and other guidelines relevant for biosimilars) consisting of 15 guidelines in total, FDA has 8 guidelines regarding formal meetings between FDA and sponsors, demonstration of biosimilarity, quality considerations, clinical pharmacology data, reference product exclusivity, Q&A regarding implementation of the biologics price competition and innovation act of 2009, demonstration of interchangeability, and TMMDA has 1 guideline. In terms of legal status, EMA and TMMDA guidelines are legally binding in contrast to FDA. Regarding selection of reference product; EMA requires the reference product to be previously approved by EC, FDA requires the reference product to be previously approved by FDA (otherwise the reason should be justified), TMMDA requires the reference product to be approved by an authority. In terms of extrapolation of the clinical data between different indications, all the authorities require applicants to provide sufficient scientific justification for extrapolating clinical data to support a determination of biosimilarity for each indication. **Conclusion:** Despite several differences, the main requirements stated by EMA, FDA and TMMDA were found to be highly similar. Basically, biosimilarity is expected to be justified by demonstrating that there are no major differences in terms of quality, efficacy and safety in non-clinical and clinical issues between biosimilar drug and reference drug as a result of comparative in vivo and in vitro studies.
PHP297: THE IMPLICATIONS OF BREXIT ON THE UK NHS AND THE UK PHARMACEUTICAL INDUSTRY

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OBJECTIVE To identify the impact that the UK’s vote to leave the European Union (EU) has had on the UK pharmaceutical sector and what the potential longer term implications may be. METHODS: Structured desk research was conducted along with a qualitative survey of MAP online’s industry group to produce an analysis of the impact of the UK’s Brexit vote and to provide insights into what may happen in the longer term. RESULTS: One year on from the UK referendum, the vote to leave the EU has already had an impact on the UK pharmaceutical market. New innovative products launched in Europe are more costly for the NHS to procure, relative to a pre-Brexit era, due to devaluation in the pound. Inward investments have fluctuated due to uncertainty surrounding the UK’s future, despite the attractiveness of a weaker currency. CONCLUSION: The current implications of Brexit point to profound ramifications for access to medicines. The EMA headquarters is set to leave London by 2019, posing a threat to the UK as the central hub and first port of call for companies not currently set up in Europe. The Brexit deal will be crucial in determining how much money is available for scientific research and development (R&D); maintained funding is essential if the UK is to remain one of the top countries for R&D. In addition, tightening border control may cause a fall in high-quality researchers being available to work in UK research facilities. Any Brexit deal should take this into account. Quickly re-establishing a stable and attractive market will be key to the UK’s success. Having lost its influence over the future direction of EMA policies, the UK should look to its own needs, giving rise to creative possibilities to cement the UK’s position as one of the most popular European markets.

PHP298: AN INNOVATIVE SOLUTION TO ACHIEVE COST-EFFECTIVENESS AND A POSITIVE NICE APPRAISAL? – THE CABAZITAXEL CASE STUDY

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Oncology therapies have historically struggled to receive positive appraisals by cost-effectiveness health technology assessment (HTA) bodies, such as the National Institute of Health and Care Excellence (NICE). Indeed, between March 2000 and March 2017, 30% of NICE single technology appraisals (STAs) within oncology received a negative appraisal versus 11% of appraisals outside oncology. Many high-cost innovative oncology treatments are dosed via an intravenous route based on a patient’s weight or body surface area. The patient-specific nature of this dosing means that within opened drug vials there is leftover drug that is typically discarded (both the European Medicines Agency [EMA] and Medicines and Healthcare Products Regulatory Agency [MHRA] advise that vial-sharing should not be practiced). Such vial wastage may substantially increase the cost of treatment and may significantly impact cost-effectiveness estimates. In May 2016, NICE published a positive recommendation for cabazitaxel for metastatic prostate cancer that was contingent upon, among other things, the company making cabazitaxel available in pre-prepared intravenous-infusion bags containing the precise dosing needed per patient to minimize wastage. Subsequently, in August 2016 the manufacturer agreed to be able to supply the drug in vials with an additional discount to apply that reflects wastage costs. The rationale for seeking this additional vial-supply was not publically stated. However, this may have been driven by the associated costs in implementing quality and audit systems alongside infusion preparation procedures to ensure the safety/quality of resultant ready-infusions. Further, the shelf-life from point of infusion preparation is typically 24 hours, which will have associated wastage. In conclusion, HTA bodies may be receptive to company-sponsored innovative delivery mechanisms to minimise wastage associated with weight-based dosed intravenous-infusion products. This can support zero-wastage assumptions in cost-effectiveness modelling and public reimbursement. As this case-study shows, the associated costs should be carefully considered with potential preference to simple-discount/rebate schemes.

PHP299: MANAGED ACCESS AGREEMENTS (MAAs) IN APPRAISALS CONDUCTED BY THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

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INTRODUCTION: MAAs are risk-sharing agreements, where the NHS provides conditional reimbursement whilst additional data is collected for new products. We reviewed MAAs included in NICE appraisals and explored trends concerning their design and uptake. METHODS: NICE appraisals involving MAAs were identified through online searches. All assessments to May 2017 were reviewed to ascertain: the process under which the MAA was considered; the key elements of the MAA; and the assessment outcome. In addition, a review of the NICE methods guidelines was conducted to understand how MAAs are considered. RESULTS: MAAs are required for entry into the Cancer Drugs Fund (CDF) and are utilised in assessments of ultra-orphan products via the Highly Specialised Technology (HST) process. They may be developed early in the assessment process or following the initial evidence review. MAAs are not considered in NICE appraisals outside of the CDF and HST processes. Of four HST
recommendations, two were dependent on an MAA. NICE has only recommended one product for use via the CDF. Following reassessment of 14 products included in the previous CDF, NICE has recommended all for routine use (no MAA required). The MAAs relating to the HST appraisals are for a maximum of 5 years from guidance publication, whilst the timescale for the oncology product is dependent on the availability of survival data. All schemes include collection of outcome data and include a mechanism to reduce the budget impact to the NHS. CONCLUSIONS: MAAs used as part of NICE assessments in England generate evidence to inform reassessment and limit the financial risk to the NHS, but are limited to ultra-orphan and oncology products. Products assessed by NICE that are not rare enough to meet the HST appraisal criteria cannot be funded with an MAA and therefore require stronger data on clinical effectiveness to gain reimbursement.

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**PHP300: Payers, Politics and Pandemonium: An Insight into the Future UK Pricing and Market Access Environment**

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**OBJECTIVES:** The UK political environment is causing both macro and micro-economic turbulence to a life science sector which still retains a reputation as one of the most attractive markets in the Western world. The research seeks to assess how political phenomena such as Brexit and the General Election result in June 2017 will affect the pricing and market access environment in the UK. **METHODS:** The research used a primary documentary approach to obtain data, which was then analysed using a qualitative interpretative method. The research was subsequently enhanced with semi-structured qualitative interviews and informal consensus groups with key stakeholders in the UK political/pricing and market access environment. **RESULTS:** Building out of the Accelerated Access Review (AAR), the future UK pricing and market access environment has many positive elements to help retain a leading role in the research, development and commercialisation of pharmaceuticals. However, concerns remain about the transparency of NHS England, the role of NICE, devolution and the wider impact of Brexit on the life science sector. Stakeholders stressed the requirement for stability and positive policy amid the political turmoil. **CONCLUSIONS:** Market access and policy are inextricably linked in the UK; and the importance of policy and political actors in the decision-making on pharmaceuticals cannot be underestimated. The UK faces considerable uncertainty both on a macro and micro-economic level and therefore stability in the 2019 PPRS renegotiations is vital if the UK wants to retain a leading global role in the life science sector.

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**PHP301: Affordability and WTP Challenges of Combinations of High Value/High Priced Products in Oncology – Identifying Solutions for Immunotherapies, Precision Medicines, and Anti-Body Drug Conjugates**

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**OBJECTIVE:** To understand how pharmaceutical companies and payers are approaching the affordability and willingness to pay challenges of combinations of high value high cost oncology drugs **METHODS:** A targeted literature review was undertaken of provisional and final HTA recommendations, and other payer / pricing and market access assessments, of “cancer stacks” (cancer drugs used in combination with one or more additional cancer drugs), reported in the public domain from 2014 to 2016. The review focused on payer awareness and understanding of new treatment paradigms and their implications for oncology budgets, assessment time horizons; and the market access solutions being proposed by both payers and manufacturers including cost shifting, cost and risk sharing, payer/pharma partnerships, and pharma/pharma collaboration. **RESULTS:** Payer understanding of new approaches to treating cancer (immunotherapies, precision medicines, and anti-body drug conjugates) and their multifactorial consequences is low. Payer awareness of future pressure on budgets triggered by the arrival of high profile cancer immunotherapies is high. At the national level the high prices of established products are an access barrier to new cancer stacks that include those products. At local/regional levels there is limited growth in annual budgets that would facilitate implementation of solutions agreed at the national level. Solutions include “Ring Fencing” (Indication-based Pricing, Value-based Pricing, and Personalized Reimbursement Models), Treatment Sequencing Assessment, Value Frameworks, and “Innovative Collaborations” between manufacturers, and between manufacturers and payers. **CONCLUSION:** There is a trend towards “co-dependency” in solution (co-dependent pricing / reimbursement / access). Future success may require negotiations that involve the manufacturers of all the products in the “stack” with the goal of “shared pain equals shared gain”. Implementation challenges will need to be overcome. Further research is required in this area.

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**PHP302: Shouldn’t NICE Cost-Effectiveness Thresholds be Changing with the Times?**

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Background
A 2004 retrospective study of the National Institute of Health and Care Excellence (NICE) past cost-effectiveness appraisal decision making identified a hypothetical cost-effectiveness ceiling ratio between £20,000 to £30,000 per quality adjusted life year (QALY) gained. Over a decade has passed since this article was published yet there is no evidence that this threshold has changed over time, leading to growing discussion over its static nature. Analysis A static range is of benefit to NICE and the NHS as it allows for cost containment over time, threatening new drugs with negative reimbursement, ensuring industry prices new drugs competitively. It also provides stability for the pharmaceutical industry who rely on knowledge of cost-effectiveness threshold ranges when researching and developing their pipeline and understanding the likelihood of future reimbursement. Static interpretation of cost-effectiveness thresholds could be seen to be inappropriate however due to growth in inflation since identification of this threshold range. According to Bank of England’s inflation rate data, inflation was 2.9% on average between 2004 and 2016, therefore a range of £20,000 to £30,000 per QALY should have expanded to £28,179 to £42,287 to account for changes in the costs of living over time. Conversely, it could be argued that dynamic NICE thresholds are inappropriate themselves as expected improvements in the industry’s productive and research efficiency could cancel out growth in inflation and therefore any changes to the ceiling ratio in sympathy. Movement towards multi-criteria decision analysis frameworks or the dynamic World Health Organisation (WHO) gross domestic product (GDP) approach to ceiling thresholds may provide the transparency in threshold setting that the current NICE approach lacks. Conclusion NICE should be considering augmentation of its cost-effectiveness thresholds to reflect growth in the costs of living since its original ceiling threshold was identified over a decade ago.

PHP303: ARE PATIENT OUTCOMES BEING RELEGATED BY NICES BUDGET IMPACT TEST?

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Background
As of April 2017, NICE provided a tool to assist NHS organisations achieve financial balance in the form of the Budget Impact Test. This test provides the NHS opportunity to delay patient access to drugs on the basis of affordability, not just cost-effectiveness. Analysis The test stipulates that drugs costing more than £20m in any one of their first three years from introduction (approximately 20% of the treatment appraised by NICE) will prompt pricing negotiations between the manufacturer and NHS England to moderate potential long-term budgetary impact. When agreement to contain pricing cannot be reached, NHS England can now extend the current maximum 90 day adoption delay limit to 3 years. Whilst financial benefits of the budget impact test are evident, it ultimately fails to maintain the patient’s interest at the heart of decision making. Budget impact analysis essentially represents multiplication of the cost per patient by the number of patients likely to be treated. Therefore patients in more prevalent disease areas are likely to be discriminated against given larger budget impacts these calculations would result in. This results in larger patient groups being used as a bargaining chip by the NHS to drive down drug prices. The test could also be contradictory to the NHSs Constitution, which states patient access to interventions should not be limited on the basis of net acquisition and administration costs. Furthermore, the test may disproportionally impact first to market drugs who often represent a considerably cost-effective alternative to current standards of care but may also be costly to introduce due to existing unmet need. Conclusion Whilst the Budget Impact Test provides the NHS opportunity to contain future costs, it pushes the patient further into the back seat in terms of service commissioning, allowing financial interest to increasingly drive decision making.

PHP304: CHALLENGES AND FUTURE PERSPECTIVES ON THE REIMBURSEMENT OF ADVANCED THERAPY MEDICINAL PRODUCTS

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Objectives: Advanced therapy medicinal products (ATMPs) are a new class of therapeutic interventions, based on gene, cell and tissue manipulations, offering potentially curative treatment options for a range of diseases. While the ATMP classification system is solely a European phenomenon, gene and cell-based therapies (ATMP-like therapies) are emerging across markets and so the question of how these innovative, yet costly, treatments are to be reimbursed is pertinent worldwide. The aim of our research is to: review the current situation surrounding ATMP HTA and reimbursement in Europe, Canada and the US; identify specific challenges to ATMP market access; ascertain if and how assessment procedures are likely to change over the next 3 years. Methods: Targeted literatures searches and payer interviews (n=10) were carried out focussing on ATMPs and ATMP-like therapies awarded centralised marketing authorisation by the EMA, FDA or CADTH. Results: The national systems for HTA and reimbursement of ATMPs, like those for conventional drugs, vary country-by-country. While regulatory agencies have ATMP, or gene- and cell-therapy specific policies, HTA and reimbursement bodies do not; hence in many cases, the assessment of ATMPs for reimbursement is largely in line with that for conventional therapies. For ATMPs offering long-term curative effects, the majority of payers identified uncertainty over long-term efficacy as the greatest challenge to optimal reimbursement. Payers discussed, among others, pay-for-performance contracts, rebate contracts, and real-
world evidence collection as strategies that can be utilised by manufacturers to mitigate the uncertainty and high costs associated with ATMPs. **Conclusion:** The high cost of ATMPs coupled with the uncertainty of long-term efficacy is the greatest challenge to ATMPs gaining market access. Overall, the key concern for payers is how to mitigate the risks of reimbursing a treatment with uncertain long-term outcomes.

**PHP305: HEALTH TECHNOLOGIES’ TAXONOMY AND CHALLENGES TO APPLY THE ASSESSMENT**

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The international professional organizations, academies and national competent authorities currently use different approaches for covering the health technologies’ taxonomy and therefore different scope of health technology assessment (HTA). Theoretically is defined that the health technologies include pharmaceuticals, medical devices, diagnostic and treatment methods, rehabilitation and prevention methods; as well as organizational, financial, delivery and support systems. At the same time the HTA is defined as a multidisciplinary field of policy analysis, which studies medical, social, ethical and economic implications of development, diffusion and use of health technology. Practically, by international surveys results, can be observed that HTA is applied mostly for pharmaceuticals and medical devices, and it is specified as a comprehensive national HTA systems. However these systems demonstrate the lack of methods and policy analysis of medical, social, ethical and economic implications of specific health care financing and managerial models, as well as the impact of health technologies interactions. To develop the common approach and avoid misunderstandings could be recommended: firstly, to consider possibility to define the medical technologies as a subgroup of health technologies, which are directly used in treatment process (pharmaceuticals, medical devices, diagnostic and treatment methods) and for which full HTA are applied; secondly, to clarify the separation of diagnostic, medical and surgical procedures from pharmaceuticals and medical devices, as there is not a common approach for their assessment separately or as a part of medical procedure (for pharmaceuticals) or diagnostic and surgical procedure (for medical devices); thirdly, to continue the development of specific HTA methodologies for assessment of health care financing, delivery, and managerial models, prevention activities and complementary medicine, rehabilitation programs and long-term care, and for other health technologies’ subgroups. The common approach for health technologies’ taxonomy and appropriate assessment methods could soften HTA challenges and improve the credibility and value of its results.

**PHP306: TISSUE/SITE AGNOSTIC REGULATORY APPROVAL OF ONCOLOGY DRUGS: ARE HTAS READY FOR A NEW ERA IN PERSONALISED MEDICINE?**


The recent FDA approval of pembrolizumab (Keytruda) for the treatment of all MSI-H and dMMR unresectable and metastatic solid tumors is believed to signal a more general move towards the regulatory approval of oncology drugs for the treatment of genetically defined tumours across multiple locations in the body (tissue/site agnostic approvals). We sought to review clinical data available on drugs likely to be considered for tissue/site agnostic approvals with a view to considering the likely hurdles that manufacturers and HTA bodies will encounter in ensuring patients can access these drugs. Publicly available clinical data on pembrolizumab (for the treatment of MSI-H and dMMR solid tumors) and larotrectinib (for the treatment of TRK fusion cancers) were extracted and reviewed. Pembrolizumab received FDA approval based on data from 149 patients with MSI-H or dMMR solid tumours enrolled across five uncontrolled, single-arm clinical trials. 90 patients had colorectal cancer and 59 patients were diagnosed with one of 14 other cancer types. Loxo Oncology are expected to submit for tissue/site agnostic FDA approval of larotrectinib for TRK fusion cancer based on data from TRK fusion patients recruited across 3 trials. Interim data indicates that 13 discrete TRK fusion tumour types have been treated across 55 patients: salivary (12), sarcoma (10), infantile fibrosarcoma (7), lung (5), thyroid (5), colon (4), melanoma (4), cholangio (2), GIST (2), and other (4). HTAs of oncology drugs that receive tissue/site agnostic approvals are likely to prove problematic as the grouped efficacy data that regulators may be willing to accept are unlikely to be fit for the purpose of assessing drugs for reimbursement for specific indications within the current HTA frameworks. Reconsideration of the HTA framework for such drugs may be necessary to avoid withholding patient access to drugs for licenced indications.

**PHP307: AN ANALYSIS OF THE CURRENT JORDANIAN PRICING SYSTEM AND DEVELOPING RECOMMENDATIONS FOR ITS ENHANCEMENT**

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**OBJECTIVES:** The current list pricing system in Jordan is based on international price referencing. The system has been delivering effective outcomes since 2003. Within a dynamic healthcare and economic environment it is essential
to assess periodically the robustness and effectiveness of the system in delivering its objectives. **METHODS:** A workshop of 28 participants followed by a focus group of decision makers that included experts in health economics, healthcare policy, pricing and reimbursement systems in Jordan was conducted. The group reviewed the Jordanian pricing system and compared it to other systems in UK, Germany, France and Turkey. Based on that, the group ran a comparative analysis to identify the major considerations in developing recommendations for the Jordanian pricing system. **RESULTS:** The Jordanian system’s major strengths lie in being a well-structured and cohesive system. For brand products, the price is set to match the lowest outcome of requested price by the manufacturer, price in country of origin, price in Saudi and median among prices in 16 pre identified countries. The system allows for appeals and exceptions according to patient centric criteria. Areas of development in the Jordanian pricing system include; developing specific considerations for pricing of biologic products and the evolution of the system towards value based pricing. Availability of data remains a challenge towards value based pricing. **CONCLUSION:** An effective and cohesive pricing approach is a cornerstone of patient focused healthcare system. This is ideally done by continuously improving and advancing the regulations to meet that objective while ensuring that patients still have access to innovative drugs. The focus group agreed on a set of recommendations adopting good pricing practice that provides a support of a cohesive and uniform process in the evaluation of innovative healthcare technologies.

**PHP308: EFFECT OF HEALTH SYSTEM, FINANCING, AND MACRO-ECONOMIC CHARACTERISTICS ON THE MIGRATION OF FOREIGN PHYSICIANS TO OECD COUNTRIES**

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This study specifically focuses on ‘pull’ factors affecting physician migration to OECD countries. The demand on human resource in healthcare is rapidly growing worldwide, and there is a chronic need for some 2.4 million more physicians. These shortages provide that many countries have insufficient numbers of healthcare workforce to deliver necessary interventions producing health. The global migration of physicians is increasingly playing a key role in compensating for an inadequate domestic supply in many countries of the Organization for Economic Cooperation and Development (OECD). Physician flows that is the way for the countries to solve the shortage of medical professionals is receiving increased attention. For example, on average in the OECD, there are around 20% of foreign born employed physicians. In total, 243,000 foreign trained physicians registered to practice in the United States while 91,000 in the United Kingdom (in 2011), 18,000 in Australia (in 2009), and 18,000 in Canada (in 2012) registered to practice. In general, the OECD countries that have more migrated physicians tend to have more professional health workforce to use them as a “quick fix” to address the needs, because training extra physicians takes many years to have an effect. Based on the previous studies and widely accepted literatures, three main categories have been found crucial on the migration physicians to OECD countries; Healthcare Resources Characteristics (Physicians, Medical graduations, and Medical Technology density), Healthcare System Characteristics and Financing (Health expenditures, Financing of expenditure, Social Protection, healthcare utilization, Health Status), and Macro-Economic Characteristics (GDP, PPP, NCU, GNP, GNI, wages, and unemployment rate). Overall, the migration flows to OECD countries are expected to grow in coming decades due to increasing demand in the aging population as well as technological changes anticipated to increase the demand for health care services.

**PHP309: VALUE ADDED MEDICINES: ADJUSTEMENTS OF HTA DECISION FRAMEWORKS TO CAPTURE THEIR FULL VALUE**

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Value added medicines (VAMs) are medicines based on known molecules that follow 3 drug repurposing models, i.e., reformulation, repositioning and combination, which deliver substantial value for patients and society. However, current European health technology assessment (HTA) decision frameworks, depending on country, represent various challenges for full value recognition of VAMs. Several challenges have been identified for VAMs in current HTA decision frameworks: 1) May not be eligible for HTA, 2) May not be eligible for early HTA dialogues, 3) May not be eligible for coverage with evidence development, 4) Their benefits, e.g. improvements in patient preference, adherence, and convenience of use, may not be adequately captured, as they can be complex to demonstrate through RCTs or not readily captured via QALYs, 5) Are usually perceived as generic-like products and therefore penalised in the deliberative process. The recommended HTA policy changes should include: 1) Promoting alternative methods, such as multiple criteria decision analysis techniques and constraint optimisation modelling; 2) Adjusting current HTA decision frameworks. Whenever requested, all medicines should be eligible for HTA and early HTA dialogue. HTA decision frameworks should encompass all attributes recommended by the EUnetHTA Core Model®, integrated in a standardised and explicit way through a transparent and reproducible deliberative process. Attributes not already included, or included informally, should be used as appraisal modifiers. HTA decision frameworks should be patient-centric, including patient-reported outcomes, patient-centered outcomes and patient
preferences, consider alternative study designs beyond RCTs, and allow coverage with evidence development to capture the benefits that are complex to demonstrate pre-launch. The societal perspective should be adopted, and a broad range of stakeholders – including patients – should take part in the decision-making process. HTA policy changes and robust research support are recommended to enhance VAM value recognition and encourage industry investment in medicines with high potential value to society.

**PHP310: ESTIMATION OF PREVALENCE IN RARE DISEASE**

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**OBJECTIVES:** Overestimation of real-world prevalence in rare diseases can be a significant issue for policy makers and the pharmaceutical industry. This work explores reasons for the overestimation and develops an outline methodology for the application of drag factors when calculating prevalence based on reported incidence. Two rare epileptic encephalopathies Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) were used as illustrative examples. **METHODS:** For both rare diseases, a targeted literature review without restriction on publication date was performed to (1) identify all reports of incidence, prevalence and mortality rates and (2) develop a detailed description of how diagnostic practice has evolved over time. The themes considered included time from syndrome identification, developments in disease definition/diagnostic criteria and inclusion (or lack of) in clinical guidelines, availability of any or improved therapies and the development of diagnostic tools. A conceptual model was developed to calculate prevalence based on reported incidence (traditional approach) versus adjusted incidence (according to factors that cause a diagnostic drag). **RESULTS:** For DS patients, calculated prevalence based on diagnostic incidence data matches the real-world prevalence for patients under 18 years old, but overestimates the 18 years and older real-world prevalent population. In the case of LGS, the available epidemiological data are heterogeneous and we were not able to reliably compare calculated with real-world prevalence. The proposed conceptual model incorporating diagnostic drag reflects predicted real-world prevalence of adults with DS in Sweden (104 individuals) more accurately than traditional calculated prevalence (191 for the conceptual model vs 257 for the traditional model). **CONCLUSIONS:** Methodological challenges in measuring epidemiology, coupled with advances in rare disease discovery may cause discrepancies between real-world and calculated prevalence. Care should be taken with calculated prevalence figures to not overstated the real-world prevalence in rare diseases.

**PHP311: A HEALTHCARE POLICY STUDY TO BUILD A ROADMAP FOR RARE DISEASE MANAGEMENT UNDER THE EGYPTIAN HEALTHCARE SYSTEM**

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**Objectives:** This policy study aims to identify the gaps alongside the patient journey of rare disease (RD) patients in Egypt, and to build a roadmap for the enhancement of RD management, as well as to maximize the access of RD patients to treatment and support. **Methodology:** An Expert panel meeting was conducted with RD physicians, Key decision makers, Non-Governmental Organizations, payers, patients and their families. The meeting was moderated by an external facilitator to gather all insights and opinions about the objectives as well as building the roadmap milestones, focusing on 3 RDs: myelofibrosis, cystinosis, and tuberous sclerosis-complex (TSC). **Results:** A consensus on the following call to action milestones was established: 1- Create a list of RDs in Egypt estimating their respective prevalence. 2- Create a central hub of data and a research center connecting RD units allow Egypt. 3- Apply unique patient ID in all RD units to avoid duplications. 4- Initiate a national registry program that connects the RD units. 5- Initiate a screening program for patients at risk (focused screening) starting with programs for pregnant mothers / high risk mothers/ mothers with family history. As well as prenatal diagnosis program. 6- Build National Egyptian guidelines for RD with special focus on multidisciplinary management 7- Add the necessary RD drugs to the public-sector formulary. 8- Build a national office for RDs responsible for implementing all the above-mentioned points. **Conclusion:** Achieving the milestones of the RD roadmap needs more compelling actions from policy makers, public authorities, industry representatives, and health professionals about the seriousness and importance of treating RDs in Egypt. Great efforts are still needed from the governmental sector to alleviate the obstacles across the entire patients’ journey mainly the financial burden aspect, the availability of medications and most importantly the creation of the RD committee.

**PHP312: ADAPTING PHARMACOECONOMICS TO SHAPE EFFICIENT HEALTH SYSTEMS EN ROUTE TO UHC - A CONCEPTUAL FRAMEWORK**

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Today, many countries are in some stage of implementing or using pharmacoeconomics to improve patient and health system outcomes. This conceptual paper aims at identifying the factors that determine the design and applications of the pharmacoeconomic toolkit in different health systems internationally. With a focus on methodological alternatives and different approaches towards integrating and institutionalising pharmacoeconomics within health systems, the paper seeks to provide guidance on processes for the design, implementation and optimisation of pharmacoeconomics as a steering tool within a health system under the universal health coverage (UHC) paradigm. The design of the underlying conceptual framework is based on a review of international literature as well as on policy observations and case studies. The paper analyses ways in which the choice of pharmacoeconomic instruments, their mode and timing of introduction and embedding in an overarching regulatory framework have been shaped by factors that fall into two spheres: health systems characteristics on the one hand and specific contextual factors on the other. The very distinct case studies of South Africa and Germany inform the identification of these determinants and guide the analysis of their influence on forming pharmacoeconomic policy and practice in different contexts. The case studies also serve to illustrate the relevance of particular policy decisions by highlighting the dynamic dimension of decisions made in the case study countries, e.g. regarding certain elements of the General Methods of the German Institute for Quality and Efficiency in Health Care and of the South African National Department of Health’s pharmacoeconomic guidelines. The paper concludes with a structured analytical overview of determinants, designs and implications. The findings are used to spell out clear recommendations for a context-sensitive process towards optimising pharmacoeconomic policy and practice in specific country contexts with a view to UHC.

### PHP313: SPECIFICITIES OF CANCER IMMUNOTHERAPY – CHALLENGES FROM MARKET ACCESS PERSPECTIVE

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**Background**: By targeting immune cells rather than tumour cells, immuno-oncology therapies (IOs) have shifted the cancer treatment landscape offering the potential for long-term quality survival to many patients for whom treatment options were previously limited. Since the approval of immune checkpoint modulators in metastatic melanoma in 2011, a great deal of knowledge was generated on specificities of IO and many thereof remain challenging from market access perspective. Discussion: Pricing and reimbursement of IO therapies remain a key challenge for decision-makers due to immature evidence at time of market launch. IO therapies showed a delayed tumor response and potential long-term survival in some patients limiting use of standard endpoints (e.g. median overall survival, surrogate endpoints, such as progression-free survival) and raising much uncertainty on long-term efficacy data. Assessment of relative efficacy of IO therapies poses substantial challenges while fast evolving treatment patterns make evidence on successive lines becoming rapidly obsolete. IO response was reported as heterogeneous between patients; lacking predictive biomarkers precludes from selecting proper target populations. Immune-related side effects make long-term safety uncertain. IO response kinetic and heterogeneous populations in terms of survival are problematic vis-à-vis standard methods used to extrapolate survival data. Anticipation of potential budget impact is more complex by uncertainty in dose selection, unclear rules for treatment hold/discontinuation and increasing number of potential drug combinations. Finally, given IO potential for long-term quality survival, decision-makers should consider a societal perspective to fully capture indirect costs, such as work productivity and caregiver time. Conclusions: Recognition of entire benefits of IO therapies depends largely upon addressing the discussed challenges. Mature and long-term clinical data are needed to quantify additional benefits and to support decision-making. On-going research and debates on new clinical endpoints, specific survival extrapolation methods, research on biomarkers, drug value frameworks should contribute to addressing gaps in IO assessment.

### PHP314: WILL 2017 UPDATES TO THE HIGHLY SPECIALISED TECHNOLOGIES PROGRAMME BENEFIT OR HARM VULNERABLE PATIENTS?

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**Background**: The Highly Specialised Technologies programme (HST) assesses drugs for people who suffer rare conditions and whose indicated population is sufficiently small that treatment has to be concentrated in a few centres only. Changes to the National Institute of Health and Care Excellence (NICE) decision making process have recently been announced adding a cost-effectiveness assessment and there is therefore need to examine the impact this change will have for these underserviced and typically vulnerable patients. **Analysis**: NICE had previously based decision making upon 1) the epidemiology of the disease, disease morbidity and existing treatment options, 2) The robustness of clinical efficacy arguments, 3) budgetary impact to the NHS and 4) impacts beyond health such as the benefits of research and innovation. These considerations are then communicated through a consultation process.
after which a decision is made on whether to nationally commission the technology. As of April 2017, NICE has introduced a cost-effectiveness element to the appraisal process requiring an additional cost per quality adjusted life year (QALY) assessment prior to approval with a threshold set at £300,000/QALY. The benefits of such analysis beyond augmentation in economic efficiency is to allow greater consistency and comparability of patient access as other drugs undergoing NICE appraisal have to identify their cost-effectiveness estimates. The counter argument however is that the cost-effectiveness framework does not adequately account for unmet need as real world evidence is limited in these patient groups (therefore widening confidence intervals for efficacy parameters) whilst the disjointed nature of existing service provision within the NHS systematically inflates the costs of treatment. Conclusion: HST evaluated drugs will be less likely to gain approval even at the £300,000/QALY threshold, and this extra health economic burden will only further slow access to drugs for these vulnerable patients with considerable unmet need.

**PHP315: BUT WILL THEY TRADE HEALTH? DEVELOPING AN ECONOMIC VALUE FRAMEWORK FOR ONCOLOGY**

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**OBJECTIVES:** Value frameworks in health care are proliferating often with very little input from economists. In particular, a number of oncology value frameworks have emerged, perhaps due to the greater costs of novel therapies in the cancer space. But none of these value frameworks include weights that economists would recognise as legitimate values. Building on previous qualitative work that identified health and non-health attributes of cancer treatment, the aim of this study was to design a discrete choice experiment (DCE) to identify trade-offs between identified attributes. **METHODS:** Previously reported qualitative focus group work with cancer patients, oncology clinicians and oncology nurses identified treatment convenience, existence of treatment alternatives, disease rarity, quality of evidence and prognosis without treatment as important attributes alongside the traditional health gain associated with treatment. These results informed the design and undertaking of a DCE piloted in June 2017 with a convenience sample (n=45) where subjects were asked to choose between covering two alternative treatments in a new health plan. Quality-adjusted life expectancy (QALE) is used as a payment vehicle and the pilot tested whether respondents would be willing to give up health gains associated with treatment for the other identified attributes. **RESULTS:** Conditional logistic regression identified statistically significant preferences for less inconvenient treatments, treatments with no alternatives, higher evidence quality, helping those with shorter prognosis and provide more QALE gains. Only the number of people affected (rarity of disease) was insignificant. **CONCLUSIONS:** The pilot phase of this ongoing study demonstrates that whilst the health-gains of cancer therapies are predominantly prioritised, other attributes are important and participants were prepared to trade health gains. The pilot results will be used to inform the design of a population study to identify the relative weight for the creation of a value framework in oncology with economically robust weights.

**PHP316: BIOSIMILAR UPTAKE IN THE UK- AN EVOLVING STORY?**

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Since the first approval of a biosimilar medicine in the EU in 2006, biosimilars have promised to deliver a more cost-effective solution for off-patent biologics, and by extension improve patient access to these medicines. A recent report highlights that the entrance of biosimilars into a therapeutic space increases price competition, thus driving down the price. Between 2016 and 2020, the addressable biosimilars market (i.e. biologics losing patent protection) in the EU5 and US has been estimated at €47bn, of which the UK accounts for €9bn. Despite this potential for saving in a health service facing substantial funding challenges, coupled with NICE recommendations for the use of biosimilars where possible, the uptake of biosimilars across the UK has been noted as slow by several reports. The factors influencing this should be addressed to ensure that maximal benefits of biosimilars can be realised in the UK. Several studies and reports have been identified between 2010 and 2017 which examine the slow uptake of biosimilars in the UK. These range from physician concern over biosimilar efficacy/safety to a general perceived lack of information from manufacturers and across the NHS. There is evidence to suggest that these concerns persist to this day, although recently the NHS have taken a more active leadership role to "to improve clinician confidence and clarify understanding amongst decision makers."

**PHP317: REGULATORY REQUIREMENTS FOR NON-INTERVENTIONAL STUDIES COLLECTING PATIENT PREFERENCES AND EXPERIENCES IN FRANCE, GERMANY AND THE UK**

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**Background:** Patient participation in medical decision making is increasingly recognized as a key component in the
redesign of health care processes and is advocated as a means to improve patient safety. The European Medicines Agency (EMA) has understood that patient preferences, notions and experiences have the potential to improve the quality and delivery of medical care, reduce overall costs and improve outcomes by accelerating the understanding of how best to incorporate new therapies and technologies into everyday clinical practice. Essentially, these data help fill the knowledge gap between clinical trials and actual clinical practice. Therefore, the demand for data, directly reported by a patient that is based on his or her perception of a disease and its treatment, has strongly increased over the last few years. Today, the legal framework required to set-up these studies varies across European countries. **Methodology:** Documentary Method – critical analysis of country specific legislation, government body requirements and recommendations. **Results:** Non-interventional studies collecting patient reported outcomes, preferences and perceptions of a disease and its treatment, require a formal review from an Ethic Committee (EC) in France, Germany and UK. In France, these studies involve human subjects and therefore require a formal review and approval from patient and data protection agencies. In Germany, they can be classified as an ‘Anwendungsbeobachtung’ and an EC review is highly recommended. In the UK, studies without ‘material ethical issues’ are suitable for a Proportionate Review instead of full REC. **Conclusions:** Considering the increasing demand and the extended benefits brought by these patient studies, we wonder why they are excluded from the upcoming regulation for a European harmonized process. We encourage legislators to extend the scope of this new regulation and offer a common and faster ethics review to facilitate the conduct of such studies without mitigating patient protection.

**PHP318: BRINGING MOLECULAR DIAGNOSTIC TESTS INTO CLINICAL PRACTICE: MAPPING THE EVIDENCE PATHWAY**


Currently, there is a lack of clarity as to how new molecular diagnostics can navigate the development ‘pathway’ and go from discovery and research into routine clinical practice. Compared with therapeutics, the development pathway for diagnostics is more complex and fragmented, leading to low uptake. At the end of the current pathway, regulatory organisations such as NICE in the UK often have to assess diagnostic technologies without robust ‘end-to-end’ studies demonstrating the full impact on patient benefits and costs. Where significant evidence gaps exist, assessment by NICE can often prove a challenge with promising technologies failing to secure positive recommendations as a result. Unlike therapeutics, implementation within the NHS for NICE-approved diagnostics is not mandatory, leading to further uncertainty for developers as to whether there is a return on investment. A clear and explicit description of the diagnostic pathway and the role of economic evidence could help to (1) improve research efficiency by informing the identification and collection of appropriate data earlier in the development process; (2) identify methodological work needed to improve the rigor of such research; and (3) align evidence generation to the needs of local and national decision-makers. The objective of this conceptual study is to describe a ‘map’ of the current development pathway for new diagnostic technologies within England and Scotland and describe the type of economic evidence needed to support the development process at each defined stage of the pathway. Drawing upon the collective experience of health economists working within the UK diagnostics landscape, the pathway will differentiate between types of diagnostics (e.g. ‘companion’ versus ‘standalone’) and delineate the differences between evidence generation and assessment for diagnostics compared with therapeutics. The different types of economic evidence required by NICE and local funders will also be discussed and the implications for likely implementation highlighted.

**PHP319: CONCEPT OF PHARMACEUTICAL CARE IN THE BRAZILIAN LEGISLATION**

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Pharmaceutical assistance, pharmaceutical care, pharmaceutical services, pharmacotherapeutic profile, and dispensing are designations used in laws, decrees, resolutions, and edicts concerning activities of pharmacists, without a specific distinction among them. **OBJECTIVES:** To analyze designations that cover the duties of clinical pharmacists, that is, professionals who participate in the healthcare system with regard to health promotion, prevention, and recovery. **METHOD:** Analysis of legal documents, since Decree no. 20.377/1931, which regulated the practice of the pharmaceutical profession in Brazil, until Law 13.021/14, which recognized pharmacies as healthcare facilities. **RESULTS:** Seventeen legal documents were identified, including decrees, laws, resolutions, and edicts
issued by Brazil’s Presidency of the Republic, Ministry of Health, Pharmacy Federal Council, and National Health Surveillance Agency. There is no standardization of concepts of the terms used, causing conceptual misunderstanding. CONCLUSION: The lack of standardization of terms associated with pharmaceutical activities brings negative consequences for the practice of the profession. Pharmaceutical care is the most appropriate expression to cover the duties that pharmacists must assume as components of the healthcare system.

**PHP320: IMPROVING TRANSPARENCY IN HEALTH TECHNOLOGY ASSESSMENT**

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**INTRODUCTION:** The goal of Health Technology Assessment (HTA) agencies is to issue recommendations to inform decision makers about the incorporation of technologies. In general, the HTA process lacks transparency due to the effectiveness and safety data dependent on ex post evaluation, the possibility of selective outcomes and bias in sampling, dosing and statistical analysis and economic evaluations based on unvalidated models and arbitrary threshold values. **OBJECTIVES:** The aim of this work is to evaluate methods to improve transparency on the HTA process. **METHODS:** Electronic search on Medline, Lilacs, Science Direct and Google Scholar and a complementary search in references of included studies and conference abstracts in January 2017. **RESULTS:** The transparency of the HTA process can be improved with the adoption of some concepts. The definition of a preferable health outcome can minimize uncertainty and make possible the evaluation of results of cost-effectiveness studies through a well-established explicit threshold value, preferably defined by an opportunity cost approach. The use of risk sharing can be beneficial to public systems and suppliers provided that a good monitoring system is in place. Multicriteria Decision Analysis (MCDA) matrices can be useful to inform health professionals and society about the variables and weights considered in the analysis and facilitate the decision process. Public consultations previous to a recommendation are useful to include the general population’s preferences and social values into the HTA process. The adoption of the principles of value-based healthcare (VBH) tends to limit the price range of new interventions and facilitate negotiations between healthcare providers and suppliers. **CONCLUSION:** Adopting a well-established preferable health outcome and the concepts of opportunity costs, VBH, risk sharing, MCDA and public participation, the HTA system tends to a situation where the decisions made are explicit and improved through rational methods adjusted by society’s preference.

**PHP321: ALTERNATIVE REIMBURSEMENT MODELS FOR HIGH COST HEALTH TECHNOLOGIES**

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High cost health technologies, mostly targeting rare diseases and genetic disorders, are becoming a growing source of concern to public and private payers due to their potentially disruptive front-loaded budget impact. Current funding mechanisms, structured to cover incremental costs usually required to treat patients with chronic conditions, will have to be re-designed as highly effective curative therapies are disrupting the distribution of treatment cost with the long-term realisation of clinical benefits to patients. Pressure to make these treatments available and accessible to patients on the basis of effectiveness (i.e. cure) and future medical cost offsets was observed already with Hepatitis C drugs. Rapid advances in gene therapies and promising clinical trial results are likely to further increase the number of patients eligible for these high cost treatments. Sponsored by the Society of Actuaries (SOA) - Health Section, this work presents a framework for evaluating alternative reimbursement approaches, with considerations specific to public and private payer perspectives in the US and UK. Various financing and insurance-like models are explored, ultimately highlighting the strengths and weaknesses of each of these approaches to the type of health technologies at hand, and identifying areas where traditional insurance risk principles may break down. Illustrative scenarios using real-world data explore the applicability of these alternative reimbursement models to selected disease areas and therapies, and demonstrate the magnitude of the financial risks to payers. While traditional actuarial approaches are normally used to quantify the potential financial risk to payers of introducing novel technologies, health economic evaluations tend to focus on predicting long-term costs and outcomes of new treatments. Therefore, managing the financial uncertainty of high cost technologies while maximising patient clinical benefits is an area where both disciplines can leverage each other to develop effective and durable alternative reimbursement models.

**PHP322: THE IMPACT OF HEALTH POLICY ON THE PHARMACEUTICAL SUPPLY CHAIN IN FRANCE**

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Objective: This paper discusses the impact of health policy on the pharmaceutical supply chain in France from 2008; it provides an analysis of the current situation and reflects on future reforms. Method: This study is based on
secondary data analysis and information available from peer review literature and publically available data given on governmental websites. It focuses mainly on prescription drugs which are reimbursed by social security. Results: Since 2008, the French Government has enforced a number of measures to reduce the cost of pharmaceutical spending, representing 15% of health care expenditure. The measures taken have gradually impacted all supply chain steps, from manufacturing to distribution and dispensation. While the target of reducing the growth rate of pharmaceutical expenditure has been achieved, a number of challenges have emerged, market allocation, parallel distribution channels and pharmaceutical stock-outs. In an already highly regulated environment, the effects of new regulations can be rather unpredictable as manufacturers and wholesalers are international but also have domestic interests; the government’s corrective measures do not take into account the inter-organizational dependencies of the actors. An integrated view of the supply chain should be fostered so as to monitor all steps of the supply chain with similar objectives, and to share information between the actors.

PHP323: POSSIBILITIES OF DOMESTIC PRODUCERS OF THE REPUBLIC OF KAZAKHSTAN IN THE FIELD OF MANUFACTURING ANTI-TUBERCULOSIS MEDICINES

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Introduction. The objective of the study is to explore the possibilities of the domestic manufacturers of drugs and to produce drugs for treating patients with tuberculosis. Methods of the study include a content analysis, social and marketing study of the manufacturers of medicines in the Republic of Kazakhstan. Results As shown by the social and market studies a real way to solve the problems of drug supply for patients with tuberculosis of the country may be the development of the domestic pharmaceutical industry on the basis of state economic support in the form of investment in the innovative economy and the pharmaceutical industry to expand production with using advanced technologies. To conduct the study, we developed a questionnaire consisting of 26 questions for the heads of pharmaceutical industry. The questionnaires consisted of questions both of open and closed types. So in the questionnaire there were questions concerning decisions of problems of the medicinal help for tuberculosis patients. During the carried out study the following results have been obtained: there were registered the most perspective enterprises on manufacturing medicines for tuberculosis patients treatment, certain potential pharmaco-therapeutic groups of preparations which production is possible at the perspective enterprises of RK. Conclusions 1. Most heads of pharmaceutical enterprises stated that they could compete on production of quality products with other CIS countries enterprises (73.0%). By the points of view of the heads of the pharmaceutical companies it is necessary to reduce tax loading on businesses, as well as to provide a permanent state order for domestic manufacturers. Literature 1. Satayeva L.G. Analysis pharmaceutical industry of Kazakhstan in improving the process of drug in the country // MediAl. 2015. - №1. - p.261

PHP324: A CONCEPTUAL YET PRAGMATIC FRAMEWORK FOR VALUE-BASED AGREEMENTS

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Value-based contracts (VBCs), or performance-based managed entry agreements, are regularly proposed as important instruments to achieving sustainable access to innovative medicines, but still few seem to be implemented. Various factors leading to the success or failure of VBCs have been reported in the literature. However, the standpoint has been mainly academic, with little insight into where the interested parties (pharma and payers) should focus their efforts to make these arrangements happen. This paper is revisiting the conceptual framework for VBCs to inject a needed dose of pragmatism, based on extensive experience of the authors in these approaches when working with payers and pharma companies. It will identify, in a structured way, the incentives and hurdles most heavily involved in successful VBCs, clarify when payers want to consider and pursue these agreements, and delve into attitudes to risk sharing and the dynamics of negotiation. To provide richness to the analysis, the EU and US markets will be contrasted, since their respective payer philosophies are distinct in various ways. The current practices of pricing and reimbursement/coverage in both markets will first be considered. Changes needed in the ways of thinking and infrastructure will then be proposed: among others, these include consortium/partnerships approaches to build integrated, suitable data platform (e.g. to support indication-based pricing) or (in the US) finding practical ways to bridging from traditional formulary-based contracting to (truly) value-based contracting. The thesis will conclude with a summary of ‘best scenarios’ to illustrate the roadmap to more consistent and sustainable use of VBCs.

PHP325: WHAT CAN BE DONE FOR ACCESS AND REIMBURSEMENT PROCESSES TO REWARD INNOVATION IN DIGITAL “BEYOND THE PILL” SOLUTIONS?
Emerging digital technologies are one of the fastest growing sectors within the healthcare industry and are starting to reshape our perspective on how some diseases can be managed. Utilizing big data, sensors, artificial intelligence and software platforms provides the opportunity for improved disease management across multiple disease areas. Pharmaceutical companies are aware of this opportunity and are looking at ways in which these types of technologies can complement their products to offer “beyond the pill” solutions. Until now, many of the currently available digital technologies within the healthcare sector have targeted patients as the consumer and customer, meaning most technologies are paid by patients out-of-pocket or offered for free by manufacturers or pharmaceutical companies, a situation which is not ideal for uptake or innovation. In contrast, prescription drugs and most medical devices go through national reimbursement systems, thinking of the patient as the consumer and the payer or insurance company as the customer, this system allows universal access for patients and is something digital health technologies could also benefit from. Some Health Technology Assessment (HTA) bodies in Europe have started to look at how they can evaluate digital technology solutions alone or in combination with pharmaceutical products; however, access pathways remain unclear posing a hurdle for manufactures trying to deliver solutions and benefits to patients. Developing structured access and reimbursement pathways for digital health solutions will likely have a number of positive effects for the health care industry across multiple stakeholders types. Broader access will allow more patients to benefit, HTA bodies can have control on pricing and reimbursement of these type of solutions and additional appetite for innovation and investment within the sector will be generated.

**PHP326: HOW POLICY-MAKERS SHOULD UNDERSTAND QUALITATIVE EVIDENCE REGARDING PUBLIC OPINION**

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I investigate the role of qualitative evidence of patient and public opinion in healthcare policy-making. When policy-makers seek input from patient representatives, Citizens Juries etc, on the traditional picture this is a quick or cheap alternative to quant: another way to understand public preferences and thus enhance democratic legitimacy. But this has various problems, eg the sample sizes don't justify any inferences regarding public opinion. A better account is inspired by observations of several real world cases in which qualitative evidence has influenced policy. In such cases, policy-makers end up sharing the opinions expressed by respondents. I argue that where qualitative research respondents find a certain consideration to be important, and policy-makers act on that finding, it's because they've seen the importance of that consideration for themselves; perhaps they see that a certain policy is morally obligatory, or a good idea. There is typically no need to generalise about what the public thinks. Thus I propose that the distinctive value of qualitative evidence is to provide direct insight into the substantive issues, eg to reveal reasons or normative considerations. In contrast, quantitative evidence will generally only reveal a factual claim about public opinion. Decision-makers then have to combine this factual claim with norms justified by other means before they can derive practical conclusions. Although the two kinds of research may address exactly the same policy question, they support completely different types of conclusion regarding that question. The new model explains why qual is useful despite lacking statistical significance; why deliberative forums are useful, despite being unrepresentative; and why even input from individual stakeholder representatives can be useful. I survey various implications for practice. For example, policy-makers using qual should not see themselves as neutral channels of public opinion; they should engage with the issues that respondents addressed.

**DISEASE-SPECIFIC STUDIES**

**MENTAL HEALTH - Clinical Outcomes Studies**

**PMH1: PSYCHOTROPIC DRUG USE IN NON PSYCHIATRIC WARDS: INDIAN SCENARIO**

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**OBJECTIVES:** To identify the prevalence of psychotropic drugs in general medicine and surgical wards and to identify and manage the DRPs associated with the use of psychotropic’s. **METHODS:** A period prevalence study was conducted in the general medicine and surgical wards of a University teaching hospital over a period of six months. All patients admitted to general medicine and surgery wards with at least one psychotropic prescription without a previous history of psychiatric illness were included in the study. All the patients with psychotropic drugs were intensively monitored for the occurrence of any DRPs from the day of admission till the day of discharge. Clinically
significant drug related problems along with its management strategies were communicated to the concerned clinicians through the peer clinical pharmacists. **RESULTS:** Of 3000 patients reviewed, 322 were prescribed with 452 psychotropics. Average number of psychotropics per patient was 1.40±0.76 (range: 1 – 4). Psychotropic prescriptions rates were relatively more from the non-psychiatrists [n=250 (55.30%) vs n=202 (44.70%)] than the psychiatrists. ADs [n=90 (26.71%)] and pain [n=43 (43.87%)] were the frequently observed psychiatric and non-psychiatric indications. The frequently prescribed psychotropic classes were benzodiazepines [n=184 (39.06%)] and antidepressants [n=150 (41.78%)], [n=11 (57.89%)] of the psychotropic fixed drug combinations were by the psychiatrist. The overall incidence of DRPs associated with psychotropic drug was 32.85% ranging from 1 to 3 per patient. The frequently observed DRPs were potential drug-drug interactions [n=71 (53.96%)]. Of the DRPs, n= 69 (62.16%) were observed in the prescriptions by the non-psychiatrists. **CONCLUSIONS:** Psychiatric illnesses are the main indication for psychotropic prescriptions and that suggested that the drug were prescribed aptly.

**OBJECTIVES:**

A **SOUTH AFRICAN PRIVATE HEALTHCARE SETTING**

**PMH3:** Longitudinal study into the dispensing patterns of benzodiazepines and z-drugs in a South African private healthcare setting

**OBJECTIVES:** Benzodiazepines, including the z-drugs, have anxiolytic, sedative, hypnotic and muscle relaxant effects and are used to treat anxiety, panic and sleep disorders. There is a variety of branded generics of these drugs available on the South African market. The aim was to compare the prescribing patterns of these drugs in a South African private sector patient population over a 12-year period (analyses were conducted on data collected in 2004, 2010 and 2015). **METHODS:** A retrospective, cross-sectional drug utilisation study was conducted on three datasets of benzodiazepines and the z-drugs dispensed in 2004 (27080 records), 2010 (32775 records) and 2015 (30727 records) in South Africa. Data were obtained from a private medical aid administrator. Main outcome measures were dispensing frequency of active ingredients and generic substitution. **RESULTS:** Twenty-one different active ingredients of benzodiazepines and the z-drugs were prescribed. On average over the time period, zolpidem (16.53%) was the most often prescribed active ingredient, followed by alprazolam (14.78%), diazepam (13.86%), zopiclone (11.36%) and midazolam (10.30%). These five active ingredients accounted for 66.83% of benzodiazepine and z-drug prescriptions in 2005, 2010 and 2015. These three benzodiazepines were also the products with the most generic equivalents available. Diazepam and midazolam each had seven branded generics that were dispensed in 2015, and alprazolam had six generics. Midazolam and zolpidem dispensing were the most heterogeneous (Stddev.P of 6.44 and 4.35, respectively). Zolpidem and lorazepam showed an increase in prescribing, whilst bromazepam, oxazepam and temazepam showed a decrease. **CONCLUSIONS:** From 2004 to 2015 the prescribing frequency of diazepam decreased and alprazolam, although not directly related, increased, and zopiclone was replaced by...
zolpidem as the z-drug of choice. Less expensive generic equivalents had a substantial impact on dispensing patterns in this 12-year period and have established a firm place in this sector of the pharmaceutical market.

PMH4: EPIDEMIOLOGY AND CLINICAL CHARACTERISATION OF OBSESSIVE-COMPULSIVE DISORDER IN BAHAwalPUR PAKISTAN

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OBJECTIVES: Obsessive compulsive disorder (OCD) is an anxiety disorder characterized with reoccurring thoughts (obsessions) and uncontrollable behaviors (compulsions), paralyzing patient’s comprehension and reducing his quality of life. In today’s fast changing world, periodic epidemiological studies on OCD patients are essential to ensure proper clinical diagnosis and treatment for such patients and to promote a healthier and productive society. The objective of study was to get an update on descriptive epidemiology of OCD in local population of Bahawalpur Pakistan. METHODS: A retrospective study on prevalence of self-reported OCD in patients age 11-20, 21-30, and 31-40 and above 40 years. Followed by seven months (November 2013-May 2014) longitudinal analysis of clinical predictors of OCD according to DSM-IV criteria as reported in Diagnostic and Statistical Manual of Mental Disorders, 4th edition. RESULTS: We found that the OCD prevalence rate is 46% as observed in 480 individuals over the course of seven months. Milder OCD (34%) was most occurring form and cleanness (26%) was most common obsession in OCD patients in Bahawalpur Pakistan. There was no specific pattern in gender distribution of OCD but its prevalence and severity was increased with increase in age, and it was highest in individuals >40 years age (59.5%), followed by 31-40 years (53.5%), 21-30 years (48.5) and 11-20 years (46%). Most of the OCD cases also fall under the criteria of depression, social phobia and stress CONCLUSIONS: The prevalence of OCD seems to be underestimated in local population, perhaps due to cultural and societal reasons. Our analysis suggests that despite the heterogenous nature of the disease there is a significant diagnostic overlap with other DSM disorders. Our data suggest that risk factors such as advance age, family history of depression and stress were found to contribute towards OCD, same as it is previously reported in literature.

PMH5: INCIDENCE OF PSYCHIATRIC DISORDERS IN WOMEN WITH A SUSPECTED BUT UNCONFIRMED DIAGNOSIS OF BREAST OR GENITAL ORGAN CANCER

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OBJECTIVES: Breast (BC) and genital organ cancers (GOC) are known to have a major impact on the quality of life of patients The aim of this study was to analyze the risk of depression, anxiety, and adjustment disorders in women in Germany with a suspected but unconfirmed diagnosis of BC or GOC in their past medical history. METHODS: This study included women who received a suspected diagnosis of BC or GOC and were followed between 2007 and 2015 (index date). These women were matched (1:1:1) to women with a confirmed diagnosis of BC or GOC and women without a cancer diagnosis. The main outcome measure of the study was the rate of depression, anxiety, and adjustment disorder diagnoses within three years of index date. RESULTS: A total of 4,842 patients were included in the present analysis (mean age=49.3 years). Within three years of the index date, 23.5% of women with a confirmed diagnosis of BC or GOC, 14.1% of those with a suspected diagnosis of BC or GOC, and 10.5% of those without a cancer diagnosis, developed depression, anxiety, or an adjustment disorder (log-rank p-value<0.001). Women with a suspected diagnosis of cancer were at a higher risk for these psychiatric conditions than those without a cancer diagnosis (BC and GOC: HR=1.32; BC: HR=1.21; GOC: HR=1.50). CONCLUSIONS: A suspected diagnosis of BC or GOC in a woman’s medical history is associated with an increased risk of developing depression, anxiety, and adjustment disorders.

PMH6: SEVERE DEPRESSION AS A RISK FACTOR FOR OSTEOPOROSIS: A REAL WORLD DATA STUDY CONDUCTED IN ITALY

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OBJECTIVES: Depression is a common mental disorder, with more than 300 million people suffering from it. The presence of a relationship between depression and osteoporosis has been shown by a previous real world data study conducted in Italy. The objective of this analysis is to investigate whether the association observed could have been confused by antidepressants use or by time dependent confounders’ presence. METHODS: This was a retrospective analysis based on data extracted from Italian IMS Health Longitudinal Patient Database. Three cohorts have been defined: the cohort of incident depressed patients, consisting of individuals with a diagnosis of depression (index date) during the period January 2004 - December 2010. The cohort of non-depressed patients, containing subjects
with a first contact with the general practitioner (Index date) during the period January 2004 - December 2010, and that were not included in the previous cohort (free from depression). The cohort of depressed patients using antidepressants, identified within the first cohort. Patients of all cohorts must not have an osteoporosis diagnosis or a depression diagnosis during the five years period preceding the Index Date. Extended multivariate Cox models were performed controlling for antidepressants use and for other time dependent confounders. RESULTS: No association was found between depression and osteoporosis during the follow-up period (HR 1.024, p=0.26), while a higher incidence of osteoporosis of about 7% (HR 1.07, p=0.0010) was observed among antidepressants users when compared to non-users. Focusing on patients with antidepressants, the risk of developing osteoporosis increased by 13% for each antidepressant prescribed and by 14% (HR 1.141, p=0.0012) at antidepressant switch. CONCLUSIONS: Results from this study suggest that patients receiving a higher number of antidepressants and those needing pharmacological treatment changes have an increased risk of osteoporosis. Thus, this study suggests an association between a severe status of depression and osteoporosis.

MENTAL HEALTH - Cost Studies

PMH7: BUDGET IMPACT ANALYSIS OF LONG-ACTING PARENTERAL ANTIPSYCHOTIC DRUG FLUFENAZINE IN THE TREATMENT OF SCHIZOPHRENIA IN RUSSIA: A HOSPITAL PERSPECTIVE

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OBJECTIVES: the purpose of the study was to develop an instrument for the the budget impact analysis of atypical long-acting injectable flufenazine (FLU LAI) as an alternative to typical antipsychotics (TA) chlorpromazine (CHL). METHODS: the study was based on Ying Jiao Zhao meta-analysis of 18 antipsychotics used in the long-term treatment of schizophrenia. The comparison of FLU LAI versus CHL revealed differences of statistical significance, FLU LAI was superior to chlorpromazine (OR=0.31, 95% CI 0.11–0.88) by relapse rate. The developed model-based evaluation instrument enabled to estimate the budget impact of FLU LAI for schizophrenia patients in a single Moscow hospital with 198 inhabitants, who were treated in January – December 2015. In budget impact analysis it was assumed that drug consumption (estimated in DDD/100 bed-days) per 1 treated patient remains unchangeable, while the proportion of patients, treated with FLU LAI and CHL, will change from the initial. Exchange rate in the analyzed period was €1 = 68 RUB. RESULTS: the total annual budget for medicines for 198 patients was estimated at €21,288. Initially 8.5% of patients (n=17) were treated with FLU LAI and 13% (n=26) with CHL. If the proportion of patients, receiving FLU LAI, increases by 1% while the proportion of patients, receiving CHL decreases by the same 1%, the total costs of medicines will decrease by 0.1% (€21.5). If the proportion of patients treated with FLU LAI increases by 5% and 10% (as an alternative CHL decreases in the same proportion) the budget economy will be 0.5% (€107.5) and 1% (€215). CONCLUSIONS: FLU LAI is associated with a lower cost of treatment per DDD dose and is considered to be more effective versus chlorpromazine by relapse rate. Increase by 10% proportion patients, receiving FLU LAI, saves up to 1% of annual budget for medicines in a single hospital.

PMH8: BUDGET IMPACT ANALYSIS OF ZIPRASIDONE USE IN THE TREATMENT OF SCHIZOPHRENIA IN RUSSIA

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OBJECTIVES: to evaluate the financial consequences of ziprasidone use from the perspective for Russian National Healthcare system. METHODS: budget impact analysis (BIA) was performed from two perspectives: Russian National Health system and a patient. Costs of atypical antipsychotics (AA) and rehospitalization costs of patients treated with ziprasidone (ZIP), quetiapine (QUE), aripiprazole (ARI), paliperidone (PAL), paliperidone depot (PAL LAI) and risperidone depot (RIS LAI) were calculated for median duration of treatment 48 weeks. The target population was determined using Russian statistical epidemiology data, and a national treatment guidelines. Exchange rate mean in 2017 - €1 = 62.5 RUB. RESULTS: the most effective drug was ZIP with the lower risk ratio (RR) of rehospitalization -17.08% versus 43.28% for RIS LAI, 53.36% for PAL, PAL LAI, QTP and 83.75% for ARI. With the drug cost - €1,444.34 (90271 RUB) ZIP was more expensive only compared to QTP, total costs for schizophrenia therapy for 1 patient was the lowest for ZIP – €1,626.37 (101648 RUB) – cost saving vary from 9.7% versus QTP to 54.7% versus PAL LAI. In the BIA for cohort of Russian schizophrenia patients (140,713 inhabitants, 25% from all schizophrenia patient population) total budget for ZIP will estimate at 228.9 mln € (14303 mln RUB) and will decrease by €24.6-55.4 mln (1536 or -3464 mln RUB) versus different trade name of QTP; by €182.1 mln (11381 mln RUB) vs ARI; by €93.2 mln (5824 mln RUB) vs PAL and by €274.8 mln (17174 mln RUB) vs PAL LAI. The most influential variables in the sensitivity analysis were costs of drug, dosage regimen and RR of
rehospitalization. **CONCLUSIONS:** funding ziprasidone (the most effective in case of rehospitalization rate) is an effective use of financial resources in the Russian public health – total budget saving estimated from 9.7% to 54.7%.

**PMH9:** **ALLOWING METHADONE’S PRESCRIPTION TO GENERAL PRACTITIONERS: A POSITIVE IMPACT ON THE FRENCH HEALTHCARE INSURANCE EXPENDITURES**

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Currently, Methadone (opioid agonist treatment for opioid dependent people) prescription in France is allowed only for hospital physicians working in specialized healthcare centers. In the last 20 years, many French experts have requested the ability for General Practitioners (GPs) to prescribe methadone, to improve patient care and management as it is already the case for buprenorphine. **OBJECTIVES:** The objective of the study was to demonstrate the economic impact for the French Healthcare insurance of the authorization to describe methadone given to GPs in addition to hospital physicians. **METHODS:** A Budget impact analysis (BIA) was conducted to demonstrate the financial difference between the current scenario (1) and a new scenario (2) integrating the authorization of methadone prescription by GPs as of January 1, 2018 **RESULTS:** - The study showed cost savings could be generated by a gradual transfer from health centers to general practices, as GP’s annual cost is three times less expensive than health centers annual cost. Despite a lower price of Methadone, the scenario 2 will lead to additional expenses induced by a broader access to the treatment - Savings are also generated by the fact that a large number of patients treated under scenario 2 are less likely to be infected by HCV or HIV. **CONCLUSIONS:** Allowing GPs to prescribe methadone would lead to significant cost savings for the French Health insurance, around €40 million between 2018 and 2022. Besides, it would extend the access of opioid substitution treatment (OST) adapted for injecting drug users and/or nonresponders to another OST.

**PMH10:** **BUDGET IMPACT ANALYSIS OF PALIPERIDONE PALMITATE 3-MONTHLY FOR THE TREATMENT OF SCHIZOPHRENIA IN ITALY**

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**OBJECTIVES:** To estimate the impact of paliperidone palmitate 3-monthly (PP3M) with respect to paliperidone palmitate 1-monthly (PP1M) and other long-acting therapy (LAT) treatments (aripiprazole LAT, olanzapine pamoate and risperidone microspheres) for the treatment of schizophrenia in Italy. **METHODS:** The impact is estimated from a third party payer perspective, so only direct health costs (treatment, disease, relapse and adverse events) are considered. Patients eligible for PP3M treatment are considered: about 80% of PP3M patients come directly from PP1M, the remaining part is equally distributed between aripiprazole and risperidone. The model includes the per label required treatment-specific induction phase via PP1M. Upon relapse, according to clinical practice, patients switch to subsequent lines of therapy (oral treatment with clozapine mostly). Patients may be in stable disease, experiencing relapse, experiencing acute (prolactin-related disorders and extrapyramidal symptoms) or permanent (weight gain and diabetes) adverse events, or die. Data from Phase III PSY3011 and PSY3012 trials are used to retrieve clinical outcomes for PP1M and PP3M. Efficacy data of other LAIs and oral medicines are obtained by applying relative risks elaborated from published literature data. The economic inputs derive from official prices (for all considered drugs) and publications related to the Italian context. **RESULTS:** For the next 3 years, 2235, 6320, and 9316 patients, respectively, are estimated to switch to PP3M; Total savings in 3 years amounts to € 425,500 (€ 17,340 year 1, € 127,000 year 2 and € 281,160 year 3). About 40% of the savings is due to decreasing in drug costs while the rest is due to a reduction in the number of relapses. **CONCLUSIONS:** Based on budget impact analysis, the introduction of PP3M in Italy is completely sustainable by the National Healthcare System, as it is a cost saving option compared to the actual mix of treatment (aripiprazole, olanzapine and risperidone).

**PMH11:** **COST CONSEQUENCE OF INTRODUCING PALIPERIDONE PALMITATE 3-MONTHLY FOR THE MAINTENANCE TREATMENT OF SCHIZOPHRENIA IN THE ENGLISH NATIONAL HEALTH SERVICE (NHS)**

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**OBJECTIVES:** The objective was to estimate the budget impact of introducing paliperidone palmitate 3-monthly for the maintenance treatment of schizophrenia to the English NHS setting. **METHODS:** A 1-year budget impact model was developed based on epidemiological estimates of adults who had previously experienced two relapses of schizophrenia. An English real world data study informed the number of hospital admissions and length of stay. Two scenarios were simulated: 1) the current setting, in which patients were prescribed their current antipsychotic drugs, and 2) the proposed setting, including potential displacement of current antipsychotics from switching treatment to paliperidone palmitate 3-monthly. The budget impact analysis incorporated drug acquisition, drug administration and
hospitalisation costs. Univariate sensitivity analyses were conducted, including analyses assessing the impact of differential rates of displacement. **RESULTS:** The current estimated annual cost of schizophrenia in the English NHS adult population with two relapses was approximately £660m, with 46,479 admissions and 1,389,985 bed days. Assuming a displacement of 25% oral anti-psychotic and risperidone long acting injectable (RLAI) patients, and 70% of paliperidone palmitate 1-monthly patients, paliperidone palmitate 3-monthly was associated with estimated net savings of £42m, a reduction of 7,241 admissions and a reduction of 240,084 bed days. In an alternative scenario, increasing only the displacement of oral anti-psychotics and RLAI to 50%, paliperidone palmitate 3-monthly was associated with estimated net savings of £79 million, a reduction of 14,483 hospital admissions and a reduction of 506,549 bed days. **CONCLUSIONS:** Introducing paliperidone palmitate 3-monthly was associated with significant cost savings. Cost savings were driven predominantly by reductions in drug administration costs and hospitalisation costs associated with relapse, compared to orals and RLAI.

**PMH12:** A PRELIMINARY COST ANALYSIS OF SCHIZOPHRENIC PATIENTS STABILIZED ON 1-MONTHLY LONG ACTING PALIPERIDONE PALMITATE (PP1M) INJECTION SWITCHING TO PALIPERIDONE PALMITATE 3-MONTHLY FORMULATION (PP3M) IN THE PUBLIC SECTOR OF HONG KONG

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**OBJECTIVES:** To study the potential economic impact on health care resource utilization if PP1M-stabilized patients are switched to PP3M. **METHODS:** Schizophrenia is among the most costly mental illnesses due to the indirect and direct costs involved. Poor compliance to treatment leading to re-hospitalization is the major cost driver. Long acting therapies such as the monthly injection of PP1M have been proven to be superior over oral therapies in terms of cost-effectiveness. For patients stabilized on PP1M, outcomes can be further improved by using the recent 3-monthly administered PP3M. Since there was no patient data on PP3M in Hong Kong at time of this study, we used the patient data from another local study for estimation of potential cost savings by comparing direct cost of the 2 treatments. Data from overseas studies has suggested effectiveness and safety profile of both PP1M and PP3M are similar. Local costs for outpatient visits for drug administration, professional fees and drug cost were retrieved from the Hong Kong Government Gazette and local hospitals. Study was performed from a government’s perspective. **RESULTS:** Switching PP1M-stabilized patients to PP3M may lead to a reduction of overall direct cost by 32.8% per patient/year (USD6,576 vs USD4,422). The major cost reduction is due to 66.7% reduction in outpatient visits (USD2,184 vs USD728) and 16% in drug administration (USD4,391 vs USD3,694). This may be a conservative estimation as reduced hospitalization due to improved compliance has not been included in our calculation. **CONCLUSIONS:** Results of the present study suggest that switching PP1M-stabilized patients to PP3M is likely to lead to cost savings by reducing outpatient visits and drug cost in the public sector of Hong Kong. This should be considered for inclusion into the local management guideline. A post-launch cost effectiveness analysis using real-world patient data will provide more information on the potential cost benefits.

**PMH13:** COST-EFFECTIVENESS COMPARISON OF OPIOID SUBSTITUTION THERAPY VS. NON-PHARMACOLOGIC THERAPY IN THE STATE OF KUWAIT

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**OBJECTIVES:** The primary goal of our study was to compare comprehensively cost-effectiveness of treatment option for pharmacologic opioid substitution therapy with buprenorphine/naloxone combination and non-pharmacologic treatment in the State of Kuwait (SoK). **METHODS:** We have adapted two different micro-simulation decision models to the real-life conditions in SoK using locally specific data for treatment costs of buprenorphine/naloxone combination. In the first model, we took into account the protocol that is applied in SoK for pharmacologic treatment arm and non-pharmacologic treatment arm. In the second alternative model, costs in the pharmacologic treatment arm and non-pharmacologic treatment arm were fully based on the UK data and then adjusted to conditions of the local jurisdiction. **RESULTS:** Using the first model, we have demonstrated that comparison of pharmacologic treatment arm with non-pharmacologic treatment arm resulted in incremental cost-effectiveness ratio (ICER) of 13,307 KWD/QALY which was below conservative willingness-to-pay threshold of 15,221 KWD/QALY (50,000 USD/QALY) and way below updated value of 30,442 KWD/QALY (100,000 USD/QALY); the pharmacologic treatment was thus deemed highly cost-effective when compared to non-pharmacologic treatment arm. When including only direct costs in the first model, the resulting ICER was 22,826 KWD/QALY, i.e., below the updated willingness-to-pay threshold of 30,442 KWD/QALY (100,000 USD/QALY); even under such stringent conditions, the pharmacologic treatment arm was therefore cost effective when compared to non-pharmacologic treatment arm. In the second alternative model, we have shown that under base case scenario pharmacologic treatment arm dominated non-pharmacologic treatment arm by saving 1,670 KWD and gaining 0.1534 QALY per patient per year. The dominance was retained even when only direct costs were considered. Both deterministic and probabilistic sensitivity analysis
confirmed robustness of our findings. **CONCLUSIONS:** Results of our study indicated that in SoK, the pharmacologic opioid substitution therapy using buprenorphine/naloxone combination when compared to non-pharmacologic therapy was at least highly cost-effective if not cost saving.

**PMH14: FLEXIBLE-DOSE DEPOT BUPRENORPHINE INJECTION FOR OPIOID SUBSTITUTION TREATMENT IN HEROIN-ADDICTED ADULTS: A SWEDISH PHARMACOECONOMIC PERSPECTIVE**

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**OBJECTIVES:** Opioid substitution treatment (OST) in Sweden is unique among European countries for having a strict policy for illicit drug use while receiving OST, and largely excluding prescription opioid abusers from methadone- or buprenorphine-based OST (i.e., focusing on heroin-abusers). Heroin abuse is a risk factor for increased healthcare utilization, criminality, and overdose death: risks that are magnified by OST discontinuation. A recent, 24-week, Phase-3 clinical trial enrolling primarily heroin-dependent subjects demonstrated superior efficacy of flexible-dose depot buprenorphine (CAM2038) versus sublingual buprenorphine/naloxone (SL-BPN) in cumulative illicit opioid use. The present analysis was conducted to estimate the associated economic impact of CAM2038 from a Swedish perspective. **METHODS:** Annual direct medical costs (excluding OUD treatment costs), societal costs, and quality-adjusted life years were assessed using a 5-state Markov model wherein cohorts received CAM2038 or SL-BPN. Transition probabilities were derived from the Phase-3 trial. State-specific event probabilities and associated costs/utilities were literature-based. Uncertainty was evaluated with scenario and probabilistic sensitivity analysis. **RESULTS:** Annual total costs were 21% lower for CAM2038 vs SL-BPN in the most conservative scenario. Approximately 83% of these cost-savings were attributable to reduced criminality/victimization costs. Reduced emergency and hospital services primarily drove direct-medical cost-savings. Outcomes were sensitive to rules for how the frequency/pattern of on-treatment illicit opioid use triggered forced discontinuation and to rules regarding the minimum-allowable time to OST reengagement. **CONCLUSIONS:** OST with CAM2038 for opioid-dependent adults is estimated to lower direct-medical and societal costs in Sweden. Scenario analyses were relevant for Sweden where clinicians autonomously set discontinuation and reengagement rules. The pharmacoeconomic benefits of CAM2038 in Sweden may be more pronounced than in other European countries given relatively high costs associated with heroin addicts discontinuing OST.

**PMH15: SUBSTITUTION THERAPY WITH FLEXIBLE-DOSE DEPOT BUPRENORPHINE INJECTION TO TREAT OPIOID USE DISORDER IN THE UNITED KINGDOM: A PHARMACOECONOMIC ASSESSMENT**

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**OBJECTIVES:** Of the five most-populous countries in Western Europe, the United Kingdom (UK) has the highest rate of problematic opioid abuse and among the highest rates of prescription opioid abuse. There has never been more urgency to treat opioid use disorder (OUD) given its burden on public health and local resources, yet conventional orally-administered maintenance treatments like sublingual buprenorphine/naloxone (SL-BPN) have several limitations owing to high rates of prescription drug misuse and diversion and hence sub-optimal effectiveness. Investigational CAM2038 (a flexible-dose depot buprenorphine injection) has emerged from this need and demonstrated superiority on the cumulative density function of negative urine samples versus SL-BPN in a 24-week Phase 3 clinical trial of substitution therapy for opioid-dependent patients. This analysis assessed its potential economic impact in the UK. **METHODS:** Direct medical and societal costs (excluding OUD drug costs) were assessed over 52 weeks using a 5-state Markov model wherein cohorts received either CAM2038 or SL-BPN. On-treatment transition probabilities were derived from the Phase 3 trial. State-specific event and other transition probabilities and associated costs were literature-based. Uncertainty was evaluated with scenario and probabilistic sensitivity analysis. No discounting was applied due to the short time-horizon. **RESULTS:** CAM2038 accrued lower annual total per-patient costs (-£4382). Cost-savings were primarily attributable to lower crime-related costs (-£3281); of which 85% were attributable to lower crime-anticipation/avoidance and victimization (-£2779). Direct-medical cost-savings (-£777) were primarily attributable reduced utilization of supervised self-administration (-£361) and prescription-controlled drug fees (-£311). Savings attributable to avoided HIV/HCV infections (-£43) were modest assuming traditional interferon-based HCV treatment, but were more pronounced assuming treatment with protease inhibitors (-£885). **CONCLUSIONS:** In the UK, CAM2036 is potentially a pharmacoeconomically preferable alternative to SL-BPN for OUD, with direct-medical and societal cost-savings estimated over 52 weeks.

**PMH16: COST-EFFECTIVENESS ANALYSIS OF OPIOID SUBSTITUTION TREATMENT IN REPUBLIC OF SOUTH AFRICA**
OBJECTIVES: The primary goal of our study was to comprehensively compare cost-effectiveness of both treatment options for pharmacologic opioid substitution therapy (methadone vs. buprenorphine/naloxone combination) available in Republic of South Africa (RSA) and treatment modalities used in the clinical practice (maintenance vs. detoxification). In our study, we have thus systematically compared: (i) cost-effectiveness of maintenance treatment with methadone and buprenorphine/naloxone combination, (ii) cost-effectiveness of detoxification and maintenance treatment with buprenorphine/naloxone combination, and (iii) cost-effectiveness of detoxification treatment with methadone and maintenance treatment with buprenorphine/naloxone combination. METHODS: We have adapted a micro-simulation decision model to the real-life conditions in RSA using locally-specific data for treatment costs of methadone and buprenorphine/naloxone combination with the average dose of treatment set at 20 mg/day and 2 mg/day, respectively (base case scenario). Direct costs of detoxification consisted of the costs of a 14-day in-patient stay, while direct costs of maintenance treatment were based on COBRA (Cost-Benefit and Risk Appraisal of Substitution Treatment in Routine) study and adjusted to conditions of the local jurisdiction. To ensure that costs are estimated conservatively, no indirect costs were considered in the base case scenario. RESULTS: Our model has shown that under base case scenario maintenance treatment with buprenorphine/naloxone dominated all other treatment strategies: (i) maintenance treatment with methadone by saving 8,025 ZAR and gaining 0.1534 QALY per patient per year, (ii) detoxification with buprenorphine/naloxone by saving 31,627 ZAR and gaining 0.1475 QALY per patient per year, and (iii) detoxification with methadone by saving 31,584 ZAR and gaining 0.1534 QALY per patient per year. Both deterministic and probabilistic sensitivity analysis based on modifying parameters in the model confirmed robustness of our findings. CONCLUSIONS: Results of our study indicate that in RSA maintenance treatment with buprenorphine/naloxone combination is superior, i.e., cost-saving, when compared to any other currently available substitution treatment strategy.

PMH17: HEALTHCARE RESOURCE USE AND COSTS IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER SWITCHING FROM A GENERIC TO A BRANDED ANTIDEPRESSANT

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OBJECTIVES: To examine healthcare resource utilization and costs among adult patients with major depressive disorder (MDD) before and after switching from a generic to a branded antidepressant. METHODS: In a mirror-image study, healthcare resource utilization, costs, persistence, and adherence (medication possession ratio; MPR) were evaluated in the 6-month periods before and after switching from generic therapy to branded antidepressant monotherapy (ie, ≥1 prescription of vortioxetine, levomilnacipran, vilazodone, or desvenlafaxine) using pharmacy, medical, and hospital claims (2010–2015) from Integrated Dataverse (Symphony Health) for patients with MDD (≥2 diagnosis records). The index date was the date of the switch (prescription fill) from any generic to branded antidepressant monotherapy. RESULTS: 55,106 patients (mean ± SD age, 45.8±14.3; 77.1% women) switched from a generic (most common: escitalopram, 15.3%; duloxetine, 13.6%) to a branded antidepressant (desvenlafaxine: 50.0%; vilazodone: 37.2%; vortioxetine: 8.1%; levomilnacipran: 4.8%). For the 6-month pre- vs post-switch periods, the mean ± SD all-cause healthcare resource utilization (visits) was 4.8±6.4 vs 4.9±6.5. Pre- vs post-switch, mean ± SD total healthcare costs were $6,955±$18,457 vs $8,127±$18,492, mean medical services costs were $5,577±18,062 vs $5,661±$17,926, and mean pharmacy costs were $1,378±$2,776 vs $2,466±$3,508. Monthly total healthcare costs and medical services costs increased over the 6-month period before switching but decreased/stabilized ~2 months after switching. The respective pre- vs post-switch mean ± SD number of days to medication discontinuation and mean ± SD MPR were 98±53.3 vs 133±53.6 and 0.94±0.24 vs 0.97±0.21. CONCLUSIONS: In these analyses from a US claims database, the increases in monthly total healthcare costs and medical services costs observed at time of switch indicate that patients may be experiencing treatment failure. The data also suggest that a generic to branded antidepressant switch may have potential benefits such as improved treatment adherence and persistence.

PMH18: INDIRECT COSTS AND CAREGIVER BURDEN OF SCHIZOPHRENIA IN EUROPEAN COUNTRIES – RESULTS OF A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To summarize the magnitude of caregiver burden and indirect costs of schizophrenia in Europe, and to gain a better understanding on the most important factors influencing the variation of these costs. METHODS: A systematic literature review was conducted in MEDLINE (via Scopus), EMBASE (via Scopus), PsycINFO (Ovid), and
databases of health technology assessment (HTA) agencies in March 2017, to identify studies reporting indirect costs and caregiver burden related to patients with schizophrenia. RESULTS: Eleven studies were included in the qualitative synthesis, after screening 1,630 articles and further reviewing relevant articles that were cited in other published systematic literature reviews. The methodological heterogeneity across studies was considerable. Estimations of annual caregiver burden ranged from €9,590 in the United Kingdom to €30,256–€63,955 in Spain, after inflation adjustments for 2017. Total productivity loss (for patients and caregivers combined) in Italy was estimated between 0.7 days per patient-month between the second and the third follow-up examination of the study, and 3.5 days per patient-month at 90 days before enrollment. The indirect costs from increased utilization of criminal justice services in the United Kingdom ranged from €216 to €397, after inflation adjustments for 2017. Patient groups with higher age were associated with more indirect costs and caregiver burden in Germany, while the presence of negative symptoms of schizophrenia was associated with a 21% increase in productivity loss in Spain. CONCLUSIONS: Schizophrenia is associated with various types of indirect costs in Europe. Savings can potentially be achieved in these indirect costs by increasing investment in interventions that are targeted at specific symptoms (for example negative symptoms) or specific groups of patients.

PMH19: LITERATURE REVIEW OF THE COST OF DEMENTIA ON CHINA

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OBJECTIVES: to conduct literature search to identify existing cost estimates for dementia in China which support cost-of-illness approach to economic burden calculation. METHODS: Literature search was conducted on PubMed using pre-specified keywords. Research articles (n=50) on dementia in China were identified based on pre-specified criteria. To ensure uniformity and comprehensiveness of costs data, data collected was classified in uniform categories - Direct Costs (including medical, non-medical costs) and Indirect Costs (including, Activity of daily living (ADL) and Instrumental activities of daily living (IADL) costs, Supervision and Informal care costs). In addition, all costs data was adjusted for Purchasing Power Parity basis in USD based on UN PPP MDG data. RESULTS: Literature on costs of Dementia in Chinese was found to be limited. Five studies were shortlisted from the literature search to be taken up for comparative analysis. Due to variations in scope and methodology, findings from the studies were found to be highly variable – total costs ranged between USD 3,000 to 12,000, while proportion of indirect costs varied between 32 and 82% across these studies. Based on collected information, direct costs attributed to medical care contributed to only 20% while informal care provided by family and direct costs of social care (provided by community care professionals, and in residential home settings) contributed 40% each of the total cost of dementia in China. CONCLUSIONS: Costs data for Dementia in China is limited and further efforts are required to generate this data to support health policy and research as changing demographics, urban/rural shift and increased diagnosis rates are expected to lead to an epidemic of AD dementia in China in the near future.

PMH20: ECONOMIC BURDEN OF AUTISM AND AUTISM-RELATED SPECTRUM DISORDERS (ASD) IN EU5 COUNTRIES

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OBJECTIVES: A comprehensive review was conducted to report evidence from published studies evaluating the economic burden of autism and ASD in both children and adults in European Union (EU5) countries. METHODS: A systematic search of literature databases (Embase and MEDLINE) was conducted to identify recent economic evidence for last 5 years (Jan-2011 to Mar-2017) on ASD in the EU5 (UK, Germany, Italy, Spain and France). All studies reporting cost burden of ASD in English were included, regardless of design and interventions. Two reviewers assessed trial eligibility, with discrepancies reconciled by a third independent reviewer. RESULTS: Of the 5,223 citations retrieved, 13 met the pre-defined inclusion criteria. For the UK, total costs for children with ASD were £500 per month. The largest cost components for children were special education services and parental productivity loss. The estimated number of ASD prescriptions per 10,000 children was the highest in Spain (100), followed by the UK (63) and Germany (11). Annual costs for children in the UK increased with age (2–3 years: £6,815; 4–17 years: £29,767; ≥18 years: £49,804). The cost of supporting an individual in the UK with an ASD and intellectual disability during his or her lifespan was £1.5 million, compared to £0.9 million for an individual with ASD without intellectual disability. During adulthood, residential care or supportive living accommodation contributed the highest costs. Respite care was used by a fifth of adolescents with ASD in UK. In one Spanish study, 1.5% of total hospitalisation in 2014 was reported as relating to ASD. CONCLUSIONS: The economic burden of ASD in Europe is substantial. Further research is needed to evaluate the financial burden on families caring for patients with ASD, which can help to ensure that adequate resources are in place to reduce the barriers to care for this population.

PMH21: GDP AND POPULATION SIZE – IMPORTANT DETERMINANTS OF SCHIZOPHRENIA-RELATED HEALTHCARE COSTS IN THE EUROPEAN COUNTRIES
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OBJECTIVES: Schizophrenia is one of the most important public health issues in psychiatry. This review aims to explore the total direct healthcare cost of schizophrenia in European countries and associations of disease-related expenditures with economic performance (total GDP) and population size. METHODS: A systematic literature search was conducted in compliance with the PRISMA Statement. The literature search was performed in January 2017 using MEDLINE, EMBASE and the Cochrane Database of Systematic Reviews, and was limited to English language papers published between 2011 and 2017. RESULTS: Five relevant studies were identified that provided estimates for total direct health care costs for European countries. The data suggest that schizophrenia-related direct healthcare expenditure per 100,000 people is substantially higher in Germany (€8.6 million in 2008) and Norway (€5.3 million in 2011) than in France (€2.5 million in 2007). The proportion of direct cost of schizophrenia relative to the total GDP was highest in Germany (0.28%), although the EU27 countries plus Iceland, Norway and Switzerland show a similar proportion (0.21%) on average. Both the population size and the total GDP of a country show strong correlation (R² >0.7) with the total direct health care cost of schizophrenia. CONCLUSIONS: The direct healthcare cost of schizophrenia has been investigated in a limited number of studies which were considered to be of good quality and representative for the country population. Schizophrenia represents a substantial cost for the healthcare systems in Europe. Comparability of data is limited due to the differences in the years of costing, cost calculation methods and the estimated prevalence. Our analysis provides evidence that both GDP and population size are associated with direct healthcare cost estimates in European countries. Despite a relatively high prevalence of schizophrenia in Europe – varying between 0.4-1.2% – Central and Eastern European countries are lacking in current cost-of-illness studies.

PMH22: PROFILE OF BRAZILIAN INPATIENTS WITH MENTAL DISORDERS COVERED BY PRIVATE HEALTH CARE IN THE STATE OF CEARA: A REAL WORLD DATA ANALYSIS

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OBJECTIVES: The costs of psychiatric hospitalizations are a challenge to Brazilian Private Health care Insurance (PHI) due to the difficulty of de-hospitalizing these patients. There is a perception that psychiatric inpatients usually stay longer than others, generating significant economic impact for PHIs. Our objective was to identify the profile of these patients, the costs and average length of stay of patients who stay hospitalized longer than 100 days. METHODS: It was conducted an observational study. Clinical and economic data were obtained from a Brazilian Medical cooperative PHI database. Inclusion criteria: age > 18 years old, diagnose of psychiatric disorder and length of stay longer than 100 days at psychiatric hospitals. Inpatients hospitalized from May 12, 2006 to March 31, 2017 were included. This PHI cover 342.757 clients in Ceará - Brazil. Data was collected of the total inpatient costs, health care resources utilization and length of stay (LOS). RESULTS: A total of 36 inpatients met our inclusion criteria. The majorit was male (n=25/ 69.44%). 68% of male patients have 25 to 44 years old (n=17) and 81.82% of female have 35 to 54 years (n=9). The CID-10 more frequent on males was F-20-Schizophrenia (n=20/ 80%). Among females, F-20 represented 36.4% (n=4). Antipsychotics were the medication used more frequently (43.74%), representing 75.49% of medication costs (U$202.082.79). The total hospitalization cost was U$2.802.397,34 without medical fees and the average was U$77.844,37. The total LOS was 29,390 days and the average 816,9 days (max. 3,976 days). Four patients obtained judicial injunctions allowing them to stay at psychiatric hospitals CONCLUSIONS: Psychiatric hospitalizations are a challenge to brazilian PHI, demanding special attention due the LOS and high cost of hospitalizations. In addition, these patients are usually male diagnosed with schizophrenia at productive working-age. Strategies which could decrease LOS and consequently hospitalization costs, could benefit PHIs, patients and families.

PMH23: HEALTH INSURANCE COST OF PSYCHOTIC DISORDERS 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 psychotic disorders in Hungary. METHODS: The data derive from the financial database of the Hungarian National Health Insurance
Fund Administration (NHIFA), 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: out-patient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices. Psychotic disorders were identified with the following codes of the International Classification of Diseases 10th revision: F20-F29. RESULTS: The Hungarian National Health Insurance Fund Administration spent 23.3 billion Hungarian Forint (HUF) (112.1 million USD) for the treatment of patients with brain cancer. The annual average expenditure per patient was 67553 HUF (324.5 USD) while the average expenditure per one inhabitant was 2330 HUF (11.2 USD). Major cost drivers were pharmaceuticals (76.0 %) of total health insurance costs, acute inpatient care (12.7 %) and chronic inpatient care (6.1 %). The number of patients with psychotic disorders was 345 per 10000 populations. We found the highest patient number in outpatient care (345480 patients) pharmaceuticals (231797 patients) and general practitioners (44847 patients). CONCLUSIONS: Psychotic disorders represent a significant burden for the health insurance system. Reimbursement of pharmaceuticals and acute inpatient care are the major cost drivers for psychotic disorders in Hungary.

PMH24: HEALTH INSURANCE COST OF AFFECTIVE DISORDERS 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 affective disorders in Hungary. METHODS: The data derive from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFA), 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: out-patient care, in-patient care, CT-MRI, PET, home care, transportation, general practitioner, drugs and medical devices. Affective disorders were identified with the following codes of the International Classification of Diseases 10th revision: F30-F39. RESULTS: The Hungarian National Health Insurance Fund Administration spent 18.4 billion Hungarian Forint (HUF) (88.5 million USD) for the treatment of patients with brain cancer. The annual average expenditure per patient was 24943 HUF (119.8 USD) while the average expenditure per one inhabitant was 1840 HUF (8.8 USD). Major cost drivers were pharmaceuticals (45.0 %) of total health insurance costs, acute inpatient care (20.3 %) and primary care/general practitioners (18.2 %). The number of patients with affective disorders was 737.5 per 10000 populations. We found the highest patient number in pharmaceuticals (738560 patients), outpatient care (622435 patients) and primary care/general practitioners (543257 patients). CONCLUSIONS: Affective disorders represent a significant burden for the health insurance system. Reimbursement of pharmaceuticals and acute inpatient care are the major cost drivers for affective disorders in Hungary.

PMH25: COST-EFFECTIVENESS ANALYSIS OF THE PALIPERIDONE PALMITATE 3-MONTH FORMULATION VERSUS 1-MONTH FORMULATION FROM A HEALTHCARE PAYER PERSPECTIVE

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OBJECTIVES: Schizophrenic episodes cause socio-economic problems and compliance with therapy is a known problem for schizophrenia patients and their families. The 3-monthly paliperidone palmitate formulation (PP3M) offers long-term benefits for patients by preventing schizophrenic episodes, also reducing the partial compliance risk. This study aims to perform a cost-effectiveness analysis of PP3M in the Turkish healthcare system, using the once-monthly paliperidone palmitate formulation (PP1M) as the comparison agent. METHODS: The cost-of-illness methodology has been used in calculation of the cost data in Turkey. The analysis has been performed retrospectively in a one-year time horizon and from the healthcare payer perspective. Quality-Adjusted Life Year (QALY) caused by the difference in the administration of the two treatments, three-monthly and monthly injections, have been considered as the effectiveness value. American dollars were used as the currency unit based on the purchasing power parity (PPP) ($1=1.31 TL-OECD 2016). RESULTS: The annual mean cost per schizophrenia patient has been calculated at 6330.2 PPP-$ for treatment with PP1M and at 6066.8 PPP-$ for the treatment with PP3M. For PP1M, drug treatment cost, which consists of antipsychotic drugs used in practice, accounts for 83.7% of the total cost, while outpatient follow-up cost is the second significant cost component at 9.8%. Service and intervention costs comprise 5.7% of the total cost. For PP3M, drug treatment costs, which consist of antipsychotics used in practice, comprise 83.8% of the total cost, while outpatient follow-up cost ranks the second significant cost component at 10.3%. Service and intervention cost accounts for 5.1% of the total cost. Considering the QALY values (0.65-PP1M versus 0.70-PP3M), PP3M treatment has been found to be dominant compared to maintenance therapy with PP1M. (per QALY - 6468.0 PPP-$) CONCLUSIONS: PP3M addresses unmet needs expected by new treatments due to several positive characteristics such as reduction of the treatment discontinuation risk, prevention of
relapses, reduction in Healthcare Resource Use related to hospitalization. Therefore, PP3M has been determined to be cost-saving health technology by lowering the costs of hospitalization, drug treatment, adverse event and outpatient clinic, compared to maintenance schizophrenia therapy with PP1M.

**PMH26: COST-CONSEQUENCE ANALYSIS OF USING NEUROFARMAGEN IN THE DECISION-MAKING PROCESS DURING THE TREATMENT OF PATIENTS WITH DEPRESSION IN THE U.S.**

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**OBJECTIVES:** Almost half of U.S. population has experienced at least one psychiatric disorder in their lifetime, being major depression (MD) the most common among these illnesses. MD is highly debilitating to society, due in part to the increased utilization of health care resources and their associated cost and to frequent suboptimal treatment responses. The aim of this study is to compare the cost and consequences of using the Neuropharmagen® (NFG) pharmacogenetic tool in the decision-making process of treating depression relapsed patients in the U.S. **METHODS:** A decision-tree model was developed in order to estimate the cost and consequences of using NFG over a 3-year time horizon. Model compared NFG testing-guided treatment vs. treatment as usual (TaU) in MD patients who had not responded to 1-3 previous treatment(s). Treatment response and stabilization rates were obtained from the 3-months assessment reported in the prospective randomized controlled trial of NFG and extrapolated up to 1 year. For “responder” patients, yearly relapse rate of 0.2 was considered. “Non-responder” and relapsed patients progressed to the next treatment line. The model considered direct costs (2017 US$) for “responder” and “non-responder” patients obtained from published literature. **RESULTS:** In patients with 1-3 prior treatment failures, total management costs per patient (responder and non-responder) after 1 and 3 years were $1,307 and $4,172 lower in NFG testing-guided treatment compared with TaU respectively, not counting testing cost. 67.1% more patients achieved treatment response in NFG testing-guided treatment compared with TaU already first year (TaU response rate = 31.0%). Scenarios including other patient subgroups were tested, and one-way sensitivity analysis confirmed the robustness of these results. **CONCLUSIONS:** In patients with 1 to 3 prior treatments, NFG testing-guided treatment of patients with MD will represent a cost-saving option vs. TaU after 1 year. After 3-year time horizon, the analysis showed considerable savings.

**PMH27: HEALTH ECONOMIC EVIDENCE ON NON-PHARMACOLOGICAL INTERVENTIONS FOR PERSONS WITH DEMENTIA: A SYSTEMATIC REVIEW**

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**OBJECTIVES:** Over the last decade research on non-pharmacological interventions for persons with dementia (PwD) has gained momentum. The aim of this systematic review was therefore to assess the economic evidence on non-pharmacological interventions directly targeted at PwD. **METHODS:** A systematic literature search was conducted in the following databases: Cochrane Library, Centre for Reviews and Dissemination, EconLit, Embase, PsycINFO and PubMed. Trial-based economic evaluations published between 2010 and 2016 were included. Study quality was assessed according to the Drummond checklist. **RESULTS:** In total, nine RCT-based economic evaluations were identified. Of these, two studies evaluated exercise interventions for community-dwelling PwD. Considering the outcomes physical functioning and behavioral and psychological symptoms, these exercise programs were found likely to be cost-effective. Another study indicated that individually tailored occupational therapy for PwD exhibiting behavioral and psychological symptoms is cost-effective. Furthermore, the economic evidence on cognitive interventions was inconsistent. Joint reminiscence groups for community-dwelling PwD and informal caregivers as well as a carer-led individual cognitive stimulation therapy were unlikely to be cost-effective. In contrast, there is evidence that a group-based maintenance cognitive stimulation therapy for PwD residing in care homes or visiting day care centers is cost-effective. With regard to psychological and behavioral treatments two interventions, namely self-management group rehabilitation for PwD and their spouses as well as cognitive-behavioral therapy for PwD-caregiver dyads, demonstrated effectiveness and cost-neutrality. **CONCLUSIONS:** There is some evidence on cost-effective non-pharmacological interventions for PwD. However, the included studies showed a high degree of methodological heterogeneity with regard to outcomes, sample size, perspective and time horizon. In particular, quality-of-life values of PwD should be interpreted cautiously, this holds as well for proxy-rated values. This research work was funded by the Karl and Veronica Carstens-Foundation as part of the national graduate college ‘Optimisation strategies in Dementia – OptiDem’.
OBJECTIVES: Despite differentiated guidelines, depressive episodes often stay undiagnosed or are treated inadequately. Online-based self-help-, consulting- and treatment-services may reduce deficits in treating depressive disorders and reduce disease-related costs. This study aimed to examine the potential of the internet-based cognitive behavioural therapy “deprexis” to reduce total costs of statutory health insurance. Secondary, changes in depression severity, health-related quality of life and impairment in functioning were examined. METHODS: Participants with mild to moderate depressive symptoms were recruited from a huge German sickness fund and randomized to either a 12-week internet intervention (deprexis) or care as usual (CAU). The primary outcome measure was costs of statutory health insurance (excluding outpatient costs), secondary outcomes were depression severity (PHQ-9), health-related quality of life (SF-12 and EQ-5D-3L) and impairment in functioning (Work and Social Adjustment Scale). Outcomes were assessed at baseline, three months and six months, using an online based questionnaire. Additionally, health insurers’ administrative data were included in the analyses. RESULTS: A total of 3,806 participants were randomized. In both groups, total costs of statutory health insurance decreased during the study period, but the changes from baseline differed significantly between groups. In the intervention group the total costs decreased by 32% from €3,139 per year at baseline to €2,119 in the study year (vs. a mean reduction in total costs of 13% in CAU-group; <0.002). In comparison to the CAU-group, the intervention group also showed a significant greater reduction in PHQ-9, a significant greater decrease in impairment in functioning and a significant greater increase in health-related quality of life. CONCLUSIONS: The study underlines the potential of innovative e-mental-health programs in treating depressive disorders. The results suggest that the use of deprexis over a period of 12 weeks leads to a significant improvement of symptoms with a simultaneous reduction in cost of statutory health insurance.

PMH30: EARLY ECONOMIC EVALUATION OF THE NEW ATYPICAL ANTIPSYCHOTIC

OBJECTIVES: To assess the economic viability of the new atypical antipsychotic and to establish what price is required for an economically viable drug. In this study early economic modeling was used to estimate the price per course for difluoroclozapine, a new atypical neuroleptic drug in the treatment of resistant schizophrenia. METHODS: An early Markov model was developed, based on the data derived from preclinical and clinical trials, to estimate costs and effectiveness of the antipsychotic therapy. Comparison of new neuroleptic drug with standard therapy with clozapine was performed with the use of cost-utility analysis. Costs of clozapine therapy and management of agranulocytosis were estimated as costs of medical care according to the standards of therapy. Utility for both drugs was measured in terms of quality-adjusted life years (QALYs). The headroom method was used to calculate the acceptable price for 1 course treatment with difluoroclozapine. It was estimated using utility difference between 10-years therapies and cost of 1 QALY for clozapine. RESULTS: Analysis showed that the discounted QALY difference between difluoroclozapine and clozapine was 0.02 (ΔQALY). Estimated cost per 1 QALY for clozapine was 4,735.78$. Based on COST/1QALY the difluoroclozapine price in comparison with clozapine can’t be more than 1.14%. CONCLUSIONS: According to assumption about same efficacy of difluoroclozapine and clozapine and only safety advantages of difluoroclozapine (the ability to reduce agranulocytosis rate) the cost of difluoroclozapine course shouldn’t be more than the cost of clozapine course (over 1.14%).

PMH31: THE COST OF DIALECTIC BEHAVIOUR THERAPY (DBT) FOR PEOPLE DIAGNOSED WITH BORDERLINE PERSONALITY DISORDER (BPD): A REVIEW OF THE LITERATURE

OBJECTIVES: To produce a systematic literature review on the cost of dialectic behaviour therapy (DBT) for people diagnosed with Borderline Personality Disorder (BPD). People with BPD require extensive healthcare resources and services. This review evaluates existing literature to determine the cost of providing DBT treatment for persons with BPD. METHODS: Using the PICOS framework, cost studies of DBT for a population of persons diagnosed with BPD were included for review. The evidence was combined and summarised using a narrative synthesis. The methodological quality of the economic studies was evaluated using appropriate checklists. RESULTS: Providing BPD patients with DBT treatment has shown to have a positive effect on reducing health care utilization and related health care costs. Across the included studies, the mean average cost per patient was shown to be reduced by 21 –
PMH32: PHARMACOECONOMICS ANALYSIS OF SERTINDOLE USE IN THE TREATMENT OF SCHIZOPHRENIA IN RUSSIA

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OBJECTIVES: to conduct a comparative pharmacoeconomic analysis of atypical antipsychotics for the treatment of schizophrenia – sertindole (SRT) versus quetiapine (QTP) and paliperidone (PAL). METHODS: the primary outcomes for analysis were relapse and rehospitalization rates. Using the odds ratio (OR) of prehospitalization we calculated the related risk (RR) for three drugs. The cost of the annual drug therapy of schizophrenia in the outpatient setting, costs of hospital readmission and total costs were calculate. One-way sensitivity analysis was performed on 7 scenarios. Willingness to pay threshold (WTP) for Russian health care system was estimated at €26,380 (1648924 RUB), exchange rate mean in 2017 - €1 = 62.5 RUB. RESULTS: the drug cost for annual therapy was the lowest for SRT – €1,550 (96856 RUB) – by 6% and 45% less than for QTP and PAL respectively. The RR of rehospitalization was 2.0% for PAL, 2.13% for SRT and 16.24% for QTP, so the cost for rehospitalisation was 7 times less for SRT versus QTP and only by 6.5% greater than for PAL. Therefore SRT therapy was the most cost saving by total cost – 13.8% less vs QTP and 31% versus PAL. Cost-effectiveness ratio (CER) for 1 patient treated without rehospitalization was €1,608 (100472 RUB) for SRT, €2,180 (136226 RUB) for QTP. SRT has higher CER versus PAL, but incremental cost-effectiveness ratio (ICER) for PAL more than 20 times higher than WTP (ICER= €532,542 (33 283 846 RUB). The most influential variable in the sensitivity analysis was dosage regimen. CONCLUSIONS: SRT is the most cost-effective treatment versus QTP (CER less than CER QTP) and versus PAL (SRT has insignificant deferers in treatment effectiveness -0.13%, but will be more cost saving treatment, ICER for PAL more than 20 times higher than Russian WTP threshold).

PMH33: AN ECONOMIC EVALUATION OF A PSYCHOEDUCATIONAL SUICIDE INTERVENTION PROGRAMME

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OBJECTIVES: The Eden Programme is a psycho-educational programme targeting people who have attempted suicide or experienced suicidal ideation. The programme, developed by an Irish charity, Suicide or Survive. A licensed Eden programme is being rolled out on a pilot basis in Ireland. This study’s objective is to undertake cost-effectiveness analysis of the Eden Programme from the perspective of the Ireland’s health care provider. METHODS: Researchers identified all relevant resources and utilised a combination of micro-costing and gross costing to measure resources. A net cost per programme and per participant were calculated, accounting for the current maximum intake for an Eden Programme (n=14). To measure effectiveness, average BDI scores from pre-and post-Eden Programme surveys were used. BDI scores were mapped onto the EQ5D-3L using an algorithm developed by Grochtdreis et al., (2016). To account for uncertainty, a Monte Carlo simulation was used to do a probabilistic sensitivity analyses. A cost-effectiveness ratio was used to determine the probability of the programme being cost-effective compared to usual care. RESULTS: Preliminary results indicate an improvement in average BDI scores from baseline to end of programme. Mapping these scores onto the EQ5D-3L showed utility improvement. As the Eden programme is a complement to usual care,there are additional costs. In addition, scenario analyses reveal that should economies of scale (e.g. dual-site training) be realised, there is the potential for cost savings. There is a less than 60%. Probability of cost effectiveness of the Eden programme compared with usual care.CONCLUSIONS: As a therapeutic area, mental health has long been underfunded. As decision makers increase funding for programmes in mental health, it is important to ensure that resource allocation decisions are appropriate. One means of informing such decisions is to conduct economic evaluations to determine if the additional benefits are worth the additional cost.

PMH34: COST-EFFECTIVENESS OF GUIDED INTERNET-BASED TREATMENTS FOR DEPRESSION IN COMPARISON WITH CONTROL CONDITIONS: AN INDIVIDUAL-PARTICIPANT DATA META-ANALYSIS

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OBJECTIVES: Previous studies have shown the effectiveness of guided Internet-based interventions for depression compared to control groups. It is often hypothesized that Internet-based treatments are associated with lower costs, because face-to-face time with therapist is reduced. The objective of this study was to conduct an individual-participant data meta-analysis (IPD-MA) evaluating the cost-effectiveness of guided Internet-based interventions for depression compared to controls from a societal perspective. METHODS: A systematic literature search was conducted in electronic databases from 2000 to January 1st 2017. Studies were included if they were randomized controlled trials (RCTs) in which the cost-effectiveness of a guided Internet-based intervention for depression was compared to a control. Cost-effectiveness analyses were conducted for improvement in depressive symptoms measured by CES-D, response to treatment, and Quality-Adjusted Life-Years (QALYs) at 8-weeks, 6-months, and 12-months follow-up. RESULTS: IPD from five studies, including 1,426 participants were used. The guided Internet-based interventions were more costly than the controls, but not statistically significantly so (e.g.12-months mean difference = €406, 95%CI: -611 to 1,444). Cost-effectiveness acceptability curves indicated that high investments are needed to reach an acceptable probability that the intervention is cost-effective compared to control for CES-D and response to treatment (e.g., at 12-month follow-up the probability of being cost-effective was 0.95 at a ceiling ratio of 2,000 €/point of improvement in CES-D score). For QALYs, the intervention's probability of being cost-effective compared to control was low at the commonly accepted willingness-to-pay threshold (e.g., at 12-month follow-up the probability was 0.29 and 0.31 at a ceiling ratio of 24,000 and 35,000 €/QALY, respectively). CONCLUSIONS: Guided Internet-based interventions for depression were not considered cost-effective compared to control. However, only a minority of RCTs investigating the clinical effectiveness of guided Internet-based interventions also assessed cost-effectiveness. Therefore, it is important that future RCTs measure resource use and productivity losses alongside clinical effectiveness.

MENTAL HEALTH - Patient-Reported Outcomes & Patient Preference Studies

PMH35: EVALUATION OF BARANYA COUNTY DRUG AMBULANCE’S AND BARANYA COUNTY POLICE’S SCHOOL BASED DRUG PREVENTION ACTIVITY

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OBJECTIVES: The aim of our research was to evaluate two school based drug prevention program which have been operated by Baranya County Police and Baranya County Drug ambulance. METHODS: The research program was carried out with standard questioner at schools which were part one of in these drug prevention programs. 220 students were involved into the study. Students filled in the questionnaire twice: several days before (pre-test) and 10 days after (post-test) the drug prevention program. We processed our data with the help of SPSS and we designed a paired-sample T-test. RESULTS: The rate of those, who know more about drugs after Police's program have increased by 24.6% and Drug ambulance's result was 20%. Drug ambulance's program reached significant (p=0.048) change in self-knowledge among the students. About the Police’s program we can not report the same significant result in the same case (p=0.569). The effect of the Drug ambulance’s program also changed the student’s sense of danger regarding drugs significantly. There was a significant change in the trying of marihuana (p=0.008), hallucinogenic drugs (p=0.012) and herbal drugs (p=0.001). However the effect of the Police’s program only changed the student’s trying of designer drugs regarding drugs significantly (p=0.071). CONCLUSIONS: Continuous evaluation of prevention programs are essential. It would be important that only monitorised and professionally suggested programs are realised.

PMH36: STIGMATISATION LEVEL TOWARDS MENTAL ILLNESS PATIENTS AMONG MALAYSIAN URBAN AND RURAL COMMUNITIES

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OBJECTIVES: This study investigated the level of stigmatisation among urban and rural Malaysian communities towards mental illness patients, and assessed study variables that differentiate and predict their stigmatisation. METHODS: In this cross-sectional study, the reliable and validated self-administered questionnaires proven by Rasch analysis consisted of socio-demographic and other (n = 11 items) and attribution questionnaire (AQ-9) (n = 9 items; 9 stereotypes), were disseminated post ethics approval to urban (Shah Alam, Selangor) and rural (Rembau, Negeri Sembilan) adults (≥ 18 years old) using convenience sampling method. Data (February to May 2015) were analysed using SPSS version 21.0. RESULTS: The mean (SD) scores obtained by urban and rural respondents were 39.40 (9.77) and 42.15 (9.16); both fall into moderate level of stigma (moderate score: 28 - 54). Urban respondents demonstrated significant higher pity level, lower dangerousness, lower blame, lower anger, and lower coercion compared to rural respondents. The mean scores obtained by females were significantly higher than
males in referring to dangerousness, fear, segregation and coercion stereotypes. Respondents who were familiar with mental illness tend to have significantly higher pity but lower blame compared to respondents who were not familiar with mental illness. There was a significant decrease in blame among respondents who were familiar towards schizophrenia term compared to respondents who were not familiar. Significant predictors were found in few stereotypes including familiarity with mental illness (pity), gender and highest level of education (dangerousness), gender (fear), familiarity with schizophrenia (blame) and gender and living area (coercion). **CONCLUSIONS:** Rural respondents had significant lower pity level, higher dangerousness, higher blame, higher anger, and higher coercion compared to urban respondents. Gender was the main predictor for stereotypes of dangerousness, fear and coercion. The elements of stigmatisation toward mental illness need to be addressed be it to the public or respective sufferers in creating concerned and responsible communities.

**PMH37: PATHWAYS TO DEMENTIA DIAGNOSIS AND POST-DIAGNOSTIC SUPPORT: THE BAVARIAN DEMENTIA SURVEY**

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**OBJECTIVES:** Timely diagnosis and the provision of post-diagnostic information and support are key for persons with dementia (PwDs) and their informal caregivers. Thus, this analysis examined the time span from the onset of symptoms to a dementia diagnosis. Furthermore, the provision of information about treatment options and support services was assessed. **METHODS:** BayDem is a multi-center, longitudinal study at three different sites in Bavaria, Germany. Participants are PwD and their informal caregivers. Data is collected by means of standardized, face-to-face interviews in close cooperation with local dementia institutions. **RESULTS:** In total, 139 informal caregivers (67% female; M=60 years, SD=12; Min=23; Max=86) of PwDs were interviewed within three months of the first dementia diagnosis. Of those, 48% were children and 42% were spouses or life partners of the PwD. The median time span from initial recognition of dementia symptoms to presentation to a health professional was 12 months. 36% of the PwDs received a diagnosis within one year, 61% within two years from symptom onset. 56% of the informal caregivers reported to be given information on the syndrome and 44% stated to have obtained information about the course of dementia. 51% felt informed about pharmacological treatment options; whereas 42% of the informal caregivers indicated that they received information about non-pharmacological treatments. Solely, 21% reported to have received information about local support centers. Compared to spouses and life partners, children felt less informed. **CONCLUSIONS:** These results suggest that from the caregiver's perspective, there is a need to optimize the provision of post-diagnostic support to newly diagnosed PwDs and their relatives, since knowledge and uptake of support services are important for the prevention of caregiver burden. This research was initiated by the Bavarian State Parliament and is funded by the Bavarian State Ministry for Health and Care (StMGP) under the grant number G42-G8092.9-2014/10-146.

**PMH38: PSYCHOSOCIAL DETERMINANTS OF DEPRESSIVE ILLNESS AMONG WOMEN ATTENDING IN PSYCHIATRIC OUT PATIENTS DEPARTMENT OF BANGABANDHU SHEIKH MUJIB MEDICAL UNIVERSITY (BSMMU) DHAKA, BANGLADESH**

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**OBJECTIVES:** The rapid increasing number of depression patients in both developed and developing countries is a potential medical and health concern. There are many factors are related with depression, of which socio-demographic, socio-cultural and socio-economic factors are the potential cause of depression, especially in developing countries and generally, women are more prone to depression than men. **METHODS:** Since Bangladesh is a developing country and majority numbers of people live below normal economic condition, the number of depression patients is increasing drastically. Therefore, this study was design to assess the mental health level of women patients who attended for consultation or treatment at the department of psychiatric outpatient (OPD) at Bangabandhu Sheikh Mujib Medical University (BSMMU), Bangladesh. This study conducted following the international classification of disease (ICD-10) and diagnostic and statistical manual for Mental Disorder (DSM-iv) and maintaining inclusion and exclusion criteria. **RESULTS:** This study revealed that among 160 women attending the psychiatric outdoor of BSMMU, 70% patients were suffering from severe depression. Proportion of severe depression decreased with the increasing educational level which was maximum among the illiterates (87.5%) and minimum that crossed higher secondary level (60.0%). However, highly significant association between depression and family income was observed. There was no relation of family type- nuclear and joint family with depression. But family income was significantly associated with depression and low income family suffered severe depression (84.6%). Gender discriminated women (85.4%) were suffered significantly more than the no gender discriminated women.
(63.4%) in the family. Statistically significant relation was also found in victimized family (92.6%) compared to the family who has no history of victimization (65.4%). **CONCLUSIONS:** We identified some factors such as women who early marriage, victimize and live low earning family as potential factors that have statistically highly significant association with depression level.

**PMH39: DEPRESSION ASSESSMENT IN PATIENTS DIAGNOSED WITH PARKINSON’S DISEASE FOR CLINICAL PRACTICE**

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**OBJECTIVES:** To show the complexity of patients with Parkinson’s disease (PD) by illustrating an accurate profile based on the prevalence of depression and other complications, as well as differences observed among patients from UK and USA, for further good practices recommendations. **METHODS:** A cross sectional descriptive study was conducted using an electronic survey among patients from UK and USA diagnosed with PD. Patients (n=104) were screened for depression by using the Zung Self-Rating Depression Scale (ZSDS). Prevalence of movement and nervous system symptoms was assessed by using multiple choice questions and the distress of each category was scored from 0 to 3 (0—no, 1—mild, 2—moderate, 3—severe) where a higher score indicates greater distress. Comparisons between patient groups were made with ANOVA and two-tailed t-test. Correlations were interpreted based on calculations of Pearson’s R and descriptive statistics summarized the features of the sample. **RESULTS:** Most of the patients were from UK (65.38%), 50.96% were female and 54.81% showed depression according to the ZSDS. Comparisons between UK and USA patient groups disclosed no significant differences (all p>0.05). Patients aged 40-50 showed a higher incidence of depression and a more severe stage (p=0.025<0.05). Prevalence of movement and nervous system symptoms as well as the distress of these symptoms are up to two times higher in patients with depression than in those without (p<0.05). In patients with depression according to the ZSDS, 50.88% consider themselves not being depressed and in those that do not have depression according to the ZSDS, 14.89% consider themselves depressed. **CONCLUSIONS:** All patients with PD revealed a complex profile and require good management of frequent comorbidities. Prevalence of depression calls for medical professionals to be vigilant in the screening process.

**PMH40: SPONTANEOUS ABORTION IS ASSOCIATED WITH AN INCREASED RISK OF DEVELOPING PSYCHIATRIC DISEASES**

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**OBJECTIVES:** The aim of this study was to analyze risk factors for depression, anxiety, and adjustment disorders in women with spontaneous abortion in Germany. **METHODS:** This study included women between the ages of 16 and 45 with a first pregnancy terminated by spontaneous abortion between January 2007 and December 2016 (index date). These women were followed in 262 German gynecological practices. Women with a spontaneous abortion were matched (1:1) with pregnant women without spontaneous abortion by age, index year, diagnosis of female infertility prior to the index date, procreative management prior to the index date, and physician. **RESULTS:** This study included 12,158 women with a spontaneous abortion and 12,158 pregnant women without a spontaneous abortion. The mean age was 31.6 (SD: 5.5) years. One year after the index date, 8.9% of women with spontaneous abortion and 5.7% of controls were diagnosed with depression, anxiety, or adjustment disorder. Individuals who had previously undergone a spontaneous abortion were more likely to have one of these three psychiatric disorders compared to controls (OR=1.53). Similar results were found in the age groups 21–30 and 31–40 years. **CONCLUSIONS:** Spontaneous abortion is associated with an increased risk of developing psychiatric diseases within the first year.

**PMH41: IMPACT OF COLLABORATIVE CUSTOMIZED PATIENT EDUCATION IN PSYCHIATRIC DISEASES**

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**OBJECTIVES:** To study the impact of Pharmacist-Psychiatrist Collaborative customized Patient Education in patients with depression, Bipolar Affective Disorder (BPAD), Schizophrenia and alcohol dependent Syndrome (ADS) in an Ambulatory Care Setting. **METHODS:** A prospective randomized control study was conducted in the psychiatry out-patient department of a tertiary care hospital for a period of 9 months. Eligible patients (225) were randomized into test group and control groups by simple randomization in each disease and followed for a period of six months. Customized patient education was provided to the test group with the help of patient education materials while the control group was on usual care. The medication adherence and quality of life (QOL) of both the groups were assessed and compared once in every two months by using Medication Adherence Rating Scale (MARS) and World
Health Organization Quality of Life (WHOQOL) – BREF questionnaire respectively. **RESULTS:** Among the study population 210 completed all the follow-ups out of which 100 were in control group and 110 in test group. Mean age was found to be 38.07 ± 11.60. Majority [n=75 (35.71%)] of patients were diagnosed to have had depression followed by BPAD [n=73 (34.76%)]. A statistically significant increase in the mean medication adherence score of test group was observed in all the follow-ups. The mean medication adherence scores was high in BPAD (1.4) and depression (1.4) compared to schizophrenia and ADS. Upon the analysis QOL, the difference in the overall mean score between test group and control was 8.45 which was statistically significant. Comparison of mean medication adherence scores of all patients in each disease showed that BPAD patients had a mean increase of 2.04 than depression, 1.36 than ADS and 2.01 than schizophrenia patients. **CONCLUSIONS:** Provision of customized patient education by pharmacist and psychiatrist improved the patient medication adherence and QOL.

**MENTAL HEALTH - Health Care Use & Policy Studies**

**PMH42: THE ASSOCIATION BETWEEN BUPRENORPHINE/NALOXONE AND ALL-CAUSE MORTALITY IN THE UNITED KINGDOM (UK): AN INTERIM REPORT**

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**OBJECTIVES:** The main objectives were: (1) characterize patients in the UK who received a prescription for buprenorphine/naloxone (BUP/NLX), buprenorphine alone, or methadone; and (2) assess all-cause mortality rates in these medication groups. **METHODS:** In this retrospective observational study, electronic records from The Health Improvement Network (THIN) database were searched for BUP/NLX (sublingual tablet), buprenorphine (sublingual tablet), and methadone prescriptions issued between 1-Jan-2007 and 31-Dec-2015. Mortality rates were analyzed in the overall population (BUP/NLX=964; buprenorphine=1865; methadone=6363). Two designs were used for comparative analyses: (1) new-user cohort, defined as patients (case subjects) with ≥1 year enrollment before first prescription (BUP/NLX=615; buprenorphine=1011; methadone=2723); and (2) case-control design, nested within the new-user cohort with ≤5 matched-controls randomly sampled for each case subject. Cox regression was used to analyze hazard ratios (HRs) for mortality in the new-user cohort; logistic regression was used to analyze odds ratios (ORs) for exposure to study drug (defined as “current”, “recent”, or “past or never”) in the nested case-control cohort. Analyses were adjusted for baseline covariates, and all P-values were two-sided. **RESULTS:** Most of the 964 BUP/NLX users were male (70.5%) and aged 20-49 years (94.2%). Mortality rates per 1000 person-year (95% CI) were: BUP/NLX, 5.29 (3.02-8.58); buprenorphine, 10.79 (8.50-13.50); methadone, 28.34 (26.18-30.63). In the new-user cohort, HRs for all-cause mortality for buprenorphine and methadone relative to BUP/NLX were 1.05 (P=0.90) and 4.47 (P<0.001), respectively. ORs for “current” and “recent” BUP/NLX exposure were 0.47 (P=0.06) and 1.57 (P=0.36), respectively. **LIMITATIONS:** This was a retrospective analysis of an EMR database, with no randomization to treatment. Results may be confounded by unknown/unmeasured factors such as comorbid mental disorders and/or substance-related disorders. **CONCLUSIONS:** All-cause mortality rates were lowest among BUP/NLX users and highest among methadone users. Methadone was associated with 3-5 fold increased risk of all-cause mortality.

**PMH43: A RETROSPECTIVE OBSERVATIONAL SURVEY OF BUPRENORPHINE/NALOXONE USE IN FRANCE**

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**OBJECTIVES:** This study was conducted to characterize real-world usage of buprenorphine/naloxone sublingual tablets (BUP/NLX) in France. **METHODS:** This retrospective observational study was conducted using the French IMS Health Cegedim Longitudinal Patient Database (LPD). LPD records were searched for patients with opioid dependence in general practice settings who received a prescription for BUP/NLX, buprenorphine, or methadone between 2-January-2012 and 31-December-2014. Outcomes included: (1) characteristics of patients started on BUP/NLX; (2) switches from BUP/NLX to low-dose buprenorphine (0.4 mg) or methadone; and (3) AEs of general and specific concern in France. **RESULTS:** 10,152 patients received a prescription during the inclusion period: buprenorphine, n=7,987 (78.7%); methadone, n=2,120 (20.9%); BUP/NLX, n=495 (4.9%). Prescription cohorts were not mutually exclusive. Mean age in the BUP/NLX cohort was 37.9 years, with 73.2% of patients between 30-49 years; 81.6% were male. The most common comorbidities (>10%) were pain (34.1%), depression (20.8%), and hepatitis C (10.9%). Most patients (96.4%) had a history of mental disorders due to psychoactive substance use or drug dependence. BUP/NLX was first prescribed for a drug addiction diagnosis in 73.4% of patients, documented either as “addiction unspecified” (35.4%) or “opioids addiction” (38.0%); opioid withdrawal treatment accounted for
13.5% of first prescriptions. Mean daily dose for BUP/NLX was 9.2 mg (individual dose range, 1-32 mg). Mean treatment durations for BUP/NLX, buprenorphine (any dose), and methadone were 52.0, 107.7, and 93.1 days, respectively. Only 9 (1.8%) patients switched from BUP/NLX to buprenorphine 0.4 mg during the study period; 4 (0.8%) switched to methadone. Common AEs (>1% in any cohort) were as follows (for BUP/NLX, buprenorphine, and methadone, respectively): abscess (1.4%, 2.6%, 4.3%); depression (2.8%, 2.8%, 4.6%); drug withdrawal syndrome (1.6%, 1.8%, 2.4%). CONCLUSIONS: Few patients were switched from BUP/NLX to low-dose buprenorphine or methadone, and no safety concerns were detected for BUP/NLX compared to buprenorphine and methadone.

PMH44: INFLUENCE OF COMPUTER GAMES ON THE HEALTH AND QUALITY OF STUDENTS ACADEMIC PERFORMANCE

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Introduction. The term "computer addiction" appeared in the 90s of the last century. Therefore, the problem of the impact of computer games on the health and academic performance of the students is important. Aim: The objective of this study was to assess the duration of one’s stay in the virtual world and the nature of its influence on the academic progress of the medical students. Materials and methods: Our pilot study was conducted by way of an anonymous survey among students studying at a medical university. Results: We have been identified such negative consequences of computer games - sleeplessness, redness of eyes, loss of appetite, lethargy, disorientation, irritation, abnormal social behavior. The presence and degree of expression of these effects depends on the duration of the game play. Of those surveyed, only 10% said they play computer games only from time to time. While 20 students who played 10 hours a day complained of a feeling of pressure in the eyes, watery eyes, mild disorientation in time, frequent headaches, back pain and memory problems. 15 students who played computer games for more than 16 hours a day had a decrease in visual acuity, dry mucous membranes of the eyes, memory problems, back pain in the elbow brushes, body aches, loss of appetite, disorientation in time and space, insomnia, serious problems with memory and more. All students devote the game for more than 6 hours a day, revealed problems with academic performance. Some students (10%) set academic arrears for previous years of study. Conclusion. The majority of respondents (60%) play computer games 6 or more hours a day. Consequently, this situation indicates the need for educational work about the dangers of long-term stay in the world of computer games.

PMH45: BURDEN OF MODERATE TO SEVERE DEPRESSION IN THE US ADULT POPULATION

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OBJECTIVES: To better understand the characteristics and burden of moderate/severe depression in the United States (US). METHODS: A random stratified sampling framework was used in a 2016 survey of the US adult population to assess health conditions and impact on health related quality of life (HRQoL). Validated HRQoL and screening questionnaires for depression and anxiety were employed. Respondents with no/mild depression were compared to respondents with moderate/severe depression. Chi-squares for categorical data and general linear models were used to analyze comorbidities, age, race, medication use, productivity and resource utilization. Logistic regressions were used to assess predictors of moderate/severe depression. RESULTS: Approximately 16% of the US adult population reported PHQ-9 scores above 14 (moderate/severe depression). Respondents with moderate/severe depression compared to those with no/mild depression had a significantly lower Physical Health Composite Score (PCS) (40.26 vs. 48.84; p < 0.01) and Mental Health Composite Score (MCS) (30.96 vs. 53.77; p < 0.01), as well as a lower health utility (0.56 vs. 0.78; p < 0.01). Those with moderate/severe depression reported significantly lower levels of restorative sleep, as measured with the Restorative Sleep Questionnaire (36.85 vs. 72.38; p < 0.01), and were more likely to report difficulty initiating sleep (DIS) (47.32 vs. 4.90; p < 0.01) and difficulty maintaining sleep (DMS) (53.93 vs 9.53; p < 0.01). Those with moderate/severe depression had more hours lost over the last week due to health problems (7.35 vs. 1.10; p < 0.01) and were more likely to visit the emergency department (36.50% vs. 10.19%; p < 0.01) or have a hospital visit (23.84% vs. 6.67%; p < 0.01) over the last 6 months. A logistic regression predicting moderate/severe depression (PHQ-9 < 4 vs. > 14) found age (OR 0.95; p < 0.01), high blood pressure (OR 1.54; p = 0.04), kidney disease (OR 6.20; p < 0.01), anxiety (OR 5.02; p < 0.01), DIS (5.29; p < 0.01), DMS (4.55; p < 0.01) predictive of moderate/severe depression. CONCLUSIONS: This study identifies factors predicting moderate/severe depression in US. Understanding these factors may provide direction on best practices to help improve care benefiting both patients and society.

PMH46: COST-EFFECTIVENESS OF DIAGNOSTIC TECHNOLOGIES FOR DEMENTIA: A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS
OBJECTIVES: The objective of this study is to systematically review the economic evaluations of diagnosing dementia and to find appropriate economic evaluation model for diagnosing dementia. We focused on the methodological quality and characteristics of decision models to assess their applicability for future economic evaluations dealing with new technologies for diagnosing dementia. METHODS: MEDLINE, EMBASE, Cochrane Library, KoreaMed, KMBase, and KISS were searched for English or Korean language publications related to economic evaluations on diagnostic technologies for dementia. Any of the following studies were excluded: animal studies, patients were not mild cognitive impairment or dementia patients, study design was not an economic evaluation, interventions were not diagnostic technologies, and languages were not English or Korean. Selected studies were assessed using the framework for quality assessment of decision-analytic models. RESULTS: Initially, 2,648 literatures were identified and we finally selected 11 literatures. Among the selected papers, there were 4 papers dealing with CT, 4 for MRI, 3 for dynamic susceptibility-weighted contrast-enhanced MRI, 3 for single photon emission computed tomography, 3 for FDG PET, 2 for amyloid PET, and 1 for biomarkers in cerebrospinal fluid (overlapping count). The results of the quality assessment showed that most studies did not meet the criteria of the framework enough. In 6 studies, the percentage of answers that met the criteria was less than 50%. When the dimension was divided into structure, data, and consistency, the percentage of responses satisfying consistency was the lowest, followed by data, and then by structure. CONCLUSIONS: With regard to the topic, economic evaluations of various diagnostic methods have been carried out. However, there were many deficiencies in terms of quality, especially in terms of consistency. Future decision-analytic models for diagnosing dementia should be designed especially with consistency.

PMH47: ESTIMATING THE VALUE OF PATIENT ENGAGEMENT OUTCOMES IN PRECISION MEDICINE TO ELIMINATE HEALTH DISPARITIES IN US AMERICAN INDIAN TRIBAL COMMUNITIES: DISCRIMINANT ANALYSIS

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OBJECTIVES: To describe the value of pharmacist-led dialogue intervention within traditional communities in early Precision Medicine Initiatives to reduce mortality rates in Native American Midwestern tribes due to multiple chronic conditions (MCC). METHODS: Research Design: Descriptive, cross-sectional survey using mixed-methods approach. Data Source: In-person interview tribal survey of 2 main tribal populations, 2013 - 2015. Study Population: 14 federally designated tribes in Midwestern States with adults aged 18 years and older were identified within the 2 main tribes of research interest, depression history + one prescription medication and living on the reservation, (N = 621). Outcomes and measures: Dependent categorical variable, traditional healing practices, were defined as the main variable of interest. Independent variables included 139 traditional Native American daily activities, Likert scaling technique identified strength of practices, and summed count outcomes (such as "how many times a respondent sought healing advice from the pharmacist") defined this population. Exclusion: Pregnant, not living on the reservation, and over age of 85. Qualitative comments (n= 42) analyzed through cluster analysis for thematic domains. Word Cloud using NVivo11 revealed the most frequently used words within the comments. SPSS ver. 22. Statistical analysis: Descriptive approach to demographic data and inferential statistics, using discriminant analysis for group membership in traditional healing practices, summed count and qualitative comments were included in the results. Pearson Chi-square = 92.8. RESULTS: Statistics reveal 70% of tribal respondents live and follow traditional Ojibwe lifestyles; 64% vs. 35% participate in traditional activities; 93% of respondents state they are happy but are still prescribed medications for depression. 96% do not know how a pharmacist can help them but would be more than willing to seek consultation for medication, consistent with informed knowledge that Precision Medicine Initiative may improve their health outcomes. CONCLUSIONS: Dialogue with a pharmacist improves initiation of Precision Medicine intervention.

PMH48: TREATMENT OF POSTPARTUM DEPRESSION: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: In clinical practice, postpartum depression (PPD) is often recognized as depression with onset during pregnancy and up to 1 year after childbirth. The objective of this study was to perform a systematic review of the most recent literature to better understand the efficacy and safety of current treatment for women with PPD. METHODS: A systematic review of Medline, Embase, PsychInfo, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and several congresses was conducted according to the PRISMA Statement.
through February 2017 to identify literature on the treatment of PPD. Disease search terms included “postpartum depression”, “postnatal depression”, and “peripartum depression”. Inclusion criteria included women with PPD aged ≥15 years treated in observational or interventional studies with any pharmacologic therapy. RESULTS: In total, 889 unique studies were screened by two independent researchers by title and abstract; of these 58 full-text studies were evaluated and 31 were included in this review. In general, evidence supporting the efficacy of pharmacological therapies is limited; in particular, 3 placebo-controlled studies of 303 total patients did not report statistically significant improvements in various depression symptoms scores for nortriptyline or sertraline. In another study of 70 patients with PPD who were randomized to paroxetine or placebo, statistically significant improvements of pharmacologic therapy over placebo were shown for certain outcomes (e.g., proportion achieving remission by week 8, 37% vs. 16%; p = 0.04), whereas other measures of efficacy had borderline or non-significant differences between groups. Overall, evidence supporting the treatment of women with PPD is limited and complicated by variability in the study design and methods used to assess symptoms. CONCLUSIONS: Several treatments in women with PPD have been studied; however, evidence supporting the efficacy of these therapies is limited.

NEUROLOGICAL DISORDERS - Clinical Outcomes Studies

PND1: COMORBIDITIES IN MULTIPLE SCLEROSIS: A DESCRIPTIVE LONGITUDINAL CLUSTERING ANALYSIS OF HEALTHCARE RESOURCE UTILIZATION AMONG MS PATIENTS IN IBM EXPLORYS DATABASE

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OBJECTIVES: The comorbidities of multiple sclerosis (MS) patients are well described in the literature, with depression and hypertension being most prevalent. This research aims to use clustering analysis to characterize the timing of healthcare resource utilization for patients based on comorbidity burden (CB) and timing of disability progression (DP). METHODS: Retrospective analysis of EHRs of MS patients in the IBM Explorys database (2000-2017), a longitudinal, de-identified clinical database for >50 million unique patients in the US, was conducted using iterative, knowledge-driven clustering of patient-level data. Clustering features with predefined scores were based on comorbidities, MS-related events, follow up, healthcare interactions (physician encounters, medications, and hospitalizations), and physician reported observations. Clusters of highest and lowest tertiles were selected to map clinical journeys of patients. Twenty-six events were aggregated by order of occurrence along a given patient journey. Median time-to-event and median age were reported for each event per occurrence. RESULTS: A total of 27,744 MS patients were analyzed. Four clusters were defined as A: Early Disability/Low Comorbidity (n=876), B: Early Disability/High Comorbidity (n=5237), C: Late Disability/Low Comorbidity (n=5308), D: Late Disability/High Comorbidity (n=751). Mean # of relapses overall respectively (0.5, 3.0, 0.2, 1.3); Std. Dev (1.5, 7.0, 0.8, 3.0); median follow-up years (4.49, 5.84, 5.06, 6.98); % female (73, 81, 76, 79); % African-American (16, 20, 14, 13); number of comorbidities with >10% prevalence (17, 133, 6, 75); median encounters 2-5 years since diagnosis: MS-related (3, 9, 2.4), all encounters (5, 28, 4, 19); median comorbidities per year between ages 46-55 (2, 5, 1, 3). CONCLUSIONS: In this clustering analysis we found that MS patients with high CB and more rapid MS DP utilize healthcare resources to a much greater extent than other MS patients. Increased multidisciplinary management of medically complex MS patients may be warranted to reduce healthcare utilization.

PND2: PREVALENCE OF OBSTRUCTIVE SLEEP APNEA IN GERMAN IN-HOSPITAL PATIENTS

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OBJECTIVES: Obstructive Sleep Apnea (OSA) is a disease that leads to severe complications and adds significant morbidity if left untreated. Its prevalence in the general population is ranging between 4-40%. Accompanying OSA can impact treatment course, length-of-stay and outcomes in patients, requiring in-hospital treatment. Disease frequency in the general in-hospital population in Germany has not been determined so far. This study aims to assess the prevalence of OSA in German in-hospital patients, based on DRG claims data and determine disease frequency in specific subgroups with anticipated higher risk for OSA. METHODS: Data on diagnosis of OSA was obtained from the official German Hospital Statistics, which routinely collects data for all in-hospital treatments. All treatments performed in the German in-patient system in 2015 were analyzed for primary or secondary diagnosis of OSA. RESULTS: Total prevalence of OSA in the German in-patient system in 2015 was 1.80% (259,816 subjects of a total population of 14,426,814). Prevalence within different treatments varied significantly, ranging from 0.0-7.91%.
Non-OSA related DRG with highest prevalence of OSA as comorbidity include treatments for COPD (3.30-6.89%), renal artery denervation (6.43%) and major bariatric surgery procedures (12.99%). **CONCLUSIONS:** OSA can lead to complications and prolong treatment courses in non-OSA therapies. Epidemiological studies estimate the prevalence of OSA between 4-40% of the general population. As such, the observed prevalence in this study appears low compared to the literature. The prevalence in specific subgroups with higher risk for OSA was as well lower than expected. Possible reasons for these findings include unawareness, under-diagnosis of OSA or under-coding of this specific condition in the required billing information. These observations suggest that the actual awareness of the disease is low among patients, physicians and paramedical staff involved in coding. Further research is required to better understand the underlying reasons for the low prevalence of OSA.

**PND3: DISEASE PROGRESSION IN PEDIATRIC MULTIPLE SCLEROSIS: A NARRATIVE REVIEW**

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**OBJECTIVES:** The occurrence of multiple sclerosis (MS) before the age of 18 years is relatively rare and approximately 2-10% of MS patients have their first manifestation before adulthood. There is limited evidence on progression of disease in pediatric onset MS (POMS) and how it is different from adult onset MS (AOMS), therefore our objective is to compare clinical and long-term outcomes in POMS vs. AOMS. **METHODS:** MEDLINE, Embase, the Cochrane Database of Systematic Reviews were queried using the OVID platform to identify publications related to disease progression in POMS. Studies published in the English language, between 2007 and March 2017 were included. **RESULTS:** Search generated 2,238 records, and 313 full-text articles were reviewed and of these, 42 were included in the review. Female preponderance was observed in both POMS and AOMS. Twenty-one studies reported data on disability accumulation as measured by EDSS and almost all reported a slower development of irreversible disability in POMS. However, POMS patients reached disability milestones at a younger age than AOMS. Ten studies reported data on relapse outcomes and, of these, four reported a comparison between AOMS and POMS. Three of them reported that relapses were more frequent in POMS than AOMS. A slightly higher number of relapses were observed in patients with MS onset before 11 years of age. Relapse frequency in early phase of disease showed some correlation with the development of disability in patients. Two studies comparing cognitive outcomes for AOMS and POMS showed that cognitive impairment was higher in POMS as measured on Symbol Digit Modalities Test and Paced Auditory Serial Additional Test. **CONCLUSIONS:** Even though accrual of physical disability is slower in POMS than AOMS, cognitive decline in combination with progressive disability may have a severe impact on a child’s ability to achieve and perform in later life.

**PND4: RELATIVE EFFICACY AND TOLERABILITY OF LACOSAMIDE VERSUS LEVETIRACETAM AS MONOTHERAPY FOR ADULTS WITH NEWLY DIAGNOSED FOCAL SEIZURES: A POST-HOC ANALYSIS OF RANDOMIZED CLINICAL TRIALS**

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**OBJECTIVES:** Lacosamide was previously compared to other anti-epileptic monotherapies in adults with focal seizures in a network meta-analysis (NMA). The number of clinical trials in this NMA was too limited to assess the impact of heterogeneity on outcomes. To overcome the similarity assumption of the NMA, we performed a patient level data analysis of lacosamide and levetiracetam in newly-diagnosed adult epilepsy patients. **METHODS:** Pooled patient-level data from two clinical trials –evaluating lacosamide and levetiracetam monotherapy versus controlled-release carbamazepine (carbamazepine-CR) – were analyzed to assess efficacy (6 and 12-month seizure-freedom) and tolerability (discontinuations due to adverse events [AEs]) outcomes. A propensity score was calculated to adjust for confounding factors. Carbamazepine-CR arm outcomes were compared to assess residual confounding in the lacosamide-levetiracetam comparison. **RESULTS:** In total, 444 and 285 patients were treated with lacosamide and levetiracetam. Lacosamide treatment resulted in a higher probability of being seizure free for 6-months (OR 0.69; 95%CI 0.44-1.08 for not being seizure free) and a lower risk of discontinuations due to AEs (OR 0.59; 95%CI 0.31-1.11) compared to levetiracetam. After adjusting for confounding factors, patients treated with carbamazepine-CR in the lacosamide trial had a higher probability of being seizure free for 6-months (OR 0.81; 95%CI 0.50-1.32) and lower risk of discontinuations due to AEs (OR 0.55; 95%CI 0.32-0.95) compared to patients treated with carbamazepine-CR in the levetiracetam trial. These results were consistent in various propensity score models, subgroup analyses and 12-months seizure freedom outcomes. **CONCLUSIONS:** Carbamazepine-CR outcomes differed between the trials after propensity score adjustment, indicating residual confounding that prevents a meaningful lacosamide-levetiracetam comparison. Comparative assessments derived from NMAs are not biased by such confounding
(randomization holds); however, they describe the average treatment effect in a population without reflecting on differences in treatment response between individuals and subgroups of patients with distinct epilepsy characteristics.

**PND5: DEFLAZACORT OR PREDNISONE TREATMENT FOR DUCHENNE MUSCULAR DYSTROPHY: A META-ANALYSIS OF DISEASE PROGRESSION RATES IN RECENT MULTICENTER CLINICAL TRIALS**

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**OBJECTIVES:** Deflazacort and prednisone/prednisolone can slow the loss of ambulatory function in patients with Duchenne muscular dystrophy (DMD). We compared rates of decline in ambulatory function between patients receiving these corticosteroids, in conjunction with modern supportive care and physical therapy, on placebo arms of recent DMD trials. **METHODS:** Ambulatory patients with DMD were included from the placebo arms of recently concluded Phase III trials of ataluren (n=115, all with nonsense mutations) and tadalafil (n=116, unselected by genotype). Both trials required ≥6 months of prior corticosteroid use and stable baseline dosing. Associations between corticosteroid type and 48-week changes in ambulatory function were estimated using mixed models with repeated measures analyses adjusting for baseline age, corticosteroid duration, and functional assessments including six minute walk distance (6MWD), visit week, and interactions between visit week and other characteristics. Placebo arm analytic results from the ataluren trial were extracted from a publication; placebo arm data from the tadalafil trial were analyzed directly. Adjusted differences between deflazacort and prednisone/prednisolone were pooled across trials in a meta-analysis. **RESULTS:** Compared with patients receiving prednisone/prednisolone, those receiving deflazacort experienced slower declines, preserving 28.3 meters of 6MWD [95% confidence interval: (5.7, 50.9); p=0.01]), 2.9 seconds on rise from supine, [(0.9, 4.9); p<0.01], 2.3 seconds on 4 stair climb [(0.5, 4.1); p =0.01], and 1.15 points on NSAA total score [(−0.01, 2.3); p=0.05] in the meta-analysis results. Changes in 4 stair descend and 10 meter walk/run did not differ between groups. Associations were generally consistent in magnitude and direction across trials. A limitation of this post-hoc analysis is that steroid assignment was not randomized, and results may be confounded by unobserved baseline differences. **CONCLUSIONS:** In this adjusted analysis of corticosteroid groups from two clinical trials, patients receiving deflazacort experienced significantly slower rates of functional decline over 48 weeks than those receiving prednisone/prednisolone.

**PND6: ADJUSTING FOR TREATMENT SWITCHING IN THE RELAPSING-REMITTING MULTIPLE SCLEROSIS CLARITY TRIAL AND THE CLARITY EXTENSION STUDY**

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**OBJECTIVES:** Oral cladribine is a disease modifying treatment for multiple sclerosis. The CLARITY trial evaluated the efficacy of cladribine (LL) versus placebo (PP) over 96-weeks. After CLARITY, participants could enter a 96-week extension study, where placebo (PP) treated patients from CLARITY received cladribine (PPLL), and cladribine treated patients were randomised to placebo (LLPP) or continued cladribine. In the absence of a placebo arm across both 96-weeks (PPPP), we used statistical adjustment methods to compare 96-weeks low-dose cladribine to placebo alone over the combined CLARITY and extension periods for time to first qualifying relapse (FQR) and time to 3-month confirmed disability progression (3mCDP). **METHODS:** Adjustment for treatment switching from placebo to low-dose cladribine was performed using the rank preserving structural failure time model (RPSFTM), and the Iterative Parameter Estimation (IPE) algorithm. Other methods including the two-stage approach and inverse probability of censoring weights were not considered as all placebo patients who entered the extension study switched to cladribine. To gauge whether the effect of cladribine appeared to wane over time, hazard ratios (HR) from the treatment switching analysis (LLPP vs PPPP) were compared with the HRs from CLARITY (LL vs PP). **RESULTS:** Without adjustment, the HR for FQR was 0.44 (95% CI 0.34-0.58) (LL versus PP). The RPSFTM resulted in a HR of 0.48 (95% CI 0.36-0.62). The IPE resulted in a HR of 0.48 (95% CI 0.37-0.62). For 3mCDP, the HR was 0.60 (95%CI 0.41-0.87) (LL versus PP). RPSFTM resulted in a HR of 0.62 (95% CI 0.46-0.84) and IPE resulted in a HR of 0.62 (95% CI 0.45 to 0.83). **CONCLUSIONS:** The RPSFTM and IPE (LLPP vs PPPP) HRs compared to the unadjusted (LL vs PP) HRs indicate that there is only slight waning of the cladribine treatment effect over the extension period.

**PND7: EFFECT OF VITAMINS IN PREVENTION OF ALZHEIMER’S DEVELOPMENT: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS**

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**OBJECTIVES:** Vitamins have demonstrated anti-Alzheimer’s efficacy in clinical investigations however, results are inconclusive therefore, we conducted this meta-analysis. **METHODS:** Systematic literature searches were conducted
on electronic databases using different combinations of key words for vitamins and Alzheimer’s disease. Randomized controlled trials of vitamins reporting ADAS CoG and MMSE scores were included. Effect size and 95% confidence interval (CI) were pooled separately for both endpoints. RESULTS: The search yielded 40 studies, 6 of them met inclusion criteria. Three studies were pooled for ADAS-cog change from baseline. The combined results showed that there was no significant difference between the placebo and the vitamin group (mean difference: -0.19, 95% CI: -1.38 to 1.00, P = 0.76). The I2 value (82%), and P value for distribution (P= 0.004) showed that data were heterogeneous. The sensitivity analysis showed that the mean difference between the two treatment arms varied from -0.72 to 0.37. Six studies were pooled for MMSE change from baseline. The combined results showed that there was no significant difference between the placebo and vitamin group (mean difference: 0.28, 95% CI: -0.08 to 0.63, P = 0.12). The I2 values was 0%, showing a homogeneous distribution. The sensitivity analysis showed that the mean difference between the two treatment arms varied from 0.06 to 0.37. CONCLUSIONS: Overall, the treatment effect of vitamins was comparable to the effect of placebo. There was no significant difference between two therapies in prevention of Alzheimer’s disease.

PND8: REAL WORLD EVIDENCE (RWE) ON LONG-TERM PERSISTENCE OF FINGOLIMOD IN RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS) IN AUSTRALIA

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OBJECTIVES: This study aimed to examine and compare patient persistence of fingolimod to all reimbursed disease modifying therapies (DMTs) for relapsing-remitting multiple sclerosis (RRMS) in Australia. METHODS: The Australian Government Medicare Database was used in this study. For patients to be eligible for the study they needed to have received a script for a reimbursed MS disease modifying therapy between September 2011 and February 2016. Persistence was defined as a patient that remained on a DMT with a gap in scripts of no longer than 4 months. Individual patients could be included multiple times if they initiated a new DMT during the study period. Persistence was derived using Kaplan-Meier method and hazard ratios (HR). Persistence to individual treatments was compared to the average persistence observed across all treatments; p-values were based on the log-rank test. RESULTS: A total of 720 unique patients were eligible for the study. The majority were female (73.5%) and aged between 36-65 (64%). These patients contributed 1827 observations that were used for analysis (i.e. 2.5 new initiations/patient). Overall the median persistence (MP) to therapy was 29.6 months with 67.7% of patients remaining on therapy for 12 months. The only DMT that had significantly better persistence compared to the overall average, was fingolimod (HR 0.65 (95%CI: 0.57-0.73; p<0.001). Patients had an MP of 60 months on fingolimod and 79.5% of patients were persistent at 12 months. Patients were significantly less persistent to interferon Beta-1a (MP: 9.8-11.0 months), interferon Beta-1b (MP: 8.8 months), glatiramer acetate (MP: 11.4 months) and dimethyl fumarate (MP: 19.2 months) (hazard ratios above 1.27 (p values all ≤ 0.001) whilst the remaining DMTs, teriflunomide (MP: 27.7 months) and natalizumab (MP: 34.3 months), showed no significant difference from the average persistence. CONCLUSIONS: In this Australian Medicare utilization data, patients were most persistent to fingolimod treatment amongst all DMTs.

PND9: A RETROSPECTIVE CLAIMS ANALYSIS ON RATES OF COMPLIANCE AND DISCONTINUATION AMONG CANADIAN MULTIPLE SCLEROSIS PATIENTS TREATED WITH DISEASE-MODIFYING THERAPIES AT 6, 12 AND 24-MONTH PERIODS

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OBJECTIVES: To assess compliance and discontinuation rates with DMTs in Canadian patients with RRMS METHODS: In this Canadian retrospective claims analysis based on Rx Dynamics® data from IMS Health Canada Inc., compliance and discontinuation rates were collected at 6, 12 and 24-month (cohorts from 2013-2017, rolling 36 months total). Patients had ≥1 prescription filled for each DMT (oral: fingolimod, dimethyl fumarate (DMF), teriflunomide; injectable (BRACE): interferon beta-1a, interferon beta-1b, glatiramer acetate; infusable: natalizumab). A medication possession ratio (MPR) of ≥80% was used to reflect patient compliance to their treatment. Discontinuation rates were calculated based on patients who stopped therapy (60 day window) or who were switched to another DMT. RESULTS: Compliance and discontinuation data was collected after 6 month (n=12543, n=9460 respectively), 12 month (n=7665, n=7234) and 24 month (n=6047, n=6030) periods. The percentage of patients deemed compliant after 6, 12- and 24-months across Canada was higher for fingolimod (75%, 76%, 71% respectively), compared to natalizumab (72%, 73%, 58%), DMF (71%, 68%, 55%), and BRACE (52%, 46%, 35%) and comparable to teriflunomide (78%, 77%, 68%). Patients on fingolimod had the lowest discontinuation rate after 6,
12 and 24-month periods (26%, 25%, 29% respectively) compared to: BRACE (48%, 35%, and 55%); natalizumab (34%, 29%, and 49%) and DMF (31%, 30% and 43%); and similar to teriflunomide (26%, 25%, 31%). CONCLUSIONS: The compliance for patients treated with fingolimod remained stable at all time point and was higher than for other DMTs but was comparable to teriflunomide. Unlike other DMTs, the discontinuation rate with fingolimod did not significantly increase over the 24-month period and remained lower than other DMTs and similar to teriflunomide. These findings may inform MS management strategies in Canada which may lead to improved clinical and economic outcomes.

PND10: DISPENSING PATTERNS OF ANTI-MIGRAINE AGENTS WITH THE FOCUS ON SEASONAL VARIATIONS IN PRESCRIBING
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OBJECTIVES: Studies of weather sensitivity in migraineurs have reported some seasonal variation in migraine attacks with a slight dependency of migraine attacks on months. The primary aim of the study was to determine the dispensing patterns of anti-migraine agents in a private healthcare setting in South Africa, with the focus on seasonal variations in the prescribing of these agents. METHODS: A retrospective, cross-sectional drug utilisation study was conducted on a South African medical insurance administrator database for 2016. The database contained 3 567 170 records for medicine, medical devices and procedures. All products in MIMS category 1.9 (Anti-migraine agents) were extracted from the database and analysed. RESULTS: A total of 914 anti-migraine products were dispensed to 505 patients (69.70% females) at a cost of R167 302.00. The average age of patients was 41.57 (SD=13.77) years, with 62.38% of patients between 35 and 64 years of age. The majority (78.01%) of products were dispensed by pharmacies. Of the eight active ingredients, clonidine was the most often dispensed (34.68%), followed by rizatriptan (28.01%) and ergotamine (26.04%). Proportionally, more clonidine prescriptions were dispensed to females than to males (39.31% versus 19.82%). Prescribing peaks were observed for active ingredients in February to April, and again in October. These months coincide with the change in seasons to winter and to summer in South Africa. There was a general decrease in the dispensing of anti-migraine agents towards the end of the year. CONCLUSIONS: The sample size was too small to make definite conclusions, but it seems as if the prescribing of anti-migraine agents showed peaks during the times of year when the seasons change (autumn and spring) confirming that weather is a possible trigger factor in migraine.

PND11: EPIDEMIOLOGY OF MULTIPLE SCLEROSIS: LITERATURE REVIEW FOR PREVALENCE AND TREND OVER TIME IN 5 EUROPEAN COUNTRIES AND CANADA
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OBJECTIVES: To analyze and compare published prevalence rates and trends over time for multiple sclerosis (MS) and predict patient numbers in 2017.METHODS: Systematic search (1990-2017 May) in Medline, Embase, back-referencing and additional searches in Registries / HTA websites/ Health Insurers. Key words: "multiple sclerosis; epidemiology, prevalence". Inclusion criteria: published after 1989; p

PND12: MULTIPLE SOURCE OF INFORMATION TO CHARACTERIZE THE CLINICAL, THERAPEUTIC MANAGEMENT AND ECONOMIC BURDEN OF PATIENTS WITH MULTIPLE SCLEROSIS IN FRANCE
OBJECTIVES: The objective is to describe the characteristics, therapeutic management and cost of Multiple Sclerosis (MS) in France by using different data sources. METHODS: The French regional MS Lorraine registry (ReLSEP) contains MS patients’ characteristics, clinical data and therapeutic management, but no associated costs. Selected populations for this analysis were MS patients with first symptoms between 2000 and 2014. The French Health insurance databases (SNIIRAM and EGB) contains drug/medical device consumptions, medical visits, hospitals stays and associated costs, but limited patients’ characteristics, no clinical information, and no possibility to distinguish the form of the disease. Selected population for this analysis was prevalent MS patients in 2014. SNIIRAM is exhaustive (all French insured population), EGB is a 1/97th representative sample of the SNIIRAM. RESULTS: From the 6090 MS patients registered in the ReLSEP database, 1926 MS patients met all the predefined selection criteria: 72% were female, mean age at first symptoms was 33±11 years. 1663 patients with Remitting form of MS (RRMS) at initial diagnosis (86%) and 263 (14%) with Primary Progressive (PPMS). 180 (11%) RRMS and 73 (28%) PPMS patients have never been treated during the observation period. Median follow-up was 9 years (Q1-Q3: 5-12). From the 940 MS patients extracted from the EGB database, 71% were female and mean age at extraction was 51±14 years with more than 50% of patients having first MS Long-Standing-Condition-Status > 10 years. In 2014, 70% of cost resulted in drug expenses/hospitalizations, while 56% of patients had no delivery of treatment and 94% no hospital stay. From the SNIIRAM database in 2014, around 90000 patients were diagnosed with MS. Cost of MS patients represented 0.8% of the annual spending in France. CONCLUSIONS: Multiple source of information is necessary to evaluate clinical, therapeutic and economic burden of Multiple Sclerosis in France, as complementary/confirmatory information are retrieved.

PND13: HEALTH CARE UTILIZATION AND COSTS OF MULTIPLE SCLEROSIS PATIENTS IN THE NETHERLANDS: A HEALTH CARE CLAIMS DATABASE STUDY

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BACKGROUND: Up-to-date incidence and prevalence estimates of Multiple Sclerosis (MS) and real world information on health care use and costs in the Netherlands is lacking. OBJECTIVES: This study aimed to: i) investigate the incidence and prevalence of MS in the Netherlands by using claims data, ii) create insight in the health care use and related costs of MS patients. METHODS: A large health care claims database was analysed including approximately twenty-five percent of the Dutch population. Nine years of claims data were available: 2006-2014. Data contained an anonymized patient ID, gender, age and survival. Outpatient and inpatient drug prescriptions and drug prices were available. For hospital care, the database included the diagnoses codes and the corresponding costs. Incidence was estimated by exploring ‘first-time’ claims in the database defined as not having an MS related claim in the previous two years. Prevalence was estimated based on the number of individuals having an MS claim within the concerning year. RESULTS: Average prevalence of MS in the Netherlands over 9 years was 88 per 100,000 inhabitants (males 48, 127 females). This is comparable with previously reported prevalence in the literature. The average incidence was 9 per 100,000; somewhat higher than reported in previous studies. Yearly per patient medication costs were highest in the year after the first MS claim and then decreased about 15% in the two years after. Mean hospital costs were 30% higher in the year of the first MS claims than in the three years after. Drug and hospitalization costs remained higher than before the first MS claim. CONCLUSIONS: Dutch incidence and prevalence estimates based on claims data seem consistent with previous estimates over time. Patients’ drug and hospital costs increased strongly in the year after an MS diagnosis and then decrease again, but stay higher than before diagnosis.

PND14: INCIDENCE AND PREVALENCE OF EPILEPSY IN GERMANY

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OBJECTIVES: Epilepsy is one of the most frequent neurological diseases. No current precise data about the epidemiology of epilepsy and focal epilepsy (FE) in Germany are available. The aim of this contribution is to quantify age-/gender-specific prevalence and incidence of epilepsy in Germany, in 2013. METHODS: The analysis based on claims-data of 2.7 million members of a regional German statutory health insurance fund. Patients were classified as epilepsy prevalent if they had received at least one inpatient and/or confirmed outpatient diagnosis of epilepsy (ICD10-Code G40.-) in the observation year 2013. Patients were considered to have incident epilepsy in 2013 if they
had not received any antiepileptic medication and any epilepsy diagnosis 6 months before the first observed epilepsy diagnosis in 2013. Additionally, FE prevalence/incidence (ICD10-Code G40.0/G40.1/G40.2) was analysed separately. In a sensitivity analysis, patients were classified as prevalent/incident only if they received at least one prescription of an antiepileptic medication in 2013 in addition to the epilepsy diagnosis. Prevalence/incidence was reported as age- and gender-adjusted numbers, based on German population age/gender structure. RESULTS: Prevalence was estimated to be 1.998% for epilepsy and 0.703% for FE. Among prevalent patients, 50.9%/49.1% were male/female for epilepsy, respectively 50.1%/49.9% for FE. The sensitivity analysis resulted in a prevalence of 1.426% (0.599% in FE). Epilepsy incidence in our sample was 4.860 cases/1,000 person-years in men (1.366 cases in FE) and 3.781 cases/1,000 person-years in women (1.175 cases in FE). Based on the more conservative epilepsy definition, incidence was 1.439 cases/1,000 person-years and 0.656 cases/1,000 person-years in FE. CONCLUSIONS: Using this claims data source, the prevalence and incidence was found to be higher in Germany than reported in previous studies. Therefore, the resulting healthcare burden of epilepsy is expected to be larger than previously estimated.

PND15: THE PREVALENCE AND TREATMENT STATUS OF DIFFERENT MULTIPLE SCLEROSIS PHENOTYPES IN A ITALIAN REFERENCE CENTER

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OBJECTIVES: More information are needed on the prevalence of different Multiple Sclerosis (MS) phenotypes and their treatment management. This study assessed the prevalence and the treatment management of the main different MS phenotypes: relapsing remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS). METHODS: Patients covered by Lombardy Healthcare System with a diagnosis of MS in the period 2004-2010 were identified through regional healthcare administrative databases. Data extracted from these databases were linked with clinical information collected by a major MS center located in Lombardy. Combining the clinical and administrative data we assessed the prevalence of the different MS phenotypes at the last observed year (2010), stratifying the patients for their diseases severity, assessed with the Expanded Disability Status Scale (EDSS), and their treatment status (first DMTs, second DMTs, no DMTs). RESULTS: The study identified 831 patients with MS at 2010. The prevalence of RRMS was 79.3%, while SPMS was reported in 13.7% and PPMS in 7.0% of patients. PPMS reported the highest mean age (58.5 years), followed by SPMS (56.3 years) and RRMS (41.4 years). An EDSS lower than 7 was reported by 98.8% of RRMS, 59.6% of PPMS and 50.9% of SPMS; while an EDSS lower than 3 was reported by 70.0% of RRMS, 3.5% of PPMS and 0.9% of SPMS. The RRMS reported the high prevalence of patients treated with DMTs (63.9%), followed by SPMS (34.2%) and PPMS (1.7%). Within the RRMS treated patients, 82 patients (19.5%) were previously treated with another DMTs. CONCLUSIONS: Our study provide data on the prevalence of the different MS phenotypes, the EDSS distribution and the treatment status in a reference MS center in Italy. This information are of primary interest to estimate the target population of new DMTs that are approaching the market and to assess their possible budget impact.

NEUROLOGICAL DISORDERS - Cost Studies

PND16: BUDGET IMPACT ANALYSIS FOR DACLIZUMAB BETA IN RELAPSING REMITTING MULTIPLE SCLEROSIS IN ITALY

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OBJECTIVES: Daclizumab beta is a humanized monoclonal antibody recently approved for the treatment of adults with relapsing forms of multiple sclerosis (MS). The objective of this budget impact analysis is to estimate the economic consequences of the introduction and use of daclizumab beta in Italy, for the treatment of patients with relapsing remitting MS (RRMS), eligible to second line therapies. METHODS: The analysis evaluates the economic impact of the first three years of daclizumab commercialization, from the perspective of the Italian National Healthcare Service (NHS). Direct healthcare costs (drugs, administration, monitoring, relapse and adverse event management) were calculated comparing two scenarios: i) current scenario, where second line treatments (fingolimod, natalizumab, alemtuzumab), currently available in Italy, are used to treat RRMS patients, ii) alternative scenario, where daclizumab beta is introduced as an alternative. Target population was estimated in 9,950, 11,480 and 13,080 patients at years 1, 2 and 3 respectively, based on Italian prevalence, incidence and market data. Impact of relapses was estimated using results from recently published mixed treatment comparison. Unit costs were based on national prices, tariffs, and published literature (in euros 2017). One-way sensitivity analysis was conducted. RESULTS: According to negotiated price and reimbursement conditions, the introduction and use of
daclizumab beta would decrease total costs, compared to the current scenario. In the current scenario, estimated costs were approximately 170.2, 196.4 and 223.8 million euros in years 1, 2, and 3 respectively. In the alternative scenario estimated costs were approximately 168.9, 192.4 and 217.9 million euros. The cumulative budget impact over three years was a saving of approximately 11.2 million euros for the Italian NHS. All scenarios tested in sensitivity analysis were favorable to the alternative scenario. CONCLUSIONS: The adoption of daclizumab beta for the treatment of RRMS patients eligible to second line therapies is economically favorable (budget-saving) for the Italian NHS.

PND17: BUDGET IMPACT ANALYSIS OF ORAL GLYCOPYRRONIUM BROMIDE (SIALANAR™) FOR THE SYMPTOMATIC TREATMENT OF SEVERE SIALORRHOEA (DROOLING) IN THE UK SETTING

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OBJECTIVES: Oral glycopyrronium bromide 400 micrograms/ml (Sialanar™) is indicated for the symptomatic treatment of severe sialorrhoea (drooling) in children and young people with chronic neurological disorders. It is the only licensed medication in Europe and has been launched in the UK. The market had previously been dominated by use of unlicensed products or preparations made by specials manufacturers or pharmacists. It is not possible, using routinely collected data, to assess use of unlicensed products for this indication, therefore we carried out an evaluation of budget impact utilising real world evidence to validate assumptions around input parameters. METHODS: A budget impact model was developed for the UK setting using local epidemiological and cost data from multiple published and unpublished sources. It was assumed that licensed oral glycopyrronium bromide 400 micrograms/ml would displace unlicensed products. Data on use of unlicensed products were derived from a sample of patients receiving treatment for sialorrhoea identified in a UK observational database (Clinical Practice Research Datalink). Annual net budget impact over 5 years, from the perspective of the UK National Health Service, was estimated. RESULTS: The budget impact of the newly licensed oral glycopyrronium bromide over 5 years was estimated to be cost saving, even under assumptions of increasing prescription rates over time. Certain displacement scenarios (e.g. areas with a high prescription rate of the tablet form of an unlicensed product) resulted in substantial cost savings. CONCLUSIONS: The introduction of oral glycopyrronium bromide 400 micrograms/ml may lead to substantial cost savings for the UK healthcare service. Use of real world evidence to understand clinical practice and treatment decisions is critical to validate assumptions around input parameters when estimating the budget impact of introducing a newly licensed product into a previously unlicensed market. This allows national and local decision makers to make informed decisions on use for their patient population.

PND18: MIGRAINE BURDEN AND COSTS: A NATIONWIDE POPULATION-BASED CONTROLED COHORT STUDY USING THE FRENCH EGB DATABASE

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OBJECTIVES: To describe and analyze the burden, healthcare resource use and costs of adult patients using acute migraine treatments in France, with a comparison to a matched control group. METHODS: Analysis was based on the EGB ("Echantillon Généraliste de Bénéficiaires") database, a 1/97 random sample of the French healthcare insurance database linked with the hospital discharge database (PMSI). Adult patients with at least one delivery of any specific migraine acute treatment (triptans or ergots derivatives) in 2014 were selected. A control group matched on age, gender and geographic area was identified (3 controls per case). Treatment overusers were defined as a consumption of >20 DDD (triptans) or >10 DDD (ergots), per month for at least 3 consecutive months. The cost analysis was performed in a societal perspective by comparing healthcare costs between cases and controls. RESULTS: 8 639 patients using acute migraine treatments (mean age: 44.6 years; 78.7% of women) were selected representing a crude prevalence rate of 1.8%. Most frequent prescribers of triptans were GPs (86.6%). Only 6.9% of patients consulted a neurologist. 3.4% of patients were considered triptan overusers and 11.7% ergots overusers. 9.6% of patients had severe depression compared to 5.5% in controls and 20.8% of patients used antidepressant agents compared to 11% in controls. 19.5% of patients had at least one episode of sick leaves. In 2014, the mean annual per capita healthcare costs was €2463 in patients, 4005€ in triptans/ergots overusers and 2182€ in controls. The extrapolated nationwide annual direct cost attributable to migraine treated by acute treatments was estimated at €242M in 2014. CONCLUSIONS: Migraine generates a significant burden in patients with an increase of depression and anxiety. Drug abuse is associated with greater burden and healthcare related costs. Due to high prevalence (20%), costs related to migraine consist of a significant societal burden.
PND19: IMPACT OF OCRELIZUMAB VS. INTERFERON BETA-1A IN DELAYING THE DETERIORATION OF PATIENTS’ DAILY FUNCTIONS AND ASSOCIATED COSTS IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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OBJECTIVES: Ocrelizumab has better efficacy in delaying disease progression than subcutaneous interferon beta-1a (SC IFN-β-1a) among patients with relapse-remitting multiple sclerosis (RRMS). This study compared ocrelizumab vs. SC IFN-β-1a in terms of progression over Extended Disability Status Scale (EDSS) states and associated costs.

METHODS: A Markov cohort model was developed to compare ocrelizumab vs. SC IFN-β-1a for the treatment of RRMS over 20-years time horizon, from a US payer perspective. Patients entered the model initiating treatment and distributing across EDSS states as observed at the baseline of two Phase III randomized controlled trials comparing ocrelizumab vs. SC IFN-β-1a (OPERA I and II). Patients could transition between 21 health states: EDSS 0-9 in RRMS, EDSS 0-9 in secondary-progressive multiple sclerosis (SPMS), and death. Efficacy of ocrelizumab and SC IFN-β-1a were from OPERA I and II. Data from the literature were used to inform other inputs. The model estimated the distribution of patients across EDSS states and cumulative treatment and EDSS state costs (2016 USD).

RESULTS: At the end of 20 years, a higher proportion of patients receiving ocrelizumab vs. SC IFN-β-1a were able to maintain full daily activities (EDSS<5: 20.7% vs. 15.5%) and to walk without a walking aid (EDSS<6: 23.8% vs. 18.1%). Patients receiving ocrelizumab vs. SC IFN-β-1a were predicted to spend more time in EDSS states capable of full daily activities (9.67 vs. 8.52 years) and in states capable of walking without aid (10.93 vs. 9.76 years) over the 20 years period. The treatment costs ($455,501 vs. $556,003) and EDSS state costs ($204,986 vs. $229,652) were also lower for ocrelizumab vs. SC IFN-β-1a. CONCLUSIONS: Ocrelizumab, compared to SC IFN-β-1a, is associated with delayed deterioration in RRMS patients’ ability to conduct full daily activities and to walk without aid in RRMS, which also translated to lower EDSS state costs.

PND20: THE ECONOMIC BURDEN OF DIFFERENT MULTIPLE SCLEROSIS PHENOTYPES

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OBJECTIVES: Poor specific information on economic burden of Multiple Sclerosis (MS) phenotypes are available. This study assessed the costs associated to the main MS phenotypes: relapsing remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS).

METHODS: Patients covered by Lombardy Healthcare System with a diagnosis of MS in the period 2004-2010 were identified through regional healthcare administrative databases. Data extracted from these databases were linked with clinical information collected by a major MS center in Lombardy, and for each patient we identified the MS phenotype and diseases severity assessed with the Expanded Disability Status Scale (EDSS). We identified drug prescriptions, hospitalizations, outpatient visits and diagnostic tests provided to patients for their MS during the years after the identification. We estimated the health care resources consumption and the mean annual cost per capita stratified by EDSS level and MS phenotype. RESULTS: The study identified 871 patients with a mean age of 37.9 years. At start of observation, 83.9% reported RRMS, 8.5% SPMS and 7.2% PPMS. More than 8% of RRMS developed SPMS during observational period. RRMS reported the highest annual cost per patient with a mean of €7,136 in patients with EDSS level 0-3, €9,820 with EDSS level 4-6 and €11,569 with EDSS level 7-9. The PPMS patients reported the lower annual mean cost per patient (€2,261 EDSS 0-3, €3,920 EDSS 4-6, and €6,290 EDSS 7-9). The higher cost of RRMS patients was mainly due to the use of disease modifying therapies (DMTs), with a low impact associated to relapse cost (€405 per relapse). The RRMS patients treated with DMTs reported a treatment switch rate of 12.1 per 100 person-years. CONCLUSIONS: Costs were highly correlated with disease severity and MS phenotype. These data can help health care decision-maker to better assess the burden of MS phenotypes and the possible impact of DMTs.

PND21: THE DIRECT COST OF PATIENTS WITH MULTIPLE SCLEROSIS IN FRANCE

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OBJECTIVES: To estimate the direct healthcare cost of patients with multiple sclerosis (MS) in France in 2014.

METHODS: Using data from the EGB database, a 1/97th random sample of the major French national health insurance system covering about 59 million individuals, we identified adults MS patients considering either long standing condition status (ICD-10 code: G50) hospital stays referencing MS as main or related diagnosis/ at least one reimbursement of an MS-specific drug over the 2007-2014 period. The global direct healthcare cost of patients...
with MS was estimated in a collective perspective. An incremental matched-control approach was then used to estimate the direct burden of MS. **RESULTS:** Overall 940 patients with MS were identified on January 1st, 2014. On average they were 50.9 (± 13.7) years old. 71.4% of patients were female. The sum of all 2014 health care expenditure for these patients was estimated to 12,225€ (±12,704€). Nearly all patients (91.7%) were visited at least once during the year by a GP and 38.9% a neurologist. Overall, 44.3% of patients have received at least one delivery of a primary therapy for MS in 2014 mostly beta-interferons and assimilated (28.8%). 22.1% of patients benefited of technical aids for their disabilities and 46.9% of patients were treated by a physiotherapist. Finally, 6.2% of patients were hospitalized for MS (average duration of 3.6 days). Comparing MS patients to a matched control group resulted in estimating the excess direct cost attributable to MS to 9,659€ (±6,059€) in 2014 (average annual growth rate: 3.9% over 2012-2014). Main cost drivers were pharmaceuticals (49%), hospital care (22.9%), nursing care (7.8%), medical devices (6.5%) and physiotherapy care (6%). **CONCLUSIONS:** The direct burden of MS was evaluated to 965 million in 2014 in France mainly due to disease-modifying therapies. Such burden highlights the importance of developing cost-effective drugs.

**PND22: EVALUATING THE REAL-LIFE DAILY-COST OF TREATMENT WITH ANTIEPILEPTIC DRUGS IN FRANCE: A STUDY BASED ON THE COMBINATION OF FRENCH NATIONAL HEALTH INSURANCE PUBLIC DATABASE, AND THE EMR LPD PRIVATE DATABASE.**

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**OBJECTIVES:** To evaluate the real-life daily-cost of treatment with antiepileptic drugs, delivered in retail pharmacies in France. **METHODS:** Two sources of data were extracted and combined for the purpose of this study. On the one hand, private EMR Longitudinal Patient Data were used to assess the daily dose of antiepileptics prescribed in real life to patients above fifteen. Besides, as GPs and neurologists have an important role in epilepsy management, both of their prescriptions data were used in this analysis. On the other hand, French health insurance Medic’AM public data were used to assess the actual price per milligram of antiepileptic drugs delivered and reimbursed in real life. The study focused on the ten main oral antiepileptic drugs of the N03 EphMRA class marketed in France, both generic or brand-name products, and immediate or extended-release formulations. The data sources were analysed based on the same definitions in terms of period, prescriber profile, analysed products and formulations. **RESULTS:** The combination of these two real-life insights lead to the estimation of the daily dose with a price per milligram, and the assessment of a daily cost of treatment in real life for each drug. Crossing the two databases between October 2015 and September 2016 showed that among the ten main antiepileptics, the daily cost of treatment ranged from 0,17€ to 3,79€ per day. Medic’AM data also gave access to the substitution ratio between generic and brand-name drugs. It showed that generic drugs accounted for 66% of the amount reimbursed by the French national health insurance. **CONCLUSIONS:** This analysis shows that combining private data on ambulatory drugs prescriptions and public data on their reimbursement enables the calculation of a real-life daily-cost.

**PND23: COST ANALYSIS OF SEVERAL TREATMENT SEQUENCES USED FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN PORTUGAL: THE CASE FOR CLADRIBINE TABLETS**

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**OBJECTIVES:** To evaluate the impact of the introduction of Cladribine Tablets in the long term costs of several therapeutic approaches used for the treatment of relapsing-remitting multiple sclerosis in Portugal. **METHODS:** An Excel based model was developed to permit the comparison for a single patient of the cost of alternative sequences of treatment, over a 1 to 6 year horizon. Time on treatment for each therapy was determined assuming switch at time of relapse. Data on probability of relapse over time was obtained from published long-term studies following RCTs, namely, FREEDOMS and TRANSFORMS for Fingolimod, ENCORE for DMF, and CLARITY and CLARITY EXT for Cladribine Tablets. Solely drug purchasing costs were included and these were obtained from national official sources. Initial treatments could occur with Cladribine tablets, Fingolimod or DMF, while second line could be done with Fingolimod or Natalizumab (as normal in Portugal). For studies with data shorter than 6 years, final observation was carried forward to year 6. **RESULTS:** When all treatment options are compared initial treatment with DMF followed by Natalizumab seems the least expensive option in the short to mid-term (2 to 4 years), however when treatment horizon is expanded up to 6 years, Cladribine followed by Natalizumab becomes a better option (79.676 € vs 82.847 € for DMF-Natalizumab). Regarding Fingolimod, in the first 3 years Fingolimod is cheaper than Cladribine, however beyond the 3rd year Cladribine followed by either Natalizumab or Fingolimod is always cost-saving when compared with Fingolimod followed by Natalizumab (67.270 € for Cladribine-Natalizumab vs 73.810 € for Fingolimod-Natalizumab, over 4 years), with the gap between the costs of the two sequences increasing over time. **CONCLUSIONS:** Used according with its label and over a 4 to 6 years horizon, Cladribine tablets can be the best financial option for the treatment of patients with multiple sclerosis in Portugal.
**PND24: COSTS AND BENEFITS OF IMPLEMENTING NON-INVASIVE PRENATAL TESTING FOR TRISOMY 21 (T21) BASED ON CELL FREE DNA (CFDNA) SEQUENCING IN MATERNAL PLASMA IN FRANCE**


**OBJECTIVES:** To estimate the costs and benefits of implementing cfDNA for T21 in prenatal screening to support recommendations on its use in France. **METHODS:** A model was developed to simulate outcomes (detected foetal T21s, miscarriages avoided, false and true negatives, screening withdrawals and test failures) and costs of using standard first trimester T21 screening in France, compared to screening strategies that include cfDNA with different T21 risk thresholds (i.e. 1/250, 1/1000 and 1/2500). The time horizon used for the model was less than one year. Methodological choices were based on HAS guidelines, a systematic literature review of health economics studies, and expert consultation. Data was derived from national datasets and completed with international studies, where needed. Sensitivity analyses and validation against international study results were carried out. **RESULTS:** Integrating cfDNA in T21 prenatal screening strategy prior to invasive diagnosis for pregnant women with a risk threshold of at least 1/250, leads to an additional cost of €440,000, while improving the number of detected prenatal T21s by more than 40, and reducing the number of invasive procedures by 13 300 and the number of related miscarriages by 18. When comparing the modelling strategies integrating cfDNA, the low bounds of 1/250 and 1/1000, and the high bounds of 1 and 1/50, appear to be the most relevant choices based on non-weighted outcomes. **CONCLUSIONS:** Implementation of cfDNA as a contingent test in prenatal screening can improve foetal T21s detection while avoiding procedure related miscarriages. From a health economic point of view, implementation of cfDNA in France seems to be most relevant for threshold risks ranging between [1/250; 1], [1/1000; 1], or [1/1000; 1/50]. Final HAS recommendations were based on model results, as well as on ethical, preferential and organisational aspects and expert opinion.

**PND25: ADEQUATELY REFLECTING THE CLINICAL BENEFITS IN RARE DISEASE ECONOMIC MODELING USING SMA TYPE I AS A CASE STUDY**

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**OBJECTIVES:** Spinal muscular atrophy (SMA) is a rare, hereditary, autosomal recessive neuromuscular disorder caused by deletion of the survival motor neuron 1 gene (SMN1). Type I SMA is one of the most severe forms of SMA that affects infants between 0-6 months of age where they never develop the ability to sit and have a short life expectancy. Nusinersen is the first approved treatment for SMA, and prior management of the disease centred on the symptomatic treatment of respiratory, nutritional, and orthopaedic function decline. The objective of this study was to build a model to adequately reflect the clinical benefits of a novel treatment (nusinersen) in a rare disease which has resulted in patients achieving motor function abilities not previously observed. **METHODS:** A decision analytic model was developed based on the clinical trial outcome measures, registry data and clinical opinion via an advisory board. Health states were based on both motor milestones consistent with Type I SMA and for motor milestones not previously experienced by Type I SMA patients, such as sitting without support and standing with assistance due to the improvement in motor function experienced by patients treated with nusinersen. Due to paucity of data, quality of life utility values were derived from a vignette study. Data for the major clinical events such as scoliosis surgery were based on the literature. **RESULTS:** The resulting model structure showed that over a 40-year time horizon patients treated with nusinersen gained an average of 6.5 life-years and over 6 quality-adjusted life years (undiscounted). **CONCLUSIONS:** The resulting model structure is a basis on which a full economic model can be developed to support nusinersen in future Health Technology Assessments (HTAs).

**PND26: A BUDGET IMPACT ANALYSIS OF AN INCREASED UPTAKE OF ALEMTUZUMAB FROM THE UK NHS PERSPECTIVE**

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**OBJECTIVES:** To estimate the impact of increased use of alemtuzumab 12 mg/day in the treatment of adult RRMS patients (per its marketing authorization) on the UK National Health Service (NHS) budget. **METHODS:** A budget impact analysis was conducted for an average of 121,200 RRMS patients in the UK over a 5-year time horizon (start year: 2017) from the NHS payer perspective. The number of RRMS patients was derived from UK Office of National Statistics (2015) by considering prevalence and incidence of RRMS in the UK. Five direct costs considered were treatment/administration, resource use/monitoring, adverse events, disability progression (assessed by Expanded Disability Status Scale scores), and relapse. The model compared the cost difference in each year under two different
PND27: DISEASE-MODIFYING THERAPY IS ASSOCIATED WITH LOWER MEDICAL COSTS IN PATIENTS WITH MULTIPLE SCLEROSIS WITH OR WITHOUT CORTICOSTEROID TREATMENT: A US RETROSPECTIVE CLAIMS-BASED STUDY

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OBJECTIVES: To compare, using corticosteroid use as a surrogate marker for relapse activity, healthcare utilization and costs among patients with multiple sclerosis (MS) who do/do not receive disease-modifying therapy (DMT). METHODS: Healthcare claims analysis included MS patients with or without DMT during the 12 months prior to the most recent claim, stratified by number of corticosteroid treatments (0, 1, or ≥2) during this period. Costs were assessed based on claims during the 1-year observation period. RESULTS: Of 7072 patients covered by Medicare, 4689 (66%) received DMT. Patients with DMT were less likely to have a corticosteroid claim than patients not receiving DMT (39% vs 62%), and less likely to have an ER visit (39% vs 54%) or hospitalization episode (18% vs 29%). Overall medical costs were lower with DMT use. For patients without a corticosteroid claim, total medical costs were $8,037 for DMT vs $13,604 for no DMT; inpatient costs were $15,085 vs $20,802; ER costs were $1,204 vs $1,508. Costs rose with increased corticosteroid treatments. In patients with ≥2 corticosteroid treatments, total medical costs (DMT vs no DMT) were $13,688 vs $18,728; inpatient costs were $14,320 vs $17,890; ER costs were $1,674 vs $2,172. Rates of post-steroid DMT switching were low (12%–16%) even in patients with ≥2 episodes of corticosteroid use. CONCLUSIONS: DMT use was associated with fewer corticosteroid treatments (potentially indicating fewer relapses), fewer hospitalization episodes, fewer ER visits, and lower medical costs, indicative of better health outcomes. DMT use lowered healthcare utilization and costs in patients with and without corticosteroid treatments. Corticosteroid treatments were associated with increasing utilization and costs, but did not prompt increased DMT switching. STUDY SUPPORT: Sanofi

PND28: COST-EFFECTIVENESS OF ALEMTUZUMAB IN THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS IN THE UNITED STATES AND SOCIETAL SPILLOVER EFFECTS

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OBJECTIVES: Caring for patients with relapsing multiple sclerosis (RMS) poses economic and humanistic burdens that are well-documented, but in the United States (US) are seldom incorporated into the cost-effectiveness appraisal of disease modifying treatments (DMTs). Alemtuzumab (ALEM) was compared to ocrelizumab (OCR) and natalizumab (NAT), accounting for societal spillover effects due to RMS treatment. METHODS: A Markov model with annual cycles and 20-year time horizon was run separately from US payer and societal perspectives. The societal perspective analysis built upon the payer perspective by including productivity loss costs, informal care costs, and caregiver disutility. For ALEM, the population represented characteristics of pooled treatment-naïve and non-naïve patients from the CARE MS I and II trials (NCT00530348, NCT00548405). The British Columbia Multiple Sclerosis cohort was used to model the natural history of RMS disease progression. Network meta-analysis provided data on the relative efficacy of DMTs in reducing relapses and slowing disability. Withdrawal rates, treatment waning, resource use, costs and utility inputs were populated using published data and clinical expert opinion. Information on adverse events was derived from package inserts and published sources. RESULTS: From US payer perspective, ALEM dominated comparators by accumulating more quality-adjusted life years (QALYs) and lower costs vs OCR (+0.499; $486,366) and NAT (+0.516; $626,578). The benefit of ALEM over comparators further increased when the analysis was conducted from the societal perspective vs OCR (+0.556; $513,813) and vs NAT (+0.575; $655,263). Sensitivity analyses identified the DMT withdrawal rate as one of the most influential model parameters. CONCLUSIONS: The cost-effectiveness of ALEM was driven by its durable efficacy in the absence of continuous treatment and by savings from treatment acquisition costs over the time horizon. ALEM generated greater
positive spillover effects to society by reducing caregiver disutility, informal care, and productivity loss versus comparators. **STUDY SUPPORT:** Sanofi

**PND29: COST-EFFECTIVENESS OF BRIVARACETAM AS ADJUNCTIVE THERAPY FOR PARTIAL-ONSET EPILEPSY IN THE FINNISH SETTING**

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**OBJECTIVES:** To evaluate the cost-effectiveness of brivaracetam and perampanel as adjunctive antiepileptic drugs (AEDs) in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent patients with epilepsy in Finland. **METHODS:** A discrete event simulation approach was used to model: 1) brivaracetam and perampanel as 3rd concomitant AEDs on top of two AEDs, with perampanel being used after brivaracetam among other adjunctive AEDs, 2) perampanel omitted from brivaracetam arm, 3) brivaracetam and perampanel as adjunctive AEDs on top of only one AED. Comparative treatment efficacy (achieving seizure freedom, ≥50% reduction in seizure frequency) and safety (discontinuation due to adverse events) of all AEDs were estimated using a comprehensive network meta-analysis. Perampanel dosing scheme was varied and tested based on a separate meta-analysis of placebo-controlled brivaracetam and perampanel trials. The primary outcomes were direct medical costs (including drug acquisition, monitoring, adverse event management, treatment initiation and switching costs) and quality-adjusted life-years (QALYs) gained. Results were discounted at 3% per annum during the 5-year modelling timeframe. **RESULTS:** Total costs were estimated at €25,788 and €25,026 for brivaracetam and perampanel, respectively. Respective QALYs were 3.662 and 3.605, resulting in incremental cost-effectiveness ratio (ICER) of €13,357 per QALY gained. ICERs ranged between €7,925 – €29,170/QALY when varying perampanel dose. When omitting perampanel from the brivaracetam arm, or analyzing brivaracetam and perampanel as adjunctive AEDs on top of only one AED, brivaracetam became dominant (cost saving and more effective than perampanel). Results were robust in both deterministic and probabilistic sensitivity analyses. Brivaracetam had high probability of being cost-effective even at low willingness-to-pay thresholds. **CONCLUSIONS:** BRV not only expands the availability of effective treatment choices, but is also affordable providing value for money in the Finnish settings.

**PND30: COST-EFFECTIVENESS OF LEVETIRACETAM FOR PATIENTS WITH JUVENILE MYOCLONIC EPILEPSY: A MODELING APPROACH BY THE BRAZILIAN PUBLIC HEALTH CARE SYSTEM PERSPECTIVE.**

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**OBJECTIVES:** Sodium valproate is the recommended antiepileptic drug (AED) in the Brazilian public Healthcare System (SUS) for the treatment of juvenile myoclonic epilepsy (JME). However, approximately 30% of patients do not achieve a satisfactory control with valproate, raising the need for add-on AEDs. Levetiracetam is the only AED with labeled indication for JME, but it is not included in the SUS formularies. This study aimed to assess the cost-effectiveness and additionally the budget impact (BI) of levetiracetam for patients with JME in comparison with the SoC. **METHODS:** A 16-week decision tree was developed with three health states: response; lack of response and death. Efficacy, QoL and transition probabilities assumptions came from a randomized trial1. A Markov model was developed for the 10-year period following the decision tree. The model accounted for discontinuation rates, QoL and costs. A probabilistic sensitivity analysis was conducted to evaluate the robustness of the results. For the BI, drug acquisition costs, dosage regimen and population growth were considered. In addition, a one-way sensitivity analyses were performed. **RESULTS:** The total number of patients with JME calculated was 44,616. From these, we assumed that 4,698 (10%) would be taking levetiracetam in the fifth year. The inclusion of levetiracetam would cost an additional BRL 43.6 million, between years 1 and 5, reaching BRL 16.3 million in the fifth year. The calculated ICER was BRL 5,882 /year / response. The ICUR calculated was BRL 58,294 /QALY. The probabilistic sensitivity analysis confirmed the results, demonstrating that levetiracetam was cost-effective in 90% of simulations. **CONCLUSIONS:** Levetiracetam is a cost-effective treatment option as add-on AED for the treatment of JME, from the perspective of Brazilian Public Health System. Reference: 1-Noachtar S, et al. Neurology 2008; 70: 607–16.

**PND31: ALEMTUZUMAB IS THE MOST COST-EFFECTIVE OPTION IN COMPARISON TO AVAILABLE THERAPIES IN THE TREATMENT OF RMMS FROM THE UK NHS PERSPECTIVE**

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OBJECTIVES: To estimate the cost-effectiveness/cost-utility (CEA) for alemtuzumab compared with other licensed disease-modifying therapies (DMTs) in the UK from the National Health Service (NHS) perspective. METHODS: The cost-effectiveness of alemtuzumab was evaluated in comparison to 11 DMTs with available 6-month confirmed disability worsening (CDW-6m) data over a lifetime horizon (i.e., 50 years). The population considered at least 80% of patients with RRMS. Direct costs considered were natural history, drug and treatment administration, monitoring, and adverse event management. Drug costs were obtained from the British National Formulary 2016 and MIMS drug database. Costs of treatment administration, monitoring, and adverse event management were acquired from NHS from 2014–2015 (annual fiscal costs). Effectiveness/utility was expressed as quality-adjusted life years (QALYs), life-years (LYs), number of relapses, and years without cane use (EDSS<6). Utilities were obtained from the literature. Efficacy data were obtained from a network meta-analysis, which included annualized relapse rate and CDW-6m. CEA outcomes are assessed using incremental cost effectiveness ratio (ICER). Cost and benefits were discounted at 3.5%. RESULTS: Total cost per person over the time horizon for treating RRMS with alemtuzumab was £276,188; total costs per person for treating RRMS population with comparators ranged from £274,401 (glatiramer acetate) to £343,790 (natalizumab), giving incremental costs for alemtuzumab versus comparators ranging from -£67,602 (vs natalizumab) to +£1,787 (vs glatiramer acetate). Incremental QALYs for alemtuzumab ranged from 1.26 (natalizumab) to 2.12 (SC interferon beta-1a 44 µg). Therefore, alemtuzumab dominates almost every other licensed DMT. The ICER for alemtuzumab versus glatiramer acetate is £863 per QALY, which is lower than the accepted willingness-to-pay threshold of £30,000/QALY by NICE, thereby demonstrating the cost-effectiveness of alemtuzumab. CONCLUSIONS: From the UK NHS perspective, alemtuzumab is the most cost-effective option in the treatment of RRMS, as it dominates almost every other DMT. STUDY SUPPORT: Sanofi

PND32: COST-EFFECTIVENESS ANALYSIS OF ALEMTUZUMAB IN COMPARISON WITH NATALIZUMAB, INTRAMUSCULAR INTERFERON BETΑ-1A, SUBCUTANEOUS INTERFERON BETΑ-1B, AND FINGOLIMOD FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN IRAN

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OBJECTIVES: In the era of representing new medicines for the treatment of Multiple sclerosis, a highly debilitating immune mediated disorder, evaluating the incremental cost-effectiveness of medicines are necessary for allocating health care resources in an efficient manner. Therefore, this study was aimed to to assess the cost-effectiveness of Alemtuzumab (ALM) in comparison with Natalizumab (NTZ), intramuscular interferon beta-1a (IM-IFN), subcutaneous interferon beta-1b (SC-IFN), and fingolimod (FNG) for the treatment of relapsing-remitting multiple sclerosis (RRMS) from Iranian healthcare perspective. METHODS: A multistage Markov model was developed using the Microsoft Excel to access the incremental cost effectiveness ratio over a 5-year time horizon in a cohort of 1000 patients with RRMS. The London Ontario dataset, published clinical trials, and long term follow-up studies was used to estimate the transition probability matrix. The costs were measured as US Dollars based on local tariffs and the effectiveness were measured as Quality-adjusted life years (QALYs). Finally, incremental cost-effectiveness ratios (ICERs) calculated as cost per QALYs gained. Sensitivity analysis were conducted to show the robustness of the model over the uncertainty of key parameters. RESULTS: Results showed that Compared with NTZ, ALM was less expensive and more effective and has been chosen as a dominant strategy (ALM: $101,868 and 2.44 QALYs; NTZ: $103,437 and 2.33 QALYs). However, compared with IM-IFN, SC-IFN, and FNG, ALM had an ICER of $50,482, $49,164, and $39,253 per QALYs gained, respectively (IM-IFN: $87,733 and 2.16 QALYs; SC-IFN: $88,102 and 2.16 QALYs; FNG: $96,765 and 2.31 QALYs). The sensitivity analysis further indicated the robustness of the model. CONCLUSIONS: ALM is dominantly cost-effective treatment strategy compared with NTZ in the treatment of RRMS patients. However, compared with IM-IFN, SC-IFN, and FNG, ALM would be cost-effective at the willingness to pay threshold of about ≥$50,000, ≥$49,000, and ≥$39,000 per QALYs gained from an Iranian healthcare perspective.

PND34: COST-EFFECTIVENESS ANALYSIS OF DACLIZUMAB BETA IN THE TREATMENT OF RELAPSING REMITTING MULTIPLE SCLEROSIS IN ITALY

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OBJECTIVES: Daclizumab beta is a humanized monoclonal antibody recently approved for the treatment of adults with relapsing forms of multiple sclerosis (MS). This economic analysis aimed at evaluating the cost-effectiveness of daclizumab beta, compared with fingolimod as a second line therapy for treatment of patients with relapsing remitting
MS (RRMS), adopting the perspective of the Italian National Healthcare Service (NHS). METHODS: This cost-effectiveness analysis was developed through a Markov model with lifetime horizon. Outcomes were measured as life years (LYs), quality-adjusted life years (QALYs), lifetime costs and incremental cost-effectiveness ratio (ICER). Data on natural history of disease were retrieved from published literature. Efficacy of treatments, expressed as reduction of relapse rate and disability progression, was simulated using a recently published mixed treatment comparison. Utilities were retrieved from daclizumab clinical trials and a previously conducted MS survey. Relapses, treatment-related adverse events (AEs) and progression to secondary progressive MS were associated with disutilities. Direct healthcare costs (drugs, hospitalization, physician visits, administration, monitoring, relapse and AE management) were calculated. Unit costs were based on national prices, tariffs and published literature (in euros 2017). An annual 3.5% discount rate was applied to both costs and outcomes. One-way deterministic and probabilistic sensitivity analyses were conducted. RESULTS: Daclizumab beta was slightly more effective and less costly than fingolimod (QALY gain: 7.69 vs 7.39; treatment costs: €222,488 vs €233,391, respectively). Both one-way deterministic and probabilistic sensitivity analyses confirmed robustness and reliability of base-case results. The cost-effectiveness acceptability curve (CEAC) analysis showed that, using a ≤ €50,000/QALY willingness-to-pay threshold, the probability of daclizumab beta to be cost-effective vs fingolimod was 72% of simulations. CONCLUSIONS: The results of this economic analysis suggest that daclizumab beta is a cost-effective option vs fingolimod for RRMS patients eligible to second line treatment in Italy.

PND35: COST-EFFECTIVENESS ANALYSIS OF PEGINTERFERON BETA-1A VS. FIRST-LINE INJECTABLE DISEASE-MODIFYING THERAPIES FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN SPAIN

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OBJECTIVES: This study assesses cost-effectiveness of subcutaneous (SC) peginterferon beta-1a 125 mcg SC every two weeks vs. other first-line injectable disease-modifying therapies (DMTs) such as glatiramer acetate 40mg SC daily, interferon beta-1a 30mcg intramuscular (IM) once a week, interferon beta-1a 44mcg SC three times a week, and interferon beta-1b 250mcg SC every other day, in the treatment of relapsing remitting multiple sclerosis (RRMS) from the payer perspective in Spain, over a 30-year time horizon METHODS: A Markov cohort economic model was developed for this analysis. Patients began in RRMS, distributed across Expanded Disability Status Scale (EDSS) score states. Every one year cycle, patients could experience a relapse, die, transition to lower or higher EDSS states, and/or progress to secondary-progressive MS (SPMS). The model predicts the occurrence of these transitions, translates the time spent in each health state into quality-adjusted life-years (QALYs), and assigns associated costs. Comparative efficacy of each DMT vs. placebo was obtained from a network meta-analysis. Administration and monitoring costs were sourced from public databases and literature. Drug costs included mandatory discounts. Clinical and economic outcomes were discounted at 3% per year. RESULTS: Over 30 years, peginterferon beta-1a was dominant (i.e., more effective and less costly) vs. all comparators. Peginterferon beta-1a was associated with incremental QALY gains of 0.47, 0.20, 0.06, and 0.62 compared with glatiramer acetate, interferon beta-1a IM, interferon beta-1a SC, and interferon beta-1b, respectively. Peginterferon beta-1a was associated with cost-savings of €16,203, €9,220, €13,393 and €23,792, compared with glatiramer acetate, interferon beta-1a IM, interferon beta-1a SC, and interferon beta-1b SC, respectively. Results were robust across a wide range of deterministic and probabilistic sensitivity analyses. CONCLUSIONS: This analysis suggests that long-term treatment with peginterferon beta-1a improves clinical outcomes at reduced costs compared with other first-line injectable DMTs, and, considering efficiency criteria, is a valuable option for treating patients with RRMS.

PND37: THE COST-EFFECTIVENESS OF DACLIZUMAB BETA VS FINGOLIMOD FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS PATIENTS WITH INADEQUATE RESPONSE TO PRIOR TREATMENT IN SCOTLAND

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OBJECTIVES: To assess the cost-effectiveness of daclizumab beta vs fingolimod in highly active relapsing-remitting multiple sclerosis (RRMS) patients whose disease inadequately responded to a prior disease-modifying treatment, from the perspective of NHS Scotland. METHODS: A cohort Markov model was constructed based on the Expanded Disability Status Scale (EDSS) in RRMS and secondary progressive MS. Transition matrices capturing natural history confirmed disability progression (CDP) and regression (RRMS only) were derived from the SELECT trial and the British Columbia dataset. Baseline EDSS distribution and annualised relapse rates (ARR) were also obtained from pivotal studies. Comparative effectiveness results for ARR and 12-week CDP were estimated via a Bucher indirect comparison of pivotal studies. Utility and cost data for EDSS health states and relapses were obtained from a U-
specific Burden of Illness study. Additional clinical and mortality data were derived from the published literature. Drug acquisition costs were based on list prices sourced from the British National Formulary with discounts considered in a series of scenario analyses. Sensitivity analyses were also conducted. RESULTS: The analysis showed that, over a 50-year time horizon, daclizumab beta was cheaper (£4,441) than fingolimod with a marginal QALY loss (0.206). Daclizumab beta was cost effective using a willingness to pay (WTP) threshold of £20,000 per QALY gained. This finding was consistent across scenario analyses including a 20-year time horizon, using alternative health state and relapse costs treatment waning and caregiver burden inclusion. Using PAS discounts, daclizumab beta was cost-effective at WTP thresholds in analyses with up to 40% discounts applied to fingolimod. CONCLUSIONS: Based on these analyses, daclizumab beta is a cost-effective treatment for this highly active sub-population. Findings were consistent when applying discounts of up to 40% for fingolimod. Amongst limited treatment options, daclizumab beta represents a valuable option with a novel mechanism of action and unique once-monthly self-administered injection.

PND38: THE COST EFFECTIVENESS OF FINGOLIMOD FOR THE TREATMENT MULTIPLE SCLEROSIS IN KOREA

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OBJECTIVES: Multiple sclerosis is a progressive and degenerative disease with an estimate prevalence of 3.5 per 100,000 people in Korea. Interferon beta is recommended as first-line disease modifying therapies for relapsing-remitting form of MS (RRMS). Fingolimod has recently been approved for reimbursement at relatively low price for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS) in Korea. The aim of this study was to evaluate the cost-effectiveness of Fingolimod compared to Interferon-β (IFNβ) in patients with RRMS in Korea. METHODS: A Markov model was designed with patients transitioning through health states based on Kurtzke expanded disability status scale (EDSS) to analyze the cost-effectiveness of Fingolimod comparing with Interferon-β. The model captured health-states defined on the Kurtzke expanded disability status scale (EDSS) with 21 states accounting for Relapse-Remitting Multiple Sclerosis (RRMS) (states 0-9), Secondary-Progressive Multiple Sclerosis (SPMS) (States 0-9) and all-cause death. Efficacy data mainly comes from FREEDOMS study. Direct medical costs were included from published data in Korea with payer perspective and utilities were derived from international literature. The analysis used a 30-year time horizon based on yearly cycle. Costs and utilities data were discounted 5% per annual. Sensitivity analyses were performed in which the costs of relapse, monitoring, as well as discounting, were varied. RESULTS: Fingolimod dominated interferon beta in patients with RRMS over 30 years’ time horizon. The expected cost saving was 21,491 USD for 30 years. Base-case result shows that Fingolimod treatment strategy could be more relapse-avoided and beneficial option. (1.38 relapse-avoided, 0.619 QALYS gained respectively). Robustness in the results were confirmed through the sensitivity analysis. CONCLUSIONS: For patients with Relapsing-Remitting Multiple Sclerosis, treatment with oral Fingolimod is an efficacious and cost-saving option compared with interferon-beta; one of current available options in Korea.

PND39: COST EFFECTIVENESS ANALYSIS OF DIMETHYL FUMARATE VERSUS TERIFLUNOMIDE FOR THE TREATMENT OF MULTIPLE SCLEROSIS

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OBJECTIVES: Multiple sclerosis (MS) causes significant disability and diminished quality of life globally. Dimethyl fumarate and teriflunomide are oral treatments for relapsing forms of MS. A health economic model was developed to assess the cost-effectiveness of dimethyl fumarate versus teriflunomide as first-line treatment for relapsing-remitting MS (RRMS) from the payer perspective in Spain. METHODS: A Markov cohort model was developed to simulate patients’ progression through a series of health states based on the Kurtzke Extended Disability Status Scale (EDSS) over a 30 year time horizon. Patients entered the model based on a distribution of baseline EDSS states, from which they could either progress/regress to higher/lower EDSS states, or remain in the same state. Relapses could occur at any EDSS state. Results from a mixed-treatment comparison were used to inform model inputs for disease progression and relapse rates for each treatment. In addition to the overall discontinuation rates reported in the trials, patients discontinued treatment on conversion to secondary-progressive MS or reaching EDSS state 7. Costs included direct medical costs stratified by EDSS state, along with relapse, adverse events, and treatment-related costs. Utilities were obtained from a literature review. A 3.5% annual discount rate was applied to costs and health benefits. RESULTS: Compared with teriflunomide, dimethyl fumarate was dominant, i.e. cost-saving and more effective over the 30 year time horizon, yielding 0.01 additional quality adjusted life years (QALYs) at a cost of €1,829 lower than teriflunomide. Cost differences between treatments were mostly attributed to the superior reduction in relapses associated with dimethyl fumarate. Results were consistent across a wide range of one-way and
PND40: LACOSAMIDE AS FIRST LINE TREATMENT OPTION IN FOCAL EPILEPSY; A COST-UTILITY ANALYSIS FOR THE GREEK HEALTHCARE SYSTEM

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OBJECTIVES: Approximately 30% of patients with focal epileptic seizures remain uncontrolled after the first epileptic treatment. Lacosamide (LCM) has been recently approved by the European Medicines Agency as monotherapy option for the treatment of focal seizures. The objective of this study was to estimate the cost-effectiveness of LCM compared to zonisamide (ZNS) as first-line treatment of focal epilepsy in patients with epilepsy aged 16 years and older to inform clinical decision-making in Greece. METHODS: A previously developed discrete event simulation model was adapted to reflect the treatment pathway and resource use within the Greek national healthcare system, as specified by clinical experts. The model captures time-varying events and patient characteristics. Clinical inputs were sourced from pivotal trials and a network meta-analysis comparing LCM to other antiepileptic drugs (AEDs). The model predicts disease progression and seizures, relevant and most common adverse events, withdrawal due to lack of efficacy or adverse events, together with epilepsy-specific and all-cause mortality over a 2-year time horizon. Unit costs were retrieved from officially published Greek sources. Health outcomes were measured as quality adjusted life years (QALYs). To demonstrate the robustness of the results, univariate and probabilistic sensitivity analyses were performed. RESULTS: LCM treatment pathway was associated with higher mean costs (€1,064) and additional 0.119 QALYs versus ZNS, resulting in an incremental cost effectiveness ratio of €8,938 per QALY gained. The sensitivity analyses demonstrated that the results are most sensitive to the efficacy and utility estimates, yet establishing the robustness of the outcomes. CONCLUSIONS: Lacosamide is shown to be a cost-effective option at a willingness to pay threshold of €30,000 per QALY, hence represents a valuable monotherapy option for the treatment of patients with focal epileptic seizures.

PND41: COST-EFFECTIVENESS OF INCOBOTULINUMTOXIN-A IN THE LONGER-TERM MANAGEMENT OF POST-STROKE SPASTICITY OF THE UPPER LIMB

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OBJECTIVES: In Australia, the reimbursement of botulinum neurotoxin-A (BoNT-A) on the Pharmaceutical Benefits Scheme (PBS) for the treatment of moderate to severe spasticity of the upper limb following a stroke (PSS-UL) is restricted to four treatment cycles per upper limb per lifetime. The objective of this study was to examine the cost-effectiveness of extending the treatment beyond four treatments among patients with an adequate response to previous treatment cycles. METHODS: A Markov state transition model was developed to perform a cost-utility analysis (CUA) of extending the use of incobotulinumtoxin-A beyond the current restriction. The Markov model followed patients in 12-weekly cycles for five years, estimating the proportion of patients with or without response over this period in each of the modelled treatment arms. A post-hoc analysis was performed to estimate probabilities of achieving and maintaining response over time. The perspective of the analysis was the Australian healthcare system meaning only direct healthcare costs were included. Utility values by response status were derived from EQ-5D data from a published double-blind placebo-controlled study. The primary outcome measure was the incremental cost per quality-adjusted life year (QALY). Univariate and probabilistic sensitivity analyses were conducted. RESULTS: The incremental cost per QALY gained of continued use of incobotulinumtoxin-A beyond the current restriction of four treatments was AUD$59,659. CONCLUSIONS: Continuing the incobotulinumtoxin-A treatment beyond four cycles can be cost-effective. Careful patient selection is required so treatment is targeted at those with the greatest likelihood to continue to respond to multiple treatment cycles.

PND42: EVIDENCE MAP OF COST-BENEFIT, COST-EFFECTIVENESS AND COST-UTILITY MODELS IN DEMENTIA PUBLISHED SINCE 1960

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OBJECTIVES: To create an evidence map of studies reporting cost-benefit, cost-effectiveness or cost-utility models for dementia, and the geographical jurisdictions for which these studies were conducted. METHODS: We searched the heoro.com database (www.heoro.com) for cost-benefit, cost-effectiveness or cost-utility modelling studies in dementia that were published between 1960 and 30th May 2017. We analysed the abstracts identified by the search
to determine the different types of interventions modelled across the range of geographical locations, by date, perspective and type of dementia. We presented the findings as an evidence map. **RESULTS:** We found a total of 131 abstracts. Of these, 76 were cost-utility models, 10 cost-effectiveness, 5 cost-benefit and 42 did not specify the modelling approach; 62 used a societal and 27 a healthcare perspective and this was unclear in 49. Most reported models for Alzheimer's disease (66 abstracts) or any type of dementia (59). Drug therapies were the most common interventions, in particular donepezil (26), memantine (25), rivastigmine (13), galantamine (12) or any anticholinesterase (15), but screening or diagnostic approaches (16) and caregiver support interventions (14) were also frequently modelled. The jurisdiction of 42 models was the United Kingdom, 16 the United States, 14 the Netherlands, 6 each Canada and Sweden, and 26 were reviews of the international modelling literature. Of the 131 abstracts, 70 were published between 2010 and 2017 and 13 were published before 2000. **CONCLUSIONS:** The focus on cost-utility models from a societal perspective reflects the high impact of dementia on quality of life of patients and caregivers. This is also shown by the substantial number of models on caregiver support and patient care interventions, as well as drug therapies. The preponderance of studies from the UK may reflect the burden on state-funded social care organisations in this country.

**PND43:** **EFFECT OF MULTIPLE SCLEROSIS ON WORK PRODUCTIVITY**

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**OBJECTIVES:** To estimate the consequences of multiple sclerosis on work productivity in France in 2014. **METHODS:** Using data from a 1/97th random sample of the major French national health insurance system covering about 59 million individuals, adults MS patients [18-60 years old] were identified considering either long standing condition status (ICD-10 code: G35)/hospital stays referencing MS as main or related diagnosis/ at least one reimbursement of an MS-specific drug over the 2007-2014 period. Daily allowance for sick leave (DA) and disability pension (DP) for MS patients were estimated using an incremental matched-control approach. **RESULTS:** 678 patients with MS less than 60 year of age were identified on January 1st, 2014. Respectively 19.5% and 27.3% of these patients have received DA or DP at least once during the year 2014. Average cumulative duration was 15.8 days (DA) and 3.1 months (DP) as compared to respectively 9.7 days and 0.3 months in the control population without MS (p=0.01 and <0.0001). Consequences of the disease on work are significantly linked with age and history of the disease. Compensation for sick leave were mainly observed in younger patients under 40 years old and conversely, disability pension are more frequent with age with over 50% of patients benefiting from DP when they were 55 years and over. Considering most disability pensioners are not able to work and using a human capital approach in a societal perspective, average yearly indirect costs per patient with MS less than 60 years of age were estimated to an additional €18,700 as compared to a matched population without MS. **CONCLUSIONS:** Progression of disability in MS patients has significant consequences on the work productivity of these patients. Such consequences include both sickness absence, mainly at the beginning of the disease, and then permanent reduction of the working capacity.

**NEUROLOGICAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies**

**PND44:** **ADHERENCE ISSUES IN MULTIPLE SCLEROSIS TREATMENT: HOW CAN ACCEPTANCE MEASUREMENT HELP UNDERSTANDING PATIENTS’ CONCERNS AND WORKING ON SOLUTIONS?**

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**OBJECTIVES:** Patients with multiple sclerosis (MS) are required to take long-term treatments to treat their chronic disease and avoid complications. However lack of adherence is very common and represents major barriers to treatment efficiency. Measuring patient acceptance of their medication help understand and predict patients’ medication-taking behavior. The objectives of this study are to evaluate the level of acceptance to medication in MS patients in real life; to identify issues and to define priorities for action. **METHODS:** Observational, cross-sectional study conducted in Europe using Carenity Online Community. Adult MS patients were invited to complete an online questionnaire including a validated patient reported outcome measure: the 25-item ACCEPTance by the Patients of their Treatment (ACCEPT©). It includes one general acceptance dimension (Acceptance/General) and five multi-item treatment-attribute specific dimensions: Acceptance/Medication Inconvenience, Acceptance/Long-term Treatment, Acceptance/Regimen Constraints, Acceptance/Side effects, Acceptance/Effectiveness, scored from 0-100 (lowest to highest acceptance). Patients were categorized according to their main treatment class: Immunostimulant versus Immunosuppressant. **RESULTS:** 371 MS patients were included. Mean Acceptance/General score in all MS patients was of 43.12 ± 32.61. Patients taking an immunostimulant scored significantly lower than those taking an
immunosuppressant on Acceptance/Medication Inconvenience, Acceptance/Long-Term and Acceptance/Regimen Constraints (p < 0.01). Pearson correlations showed Acceptance/General to be highly correlated with Acceptance/Effectiveness (R = 0.64, p < 0.001). Having side effects and difficulty accepting treatment for the future were the main reported issues. CONCLUSIONS: Treatment acceptance is not satisfactory in MS. Their treatment acceptance is primarily driven by perceived effectiveness. Experiencing side effects and needing a long-term treatment in the future are their major concerns. These findings give indications about MS patients’ priorities and unmet needs.

PND45: AN ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE IN PEOPLE WITH MULTIPLE SCLEROSIS IN IRELAND

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OBJECTIVES: Multiple sclerosis (MS) is a complex inflammatory disease of the central nervous system that typically presents in people between 20-40 years of age. Approximately 9000 people live with this chronic condition in Ireland. MS inflicts a considerable burden on the health-related quality of life of individuals, and as such, investigating the impact of MS might identify avenues for potential intervention. METHODS: A survey was developed to capture demographic, disease, healthcare use, employment, and health-related quality of life (HRQoL) of people living with MS in Ireland via the MS Ireland mailing list, social media platforms, and traditional print media. HRQoL was captured using the EuroQol-5D-5L instrument which comprises five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Univariate regression analysis was used to determine whether covariates should be included in the multivariate model using an a priori specified criterion (ps0.2). Correlation coefficients were estimated to detect the presence of significant correlations between these covariates. Multivariate linear regression models were estimated using robust (Huber-White) standard errors. RESULTS: A total of 595 people completed the survey in full and of these 541 completed the detailed EQ-5D-5L questionnaire. The mean age of the sample was 47.0 (SD: 12.0) years and 71% were female. The median duration of disease was 6 (IQR: 4-8) years. Of the sample, 57.7%, 35.5%, and 6.8% reported being in a ‘mild’, ‘moderate’, and ‘severe’ disease state, respectively. The mean EQ-5D-5L score among the sample was 0.69 (SD: 0.24). In the multivariate regression analysis, increasing disease severity, being unemployed, being male, and older age were all statistically significantly associated with a reduction in quality of life (all ps<0.05). CONCLUSIONS: Multiple Sclerosis is associated with a significant decrease in HRQoL. In particular, employment status and disease severity were statistically significantly associated with EQ-5D scores, which may provide for useful information for clinicians and/or policy-makers.

PND46: HEALTH RELATED QUALITY OF LIFE STANDARDS IN PATIENTS WITH PARKINSON

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OBJECTIVES: The aim of this work is to build representative correction standards for the most widely used generic Health Related Quality of Life (HRQoL) questionnaires. METHODS: A prospective sample of patients, suffering from Parkinson disease (PD), was recruited by 6 researchers from the Parkinson Patient Association from Madrid (Spain). The following instruments were autocompleted. HRQoL: Medical Survey Outcomes SF-36, EuroQol (EQ-5D), Mark Health Utility Index-III (HUI). Disease severity and symptoms: a brief version of the UPDRS, State-Trait Anger Expression Inventory (STAXI), Hospital Anxiety-Depression Scale (HADS). Sample population descriptive statistics and correlations were computed. All patients were under treatment for their health condition and gave their informed consent to participate in the study. RESULTS: An initial sample of 55 patients [mean age 73.6 years old (SD=9.16), 38% being women] was enrolled. Ninety four percent suffered from idiopathic PD, mean disease span was 9.9 years (SD=8.66) and 96% were under treatment. PD severity ranged between 2 and 4, 37% could be diagnosed of clinical anxiety and 78% of clinical depression (HADS). Mean score in SF-36 physical component was 30.7 (SD=7.21) and 47.9 (SD=10.97) in the mental component. Mean VAS score was 61.1 (SD=19.33). Mean utility values were SF-6D=0.475 (SD=0.227), EQ-5D=0.577 (SD=0.187), and HUI=0.482 (SD=0.265). CONCLUSIONS: Preliminary results show that generic HRQoL instruments are capable of capturing health deterioration in patients suffering from Parkinson disease, although specific instruments should be more suitable for diagnosis purposes. Meaningful differences were found between the three utility instruments, which should be taken into account when assessing or comparing groups of patients. These are initial results and a wider sample is to be gathered.

PND47: HEALTH STATE UTILITIES IN PATIENTS WITH RELAPSING REMITTING MULTIPLE SCLEROSIS TREATED WITH CLADRIBINE TABLETS

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OBJECTIVES: To estimate the health state utility (HSU) of patients with relapsing remitting multiple sclerosis treated with oral cladribine 3.5mg/kg or placebo using EuroQol 5-dimension (EQ-5D-3L) data collected in the CLARITY (NCT00213135) and CLARITY Extension studies (NCT00641537). METHODS: HSU were derived from the EQ-5D-3L questionnaires administered at baseline, during scheduled visits (24-week intervals), and at unscheduled visits coinciding with relapses in CLARITY and CLARITY Extension using the UK tariff. Mean and standard deviations (SD) for HSU and Visual Analogue Scale (VAS) were generated for scheduled and unscheduled assessments. Multivariate linear mixed modelling was used to identify factors associated with HSU, and included Expanded Disability Status Scale (EDSS), treatment, and baseline demographics. RESULTS: 5763 HSU were generated from both CLARITY (n=3518) and CLARITY Extension (n=2245). Mean HSU pooled across treatment groups in CLARITY were 0.715 (SD=0.195), 0.696 (0.229), 0.713 (0.222), 0.705 (0.236), and 0.696 (0.246) at weeks 1, 24, 48, 72, and 96. Similar mean HSU were observed in CLARITY Extension with 0.725 (0.208) at week 1, and 0.696 (0.236) at week 96. Mean HSU were consistently lower at the unscheduled assessment (0.527 (SD= 0.290) in CLARITY, 0.565 (0.251) in CLARITY Extension). Mean VAS scores were consistent with mean HSU. From mixed modelling, EDSS (p<0.01), baseline HSU (p=0.001), and sex (p=0.04) were all significantly associated with HSU. Females and increasing EDSS were associated with lower HSU, while increasing baseline HSU was associated with higher HSU during follow-up. After adjusting for these factors, there was no significant difference in HSU between treatment groups (p=0.406), age (p=0.06), and no time variation in HSU (p=0.210). CONCLUSIONS: Consistent HSU values were observed across CLARITY and CLARITY Extension. Key predictors of HSU were EDSS, baseline HSU, and sex. Overall, findings indicate that HSU is a determinant of HSU, with no additional independent treatment effect on HSU after adjusting for EDSS.

PND48: THEUTILITY OF DIFFERENT APPROACHES TO DEVELOPING HEALTH UTILITIES DATA IN CHILDHOOD RARE DISEASES – A CASE STUDY IN SPINAL MUSCULAR ATROPHY (SMA)

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OBJECTIVES: SMA is a rare, hereditary, autosomal recessive neuromuscular disorder that in its most severe forms impacts infants and young children. Capturing health utilities in infants and young children is often challenging and unadvisable in clinical trial settings since most Qol or utilities instruments are not designed for such age groups. However, the development of cost effectiveness models, required in many countries for reimbursement, necessitates generating health utilities. The objective of this work is to develop health utilities for infants and young children with SMA utilizing different methodologies. METHODS: Three methodologies were undertaken to develop health utilities for input into CE models for nusinersen, the first approved therapy for treatment of SMA. A cross-sectional study of individuals with SMA in select European countries collected parent-proxy assessed Qol using the EQ-5D-3L. A case vignette study assessed physician rated Qol using EQ-5D-5L and the PedsQol for defined motor function health states in the nusinersen economic models. Lastly, the CHERISH trial PedsQol data was mapped to EQ-5D using a published algorithm. RESULTS: The three methodologies showed differences in health utilities for defined nusinersen health states. The cross-sectional study parent-proxy Qol assessment did not provide sufficient detail on patient health to determine with any amount of certainty an individual’s state of health based on the model health states. Physicians on average differentiated between Qol in different health states in a manner consistent with disease severity, and generally ranked Qol lower than observed by parents. Parent-proxy assessments of Qol in the nusinersen CHERISH trial showed little differentiation between lower and higher motor function health states, and in general parents rated Qol high, which is consistent with studies in other paediatric diseases. CONCLUSIONS: Our findings show that different methodologies yield distinct and sometimes equivocal results with parents rating Qol higher than physicians in individuals with SMA.

PND49: PATIENT PREFERENCES FOR INTERFERON-BETA IN IRAN: A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: Multiple sclerosis is a chronic, progressive, and common disease affecting the central nervous system in young adults. Interferon-beta is one of the most widely used medicines to reduce the disease progression. Given the variety of drugs in this category, we aimed to identify the preferences of patients for IFN-β that play an important role in policymaking in this area. METHODS: Discrete choice experiment method was used in the present study to identify and prioritize those attributes that are of interest to MS patients and increases the utility of the use of IFN-β in their treatment. Questionnaires were given to 358 patients in Isfahan-Iran, who were asked to choose between the two treatment choices in each scenario. RESULTS: The results of the logit model showed that the changes in the efficacy leads to the most changes in the patient utility. Changes in side effects and ease of injection have been placed in the next rankings. CONCLUSIONS: Considering the drug attributes considered more desirable by patients
can lead to greater medication adherence and possibly better treatment outcomes. Also, pharmaceutical companies, the health ministry, the Food and Drug Administration, insurance organizations, and neurologists can benefit from this information in production and importation, policymaking, and prescription.

**PND50: PATIENTS’ INFORMATION SOURCES AND NEEDS IN MULTIPLE SCLEROSIS: THE INFoseek-MS QUESTIONNAIRE**

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**OBJECTIVES:** Patients with multiple sclerosis (MS) are increasingly demanding access to reliable information regarding disease symptoms and management. High-quality information is a key factor in patient empowerment and shared decision-making. This research aimed to develop a self-administered questionnaire to characterize the information needs and preferred sources of information for MS patients in Spain. **METHODS:** A panel of experts (a neuropsychologist, a neurologist, a nurse, two research managers, a patient organization representative, and a psychometrician) was responsible for the proposal and agreement of all items contents and wording. After literature review for content extraction and thorough conceptual discussion, a 17-item version of the InfoSeek-MS questionnaire was proposed. The instrument was pilot-tested in 15 MS patients (McDonald 2010 criteria) in order to assess acceptability, face validity, and item understanding (both in their contents and response formats). **RESULTS:** The questionnaire was well accepted and most items were easy to understand. Mean response time was 14.4 ± 7.95min. The most frequently reported source of information was the Internet (either via mobile or computer). The most frequently reported types of information sought included healthy lifestyles (84.6%), sharing experiences with other MS patients (69.2%), and research in MS and emerging treatments (61.5%). Neurologists and nurses were the most trusted source of information by the group overall. Physiotherapists and nurses were the most frequently consulted professionals on a monthly basis. Several items were revised after getting all the responses and comments from patients. **CONCLUSIONS:** The initial stage of content selection, item wording and selection of response methods needed for each item of the questionnaire was successful. A national multicentre study is being conducted in a sample of 300 patients across 20 sites to test validity and effectiveness of Infoseek-MS as a questionnaire to evaluate information needs in MS.

**PND51: DISCLOSING TRADITIONAL & COMPLEMENTARY MEDICINE (T&CM) USE TO THE HEALTH CARE PROVIDERS: A QUALITATIVE STUDY AMONG THALASSEMIA PATIENTS IN MALAYSIA**

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**OBJECTIVES:** This study is carried out to discover the trust thalassemia patients have in disclosing their use of Traditional and Complementary Medicine (T&CM) to their health care providers. **METHODS:** Twenty-one patients with thalassemia were recruited from the Thalassemia Society of Kedah, Malaysia from July to October 2015. The semi-structured interviews were audio-taped, transcribed verbatim and translated into English. **RESULTS:** Thematic analysis identified four themes from the interview analysis: the fear of the termination of provided treatment by the health care providers, the fear of the side effects of the conventional treatment received, the perception that the health care providers are not interested, and the impression that the T&CM treatment is safe and do not cause side effects. The thalassemia patients agreed that the disclosure about their use of T&CM is important to avoid interactions between the T&CM and conventional treatments. However, from a different perspective, the patients assumed that the physician’s lack of knowledge or interest in discussing about T&CM. Although, most patients believed that T&CM is harmless as it only administer natural treatment apart from its non-invasive nature of treatment as it only involves faith healing such as prayers and spiritual healing that are regarded to non-hazardous to health influencing the thalassemia patients to not disclose their use of T&CM. **CONCLUSIONS:** Effective communication between patients and health care providers is important, especially for patients who are having ongoing conventional thalassemia treatment, for the fear that there is an interaction between conventional treatment and T&CM use. The defensive behaviour of the thalassemia patients reluctance to disclose their T&CM use, and the barrier that exists between the patients and health care providers can be avoided through motivational talks to improve the relationship between the patients and their physicians so as to encourage the patients to inform their physicians about their T&CM use.
PND52: REAL WORLD CHARACTERISTICS AND PERCEIVED EFFICACY OF PEGINTERFERON BETA-1A COMPARED WITH OTHER PLATFORM INJECTABLE THERAPIES AMONG MS PATIENTS: EVIDENCE IN FIVE EUROPEAN COUNTRIES

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OBJECTIVES: Describe the demographic and disease characteristics of peginterferon beta-1a patients in a real world data set, and compare perceived effectiveness and quality of life of multiple sclerosis (MS) patients treated with peginterferon beta-1a versus other platform injectable therapies (IM interferon beta-1a, SC interferon beta-1a, interferon beta-1b, glatiramer acetate) in five European countries. METHODS: In this retrospective study, cross-sectional data from 2014 to 2016 were obtained from Adelphi MS Disease Specific Program (III, IV, V). MS patients who received peginterferon beta-1a or other platform injectable therapies were identified. Descriptive analysis was conducted to examine patient characteristics, treatment patterns and patient reported outcomes. RESULTS: Sixty-five peginterferon beta-1a patients and 3,908 patients treated with other platform injectable therapies were identified and compared. Peginterferon beta-1a patients were slightly younger with a mean (SE) age of 36 (10.5) years vs. 38 (10.9) years (p=0.05), respectively, and had a lower mean (SE) Expanded Disability Status Scale (EDSS) score of 1.7 (1.2) vs. 2.3 (1.5) (p=0.0007), respectively. Sixty-five percent of identified patients considered “efficacy” the most important reason in choosing new treatment options. Peginterferon beta-1a patients were less likely to be treatment naïve (58% vs. 80%, p<0.0001). Compared with patients on other platform injectable therapies, patients on peginterferon beta-1a were less likely to report “lack of efficacy” as a current treatment issue, more likely to report a convenient administration profile and to have “less disruption to a patient’s life.” CONCLUSIONS: The average peginterferon beta-1a patient appears younger and with lower disability as compared to patients treated with other platform injectable therapies. Of patients receiving platform injectable therapy, efficacy is the most important reason for treatment choice, and identified patients rate peginterferon beta-1a as more convenient than other platform injectable therapies. Further research will be insightful once peginterferon beta-1a has been on market for a longer duration.

PND53: CONCEPTUAL MODEL AND INSTRUMENT REVIEW IN MULTIPLE SCLEROSIS

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OBJECTIVES: The objectives were to a) develop a preliminary conceptual model based on qualitative research in patients with multiple sclerosis (MS) and b) identify and evaluate commonly used patient reported outcome measures (PROMs) in MS to assess the likelihood of successfully supporting future Food and Drug Administration (FDA) labeling claims. METHODS: PubMed was searched to identify recent (since 2010) qualitative research studies in patients with MS as well as to identify relevant PROMs for further review. The development process for a selected subset of PROMs was compared against the recommendations contained in the FDA PRO guidance. RESULTS: The PubMed search identified 3 qualitative studies focusing on key symptoms and impacts experienced by patients with MS. The most common symptoms included fatigue; pain; musculoskeletal issues such as stiffness, spasm, and difficulty walking; and balance problems. Based on these results, a preliminary conceptual model was developed displaying the relationship between the disease process, patient factors, signs/symptoms reported by patients, and the impact of MS. Nine PROMs were identified from the searches and five most relevant PROMs were selected for further evaluation (4 MS-specific, 1 generic). The measures reviewed were: MS International Quality of Life questionnaire (MusiQoL), MS Quality of Life Instrument (MSQOL-54), MS Impact Scale (MSIS-29), MS Walking Scale (MSWS-12), and the PROMIS item banks. While some of the identified measures have shown responsiveness in clinical trials, none meets all FDA requirements on PROMs. CONCLUSIONS: Based on the preliminary conceptual model, physical functioning aspects of MS are proximal to the disease and thus a potential target for future PRO labeling claims. No existing PRO measure appears likely to support an FDA labeling claim in their current format. The next phase of the project is the conduct of clinician interviews and concept elicitation focus groups to further revise and refine the conceptual model.

PND54: PRO LABELING IN PRODUCTS APPROVED BY THE EUROPEAN MEDICINES AGENCY (EMA) FOR NARCOLEPSY

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OBJECTIVES: Narcolepsy is a rare neurological disease, which prevalence is estimated between 1/3,300 and 1/5,000 (Orphanet), characterized by excessive daytime sleepiness (EDS), sleep paralysis, and hypnagogic hallucinations. Additionally, narcolepsy can occur with cataplexy, a sudden loss of muscle tone triggered by positive
or negative emotions, in 60-70% of narcoleptic patients. The objectives of this study were to identify 1) the medicines approved for the treatment of narcolepsy by the European Medicines Agency (EMA); 2) which of them had a patient-reported outcomes (PRO) labeling in their summary of product characteristics (SmPC), and 3) if the PRO measures were used as primary efficacy variables. METHODS: The EMA website was explored to identify all medicines approved for narcolepsy. The PROlabels database, through the ePROVIDE platform, was used for PRO labeling identification. All corresponding SmPCs and assessment reports (AR) were reviewed for endpoint positioning. RESULTS: The EMA approved only two products for narcolepsy, i.e., pitolisant and sodium oxybate. The review of the SmPCs and of the ARs of both products showed that two primary efficacy criteria, i.e., change in the number of cataplexy attacks and in excessive daytime sleepiness, were assessed using PRO measures. The number of cataplexy attacks was obtained from diary cards filled in by the patients. The Epworth Sleepiness Scale (ESS) score was used to assess efficacy on excessive daytime sleepiness. The ESS is a self-administered questionnaire providing a measure of a person’s general level of daytime sleepiness, or their average sleep propensity in daily life. The ESS asks people to rate, on a 4-point scale (0 – 3), their usual chances of dozing off or falling asleep in eight different situations or activities (e.g., sitting, reading, watching TV, etc.). CONCLUSIONS: PRO assessment play a major role in the evaluation of products for the treatment of narcolepsy approved by the EMA.

PND55: USE OF BIOLOGICAL BASED THERAPIES AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE AMONG THALASSAEMIA PATIENTS

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OBJECTIVES: To analyse the prevalence of Biologically Based Therapies (BBTs) use and evaluate the Health Related Quality of Life (HRQoL) in a group of thalassaemia patients. METHODS: The study involved 390 thalassaemia patients and was conducted at the Kedah Thalassaemia Society, Alor Setar, Malaysia. The Short form survey version 2 (SF-36) was used to determine the HRQoL. RESULTS: From the total of 390 patients, the use of various types of Complementary and Alternative Medicines (CAM) were reported in 313 (80.6%) of them. Among these users of CAM, a total of 268 (85.62%) was found to use BBTs, therefore they were designated as BBT users and vice versa. The common types of BBTs used by the patients are nutritional supplements such as vitamins, minerals, enzymes (n=174) and special diet such as herbs, animal products, and juices (n=97). From the total number of participants, 14.1% were found to be spending more than 100 Malaysian Ringgit (MYR) on a monthly basis for these therapies and the rest of the participants were not aware of their expenditure on BBTs per month. The source of BBTs coming from the patient themselves were 215 (68.7%) whereas from friends’ and family members’ recommendations were 63.9 %. Only 27.2 % of the participants had disclosed the use of BBTs. Better HRQoL was found among the BBT non-users compared to BBT users. On the scale of physical function, role (p=0.03) and social (p=0.03) scores showed a significant difference between the BBT users and non-users. CONCLUSIONS: Biologically based therapies are commonly used among thalassaemia patients in Malaysia. As the results revealed that the assessment of HRQoL shows better quality of life among BBT users, therefore, the potential role of BBTs in thalassaemia care should be further investigated.

PND56: QUALITY OF LIFE FOR PATIENTS WITH NEUROFIBROMATOSIS TYPE 1 ASSOCIATED PLEXIFORM NEUROFIBROMAS (PNF)

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OBJECTIVES: Neurofibromatosis Type 1 plexiform neurofibromas (pNFs) are associated with a variety of symptoms and concerns that affect patients’ quality of life (QOL); yet most research limited in studying pain. This study aimed to provide a more comprehensive understanding of their QOL by reporting their scores on measures from the Quality of Life in Neurological Disorders (Neuro-QoL) and Patient-Reported Outcomes Measurement Information System (PROMIS). These measures selected based on our previous qualitative study results. METHODS: 183 adult patients with pNF (mean=40.1 yrs; 67% female) were recruited. 45% had a diagnosis under 5 years old, and 51% had more than 20 café-au-lait spots. All completed Neuro-QOL Stigma and PROMIS Anxiety, Depression, Self-Efficacy (Manage Day Activity, Manage Emotion, Manage Medications, Manage Social Interaction, Manage Symptoms), Pain (Interference, and Intensity), Physical Function, and Social Function (Ability to Participate Social Role, and Satisfaction Roles Activities). Scores were reported using the US general population based T-score system, where mean=50 and standard deviation (SD)=10. A Tscore > 53 or < 47 (i.e., 1/3 SD from norm) was considered significant as it exceeded the minimal important difference (1/3 SD). For Social Function and Self-Efficacy measures, higher scores meant better functioning; while higher scores meant worse functioning on others. RESULTS: Patients reported similar social function (M=50.6 and 51.4) and self-efficacy/manage symptoms (M=49.2) to the US general population, yet significant worse than the general population on all other domains, with Anxiety being the worst
Multiple sclerosis (MS) is a chronic disease of the central nervous system, and a leading cause of disability in young adults of working age. The main objective of this study is to compare MS patients’ productivity, ability to perform daily self-care activities and independency by level of disability progression. METHODS: This study used data from the patient record form of the 2016 Adelphi Multiple Sclerosis Disease Specific Program, a cross-sectional study collecting data from 487 neurologists and 5402 patients in France, Germany, Italy, Spain, United Kingdom, and United States between November 2015 and March 2016. Patients with current EDSS score <3, 3-5.5, and >5.5 were categorized as with mild, moderate, and severe disability, respectively. Outcomes of interest, including activities of daily living (ADL) and instrumental activities of daily living (IADL) were compared across groups. Productivity and independency were examined by whether a patient was able to work full time and whether he/she had a caregiver, respectively. RESULTS: A total of 2,695, 1,568, and 871 MS patients were identified for the mild, moderate, and severe group, respectively. Among these groups, differences were observed in mean age (37.2, 46.0, and 51.7, p<0.0001) and percent of females (68.2%, 57.5%, and 54.8%, p<0.0001). As disability varied from mild, moderate to severe, fewer patients are being treated on a disease modifying treatment (79.4%, 69.3% vs. 48.7%, p<0.0001), a higher proportion of patients needed assistance with ADL (3.3%, 26.9%, 63.9%, p<0.001) and IADL. (12.6%, 44.1%, 72.0%, p<0.001), less likely to work full time (57.1%, 28.5%, 7.6%, p<0.001), and have a higher reliance on a professional caregiver (1.0%, 7.4%, 26.6%, p<0.001) and a family caregiver (14.7%, 39.2%, 59.7%, p<0.001). CONCLUSIONS: These findings highlight the increasing burden associated with disability progression in MS patients, which limit their ability to perform self-care activities, work full time, and live independently.
OBJECTIVES: To evaluate the impact of disease activity measures on health utilities in PPMS patients. METHODS: In the ORATORIO phase III clinical study 732 PPMS patients were randomized in a 2:1 ratio to treatment with ocrelizumab 600mg or placebo. Expanded Disability Status Scale (EDSS), 9 Hole Peg Test (measure of upper limb function), the Modified Fatigue Impact Scale (MFIS), and EuroQol five dimensions questionnaire (EQ5D) were all assessed at baseline, 48 and 120 weeks. The relationship between the disease activity measures and EQ5D was investigated and the best selected model was a repeated measures linear model that regressed health utilities on EDSS states, clinically significant fatigue and upper limb impairment. Analyses were performed using utilities scores derived with the Australian, British, Canadian, Dutch, French, Italian, Portuguese and Swedish value sets. RESULTS: Health utilities were found to be inversely associated with EDSS state: higher EDSS scores were associated with lower utility scores. Utilities were further associated with fatigue with a disutility between 0.13 (95%CI:0.11-0.15) for the Portuguese and 0.07 (95%CI:0.06-0.08) for the Swedish analysis, and upper limb dysfunction for EDSS from 5 and above with a disutility between 0.06 (95%CI:0.02-0.10) for the Portuguese and 0.02 (95%CI:0.00-0.03) for the Swedish analysis. CONCLUSIONS: In addition to higher EDSS scores, both fatigue and upper limb dysfunction were associated with independent impacts on health utilities in PPMS patient. This is the first study quantifying the impact of multiple symptoms/factors in a large cohort of PPMS patients using country-specific value sets.

PND60: IMPACT OF DISEASE ACTIVITY MEASURES AND PATIENT CHARACTERISTICS ON HEALTH UTILITIES IN RMS

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OBJECTIVES: To evaluate country-specific health utilities at different stages of RMS METHODS: In two studies OPERA I & II 1656 RMS patients were randomized to treatment with ocrelizumab 600mg or interferon beta 1a 44ug. Expanded Disability Status Scale (EDSS) scores and EuroQol five dimensions questionnaire (EQ5D) were both assessed at baseline, 48 and 96 weeks. In a previous study the relationship between EDSS and EQ5D was investigated through a repeated measures linear model that regressed health utilities on EDSS states, sex, age, relapse within 30 days prior to assessment and region of the world. This analysis provides additional utilities derived from the Australian, Canadian, Dutch, French, Italian, Portuguese and Swedish value sets. RESULTS: Health utilities were consistently found to be inversely associated with EDSS state: the higher the EDSS state, the lower the utility score. Utilities were further associated with relapse, sex, age and region of the world. Relapse had a disutility between 0.04 (95%CI:0.02-0.06) in the Swedish and 0.10 (95%CI:0.03-0.12) in the Portuguese analyses; males had higher utilities (on average between 0.02-0.03); average disutility for a 10 year increase in age was between 0.01-0.02; USA patients had between 0.02 (95%CI:0.01-0.03) and 0.05 lower (95%CI:0.04-0.07) utilities as compared to patients from other regions of the world, when using Swedish and British value sets, respectively. CONCLUSIONS: In the absence of generic quality of health measures, country specific health utilities in RMS can be derived based on EDSS state, relapse, gender, age and region of the world.

PND61: THE ASSOCIATION BETWEEN DISEASE ACTIVITY AND HEALTH-RELATED QUALITY OF LIFE IN RRMS PATIENTS

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OBJECTIVES: Relapse-remitting multiple sclerosis (RRMS) is the most common disease course of multiple sclerosis (MS) patients. Disease activity (DA) has been shown to impact intermediate clinical outcomes including relapse rates and disease progression. However, it is unclear to what extent DA is related to ultimate health outcomes such as health-related quality of life (HRQoL). This study investigates the association between HRQoL and DA. METHODS: Generic HRQoL was measured using the EQ-5D-3L utility instrument index value under the United Kingdom tariff. A cohort of 3496 adult RRMS patients enrolled in the Swedish population-based MS register during 1996-2015 (inclusive) was included from the date of first recorded EQ-5D-3L assessment (baseline). Patients were grouped according to DA within +/- 12 months of baseline. Active disease was the reference group, defined as 1+ relapse or T2 lesion. Two high disease activity groups were considered: HDA-R defined as 2+ relapses recorded within 1 year of each other, or Highly Active RRMS (HA-RRMS) defined as 9+ T2 lesions or 1+ gadolinium-enhanced T1 lesion. Patients not fulfilling any DA criteria were labelled unclassified. A general estimating equation was used to analyse the association between longitudinal EQ-5D-3L and disease activity group; adjusting for age, sex, proportion of time treated with disease modifying treatment (%DMT), and time since registry enrolment. RESULTS: HA-RRMS was associated with a statistically significant decrease in EQ-5D-3L (coefficient -0.01, p=0.04). HDA-R and unclassified patients were not statistically significantly associated with EQ-5D-3L. Female sex and increasing age were significantly associated with decreasing EQ-5D-3L, while %DMT and time since registry enrolment were
significantly associated with increasing EQ-5D-3L. CONCLUSIONS: HA-RRMS is associated with lower HRQoL over time, although it is unclear whether it is clinically significant. Additional data and modelling may be required to uncover the subtleties of the relationship between DA and HRQoL.

PND62: A THREE MONTH INTERIM ANALYSIS OF TREATMENT SATISFACTION WITH FINGOLIMOD IN PATIENTS WITH RELAPSING REMITTING MULTIPLE SCLEROSIS IN THE UK: THE PATIENT REPORTED OUTCOMES WITH FINGOLIMOD IN LOCAL EXPERIENCE (PROFILE) STUDY

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OBJECTIVES: The PROFILE study measured patient reported outcomes (PROs) in the real world in fingolimod treated patients with relapsing remitting multiple sclerosis (RRMS). This abstract presents interim data comparing satisfaction with previous treatment and fingolimid at three months. METHODS: A prospective observational study of 144 consenting outpatients with RRMS in 14 UK secondary care NHS centres. Eligibility: aged 18-55 years at first initiation of fingolimod ('baseline') and treated within the European product licence. DMT history was collected from medical records at baseline and PROs were collected at baseline, three, six, and 12 months (M). A planned interim analysis of Treatment Satisfaction Questionnaire for Medication (TSQM-9) outcomes (0-100 scale) of pre-treated patients is present. 95% confidence intervals [CI] presented where available. RESULTS: Overall mean (standard deviation [SD]) TSQM-9 domain scores at 3M were: Effectiveness domain: 63.6 (19.7)[n=89]; Convenience domain: 88.2 (14.5)[n=93]; Global satisfaction domain: 65.0 (22.5)[n=94]. The mean change in domain scores from baseline were: Effectiveness domain: +14.0 [CI:7.8,20.2][n=89]; Convenience domain: +32.2 [CI:27.0,37.5][n=93]; Global satisfaction domain: +17.1 [CI:10.6,23.6][n=94]. Mean score change from baseline to 3M across all domains improved with the number of previous DMTs received, with the exception of those receiving >2 previous DMTs in the Convenience and Global satisfaction domains, where smaller improvements in domain scores were seen. Patients switched to fingolimod from interferons or glatiramer acetate therapies had significant (p<0.05) mean changes in domain scores from baseline to 3M of: Effectiveness domain: +16.2 [CI: 9.71, 22.64][n=68]; Convenience domain: +35.5 [CI:29.85,41.16][n=71]; Global satisfaction domain: +17.2 [CI:9.95,24.46][n=73]. CONCLUSIONS: Overall, patients reported improved treatment satisfaction in all TSQM-9 domains after 3M of fingolimod treatment, compared to their previous treatment. These interim results suggest that patients switched to fingolimod from interferons or glatiramer acetate therapies perceive improvements in treatment convenience, effectiveness and global satisfaction.

NEUROLOGICAL DISORDERS - Health Care Use & Policy Studies

PND63: THE FDA APPROVAL OF ET'EPLIRSEN – NECESSARY FLEXIBILITY OR A WORRYING PRECEDENT?


OBJECTIVES: In November 2016, eteplirsen received FDA-accelerated approval for the treatment of Duchenne muscular dystrophy (DMD). This was controversial; a small, non-comparative dataset demonstrated what FDA reviewers considered to be minor benefits in a surrogate marker (dystrophin). The FDA advisory panel voted against approval but their advice wasn’t followed. This research will evaluate eteplirsen’s FDA-approval in the context of its two main competitors: drisapersen (FDA-rejected), and ataluren (not accepted for FDA-review, but EMA-approved). METHODS: Publically-available FDA Summary Review documentation on the DMD appraisals were analysed and compared. RESULTS: Drisapersen was FDA-rejected primarily due to lack of efficacy in phase 3, despite significantly improving 6-minute walk distance (6MWD) versus placebo in phase 2. Ataluren claimed positive phase 2b data based on increasing dystrophin versus baseline, but a follow-on placebo-controlled phase 3 trial did not meet its primary endpoint of significantly improving 6MWD. The FDA judged the company’s filing incomplete, not warranting review. Eteplirsen was FDA-approved on the basis of a statistically significant improvement in dystrophin levels from a non-comparative dataset versus baseline and compared with historical controls, however the analysis methodology and its clinical significance were questioned. CONCLUSIONS: The FDA-approval of eteplirsen is arguably problematic given that other putative DMD treatments showed benefits in Phase 2 that was not confirmed in Phase 3. But how strong should the level of evidence be for a positive benefit–risk profile? With eteplirsen’s benign toxicity profile and the severe unmet need, arguably this could be set quite low. Additionally, by receiving FDA-accelerated approval, market withdrawal may follow if phase 3 data is not confirmatory. Nevertheless, approvals based on non-comparative datasets with claimed improvements in surrogate endpoints and where the link to clinical benefit has not been shown may set a worrying precedent that could undermine the FDA’s credibility, reflected in the denials/restrictions eteplirsen’s coverage by some payers.
PND64: TREATMENT PATTERNS FOR ADULT PATIENTS WITH NEWLY DIAGNOSED FOCAL EPILEPSY IN GERMANY

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OBJECTIVES: No representative data about the drug treatment of German epilepsy patients exist. Therefore, the aim of this study was to investigate the antiepileptic drug (AED) treatment of adults with newly diagnosed focal epilepsy in Germany. METHODS: The analysis was based on a claims data set covering the years 2007 to 2014, provided by a regional German statutory health insurance. Patients aged 16 years or older were included if at least one in- or outpatient diagnosis of focal epilepsy in 2007 or 2008 and at least one prescription of an AED in 2014 was observed. Furthermore, patients should not have had any previous epilepsy diagnoses/AED prescriptions in the 6 months before the first focal epilepsy diagnosis. Patient observation started at date of first documented inpatient or outpatient diagnosis. Number of previously prescribed AEDs stratified by type of prescribed AEDs in 2014 were calculated. RESULTS: Of 4,555 incident adult focal epilepsy patients, we identified 1,639 patients in 2014 (mean age 53.4 years at index, 45.4% female) with prescriptions of AEDs, approved for focal epilepsies. The mean number of previously prescribed AEDs varied between the substances: 0 to 1 previous AED for Carbamazepine (0.53), Gabapentin (0.84), Valproic acid (0.87); 1 to 2 previous AEDs for Oxcarbazepine (1.07), Lamotrigine (1.08), Levetiracetam (1.13), Topiramate (1.25), and Pregabalin (1.57); 2 to 3 previous AEDs for Clobazam (2.38), Zonisamide (2.55), and Lacosamide (2.59); and more than 3 previously prescribed AEDs for Eslicarbazepine (3.42). Perampanel, Retigabine, Tiagabine, and Vigabatrin were only rarely or not prescribed in 2014. CONCLUSIONS: A variety of AEDs are available for the treatment of focal epilepsy. Many patients remain on their first- or second-line treatment with established AEDs. Novel AEDs like Lacosamide and Eslicarbazepine, which were introduced in the last decade, were only rarely prescribed and relatively late in the treatment course.

PND65: DIRECT MEDICAL COSTS OF MULTIPLE SCLEROSIS AND REGIONAL DIVERSITY IN ACCESS TO DISEASE-MODIFYING THERAPIES IN POLAND BETWEEN 2008-2016

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OBJECTIVES: Analysis of the public payer’s spending on the treatment of multiple sclerosis (MS) and regional diversity in access to disease-modifying therapies (DMTs) in Poland between 2008-2016. METHODS: Retrospective analysis of data on healthcare services related to MS treatment covered by National Health Fund (NHF) in each of Polish provinces (voivodships) between 2008-2016. Costs were reported in USDPPP (adjusted for purchasing power parity). Patient access to DMTs across voivodships was calculated by dividing the number of MS patient receiving DMTs by the size of the total MS population in each voivodship. RESULTS: In 2008 and 2016 NHF expenditure per MS patient by voivodships varied between 1168-2675 USDPPP and 3153-6103 USDPPP, respectively. The largest group of patients was treated in out-patient setting, however the majority of funds (70-90%) was spent on hospital care. The main drivers for hospital costs were DMTs funded through hospital procedures. Mean cost of patient treated with DMTs was 13,972 USDPPP in 2008 and 16,207 USDPPP in 2016. In 2008 only 7% of MS patients received DMTs with access ranging from 4% (in Silesian, Pomeranian and Warmian-Masurian) to 12% (in Lodz). In 2016 the number of patients with access to DMTs has increased 3.8 times but inequalities in coverage still remain with access to treatment as high as 31% in Lesser Poland and only around 14% in the north-west area (West-Pomeranian, Lubusz, Warmian-Masurian). There has been a change in rank for most voivodships with those previously providing less coverage moving up. Masovian and Silesian presented the biggest changes in access moving from 11th to 4th place, and 16th to 9th place, respectively. The biggest fall in rank is Lubusz moving from 5th to 15th place. CONCLUSIONS: The situation of patients with MS in Poland is systematically improving but variations in access to DMTs persist.

PND66: THE EPIDEMIOLOGY AND BURDEN OF PAEDIATRIC MULTIPLE SCLEROSIS: SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Multiple Sclerosis (MS) is a chronic, neurodegenerative condition, severely impacting functioning and quality of life (QoL). Its manifestation, and consequent burden, within the paediatric population is increasingly being recognised. To investigate areas of unmet need, a systematic literature review (SLR) was conducted on the epidemiology, economic and humanistic burden of paediatric MS. METHODS: MEDLINE, Embase, the Cochrane
Database of Systematic Reviews and Database of Abstracts of Reviews of Effects were queried on 12 April 17. Hand-searches of key conferences and reference lists of included studies were also performed. Observational and cost-of-illness studies were included if they investigated patients <18 years with MS and reported a relevant epidemiology, economic burden or humanistic burden outcome. All records were independently reviewed for relevance by two individuals, with discrepancies discussed until reaching a consensus. Outcomes from relevant studies were extracted and quality assessment was conducted using the Critical Appraisal Skills Programme checklists. RESULTS: Of 2,729 records retrieved, 66 were included in the SLR. Incidence of paediatric MS was reported in 12 studies (rate: 0/100,000-2.9/100,000) and prevalence in 24 studies (rate: 0/100,000-3.2/100,000; 0–20.0% of all MS). Five studies reported comorbidities, and 23 studies reported disease characteristics such as relapse rates and disability progression. The impact of MS on QoL, physical activity, fatigue, school performance and cognitive function was reported in three, three, three, six and 11 studies. Five studies compared these outcomes between those with paediatric MS and healthy controls, consistently showing significantly poorer outcomes in those with paediatric MS. One study reported economic outcomes, finding on average that health plans did not fully cover medication costs. CONCLUSIONS: This review has identified studies on various epidemiologic and burden outcomes in paediatric MS. Although the occurrence of MS is relatively rare in children, the burden and unmet medical needs are evident.

PND67: ADHERENCE TO ANTI-CONVULSANT THERAPY AMONG AMBULATORY EPILEPTIC PATIENTS IN A TERTIARY HOSPITAL IN NIGERIA

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OBJECTIVES: Complete adherence to anticonvulsant therapy is essential for seizure control and improved quality of life in epileptic patients. This study described adherence to anticonvulsant therapy in a resource-limited setting to generate evidence-based data for intervention studies. METHODS: The study was a prospective cross-sectional assessment of epileptic patients using standardized structured questionnaire in English Language to evaluate their adherence to treatment. Epileptic patients who have been on anticonvulsant therapy for more than 12 months who understand English and gave their informed consent to participate in the study were randomly selected and recruited for the study. Data were summarized using descriptive statistics. Study lasted from January to October 2016. RESULTS: The average age of 102 patients who participated in the study was 31.69±11.53. 10 (9.8%) of the patients were on once daily medications, 89 (87.3%) on twice daily while 3 (2.9%) were on thrice daily. Whereas 83 (81.4%) were on monotherapy, 16 (15.7%) were on dual therapy, and 3 (2.9%) on polytherapy. Adherence was high in 9 (8.8%) of the patients while 63.3 (91.2%) were non-adherent. The level of seizure control was good in 19 (18.6%), fair in 46 (45.1%) and poor in 37 (36.4). The factors affecting adherence from the study were side effect of drugs 34 (33.3%), lack of knowledge about the illness 34 (33.3), cost of medication 17 (16.7%) and forgetfulness 17 (16.7%). Physicians admitted they assessed patients’ adherence through assessment of patients’ condition 68%, pill count 17%, and patients’ interview 100%. All the physicians admitted to emphasize adherence to therapy before and after prescribing. CONCLUSIONS: Patients adherence to anticonvulsant therapy in the facility was poor. Non-adherence was associated with preventable factors bordering on the patients and health care providers.

PND68: PHARMACOEPIDEMIOLOGY OF LATERAL AMIOTROPHIC SCLEROSIS IN THE REPUBLIC OF BELarus

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PHARMACOEPIDEMIOLOGY OF LATERAL AMIOTROPHIC SCLEROSIS IN THE REPUBLIC OF BELARUS

Bondarenko T, Roman E Minsk, Belarus OBJECTIVES: The study is aimed at determining the pharmacoepidemiological characteristics of the treatment of patients with ALS for further improvement of pharmacotherapy regimens. METHODS: The study was conducted by the method of continuous active retrospective monitoring using medical records of 16 patients from the Moscow district of Minsk in the period from 2009-2016 (with the established diagnosis of ALS). Data extraction methods, pharmacoepidemiological methods (frequency analysis and DDD-methodology) were used. The ATC classification system of medicines was used. RESULTS: Of the patients, 5 were men, 11 were women. The mean age of the patients at the onset of the disease was 64±7 years, the mean age at the time of death was 66±6 years. The main groups of pharmacological drugs used to treat these patients in accordance with the ATC included: N06BX Other psychostimulants and nootropic drugs, N07AX02 Other parasympathomimetics, N07AA anticholinesterase drugs, N07XX other drugs for the treatment of nervous system diseases, N06A, A09 Monoamine reuptake inhibitors, A14AB01 Anabolic steroid preparations, A16AX01 Ticlopidic acid, R05CBMukolytics, N03A Antiepileptic drugs. An analysis was made of the ATC / DDD system with the calculation of the established daily dose for those drugs that could be traced within six months: NDDD thioctic acid - 180,000
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WHAT ARE THE STRATEGIC VALUE DRIVERS?

PND69: PREVALENCE OF ANTICONVULSANTS UTILIZATION AT A TERTIARY HOSPITAL IN SOUTHEAST NIGERIA; BRIDGING THE GAPS BETWEEN FACILITIES OUTCOMES AND POLICIES THROUGH EVIDENCE-BASED REPORTS

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OBJECTIVES: The World Health Organization (WHO) recommended regular drug utilization studies in health facilities as a tool in generating information on disease pattern, and as a guide for policy in healthcare systems. These information help in assessing disease patterns, population health status, quality of care, quality of prescribers, and treatment practices. The choice of anticonvulsants depends on individual tolerance, affordability, and efficacy. This study assessed the proportions of anticonvulsants used and determined the most commonly used anticonvulsants. METHODS: The study was a retrospective cross sectional analysis of prescription records. Study lasted between June to December 2016. Data were analyzed based on frequency of prescribed drugs, number of drugs, defined daily dose (DDD), number and frequency of anticonvulsants used. RESULTS: The number of prescriptions analyzed was 1393.0. Of these prescriptions, 7700.0 drugs were prescribed with each prescription containing an average of 5.5±0.9 drugs per prescription. The mean age of patients was 46±4.3 years. Anticonvulsant drugs accounted for 19.0 (0.25%) of the entire drugs prescribed. Carbamazepine was the most prescribed anticonvulsant 12.0 (63.2%) at a dose of 200mg daily, followed by diazepam 6.0 (31.6%), while the least was pregabalin 1.0 (5.2%). Generic prescription of carbamazepine was 84.0% while that of diazepam was 100.0%. Prescription of anticonvulsants monotherapy was 100.0%. CONCLUSIONS: Study suggested low anticonvulsants use an indication of low prevalence of seizure related disorders in the population. Patients were controlled on monotherapy. Carbamazepine was the most used anticonvulsant and suggested good tolerance, efficacy, affordability, and acceptability. The study provided baseline information for further studies to provide timely information for promoting anticonvulsant drugs utilization in healthcare facilities in Nigeria. Policy issues on the use of newer agents should be dependent on facility-based studies. Newer agents can be introduced when they match and exceed already existing ones based on key indicators.

PND70: 2017 UPDATE OF RECENT TRENDS IN MULTIPLE SCLEROSIS-RELATED HEALTH TECHNOLOGY ASSESSMENT DECISIONS: AN ASSESSMENT OF FIVE COUNTRIES

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OBJECTIVES: Innovative therapies for symptomatic management and treatment of multiple sclerosis (MS) continue to be developed; however, the expense associated with these novel agents must be evaluated alongside the benefit provided. Health technology assessment (HTA) decisions in MS aim to generate policies that produce cost-effective symptomatic or disease-modifying benefit. The objective of this analysis was to update a 2014 study by evaluating recent HTA decisions and their rationales to identify trends in selected countries. METHODS: HTA surveillance was conducted for Australia, Canada, France, Germany, and the United Kingdom (UK) from January 1, 2012 to April 30, 2017 (64 months). MS-related HTAs were evaluated by indication, decision, and rationale for the decision. Decisions were categorized as favorable, unfavorable, mixed (both favorable and unfavorable), and neutral (deferral). RESULTS: 31 MS-related HTAs were published in the study timeframe for 9 unique products. Across studied nations, 14 (45%) decisions were favorable, 13 (42%) unfavorable, 3 (10%) mixed, and 1 (3%) neutral. The UK had the highest percentage of favorable decisions (5/5; 100%), followed by France (5/6, 83%), Australia (2/8, 25%), Canada (1/4, 25%) and Germany (1/8, 13%). Nearly all favorable decisions were for products indicated to treat relapsing-remitting MS (RRMS; 13/14, 93%), while other MS-related indications (walking improvement, spasticity / paralysis, clinically isolated syndrome) were mostly unfavorable (7/8, 88%). HTAs published during or after May 2014 represented half of the decisions examined and tended to be more favorable than studied assessments before this date (53% vs 38%, respectively). CONCLUSIONS: Overall, there were a similar number of favorable and unfavorable decisions, reinforcing the need for manufacturers to develop strong data customized to the evidentiary requirements of each country.

PND71: ASSESSMENT OF MARKETED AND IN-DEVELOPMENT PRODUCTS FOR ALZHEIMER’S DISEASE: WHAT ARE THE STRATEGIC VALUE DRIVERS?

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OBJECTIVES: The increasing Alzheimer's disease (AD) population is a serious concern to governments and payers. The currently marketed products do not alter, nor affect the progression of AD, they only impact cognitive functions. The unmet treatment need in AD is significantly higher. The in-development products have yet to demonstrate their ability to modify the disease. This analysis aimed to assess the clinical, humanistic and economic value drivers for AD market. METHODS: The strategic value drivers were identified through a targeted literature search using electronic databases (e.g., PubMed, Embase), using disease terminology and clinical, humanistic and economic terms. Treatment guidelines were identified through PubMed and National Guideline Clearinghouse. The labels of marketed products were reviewed to identify the reported outcomes. ClinicalTrials.gov was reviewed to identify the in-development products and emerging therapies. Key review articles were also reviewed. Data were analyzed to draw insights. RESULTS: This analysis identified the following attributes as the most valuable drivers for AD market: Clinical Dementia Rating (CDR) and Mini-Mental State Examination (MMSE) scales score (Efficacy attributes); confusion and vomiting side-effects (Safety attributes); cerebrospinal fluid (CSF) amyloid-β42 and amyloid positron emission tomography (PET) scans (Biomarkers); Quality of Life–Alzheimer’s Disease (QOL-AD) scale measure (Humanistic attribute); and direct cost, budget-impact and cost-effectiveness analyses (Economic attributes). CONCLUSIONS: For AD therapy, the most notable value drivers from the payer’s perspective would be efficacy and safety of the upcoming new products. The disease-modifying treatments, with less cost, less invasive diagnostics (e.g. blood test vs. spinal tap) and improving patient’s QOL would be considered as priority from payer's perspective. Safety attributes can be addressed with the products having least adverse events and are more sensitive to those that have little to no impact. Other attributes such as biomarkers should demonstrate a positive impact on decreasing patient β-amyloid in the brain.